Guide for the Selection of Biological Agent Detection Equipment for Emergency First Responders

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Dr. Alim A. Fatah[2]
Richard D. Arcilesi, Jr.[3]
Dr. Tesema Chekol[3]
Charlotte H. Lattin[3]
Dr. Omowunmi A. Sadik[4]
Austin Aluoch[4]

Coordination by:
Office of Law Enforcement Standards
National Institute of Standards and Technology
Gaithersburg, MD 20899–8102

Prepared for:
U.S. Department of Homeland Security
Preparedness Directorate
Office of Grants and Training
Systems Support Division
810 7th Street, NW
Washington, DC 20531

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[2] National Institute of Standards and Technology, Office of Law Enforcement Standards.
[3] Battelle.
[4] State University of New York-Binghamton.

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We also sincerely thank all vendors who provided us with information about their products.

FOREWORD:

The U.S. Department of Homeland Security, Office of the Secretary, Preparedness Directorate Office of Grants and Training (G&T) Systems Support Division (SSD) develops and implements preparedness and prevention programs to enhance the capability of Federal, State, and local governments, and the private sector to prevent, deter and respond to terrorist incidents involving chemical, biological, radiological, nuclear, and explosive (CBRNE) devices. The Preparedness Directorate Office of G&T administers comprehensive programs of direct and grant support for training, exercises, equipment acquisition, technology transfer, and technical assistance to enhance the nation's preparedness for CBRNE acts of terrorism. The Preparedness Directorate Office of G&T SSD works closely with other ODP divisions and Homeland Security professionals gaining an intimate understanding of the emergency responder technology needs and shortfalls. In addition, SSD conducts commercial technology assessments and demonstrations, and transfers equipment directly to the emergency responders. As part of the Congressional FY–03 funding, SSD was tasked with developing CBRNE technology guides and standards for the emergency responder community. This is one of several guides that will aid emergency responders in the selection of CBRNE technology.

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COMMONLY USED SYMBOLS AND ABBREVIATIONS

A	ampere	hf	high frequency	oz	ounce
ac	alternating current	Hz	hertz	o.d.	outside diameter
AM	amplitude modulation	i.d.	inside diameter	Ω	ohm
cd	candela	in	inch	p.	page
cm	centimeter	IR	infrared	Pa	pascal
CP	chemically pure	J	joule	pe	probable error
c/s	cycle per second	L	lambert	pp.	pages
d	day	L	liter	ppb	parts per billion
dB	decibel	lb	pound	ppm	parts per million
dc	direct current	lbf	pound-force	qt	quart
°C	degree Celsius	lbf·in	pound-force inch	rad	radian
°F	degree Fahrenheit	lm	lumen	rf	radio frequency
dia	diameter	ln	logarithm (base e)	rh	relative humidity
emf	electromotive force	log	logarithm (base 10)	s	second
eq	equation	M	molar	SD	standard deviation
F	farad	m	meter	sec.	section
fc	footcandle	μ	micron	SWR	standing wave ratio
fig.	figure	min	minute	uhf	ultrahigh frequency
FM	frequency modulation	mm	millimeter	UV	ultraviolet
ft	foot	mph	miles per hour	V	volt
ft/s	foot per second	m/s	meter per second	vhf	very high frequency
g	acceleration	mo	month	W	watt
gal	gallon	N	newton	λ	wavelength
g	gram	N·m	newton meter	wk	week
gr	grain	nm	nanometer	wt	weight
H	henry	No.	number	yr	year
h	hour				

area=unit^2 (e.g., ft^2, in^2, etc.); volume=unit^3 (e.g., ft^3, m^3, etc.)

PREFIXES (See ASTM E380)

d	deci (10^{-1})	da	deka (10)
c	centi (10^{-2})	h	hecto (10^2)
m	milli (10^{-3})	k	kilo (10^3)
μ	micro (10^{-6})	M	mega (10^6)
n	nano (10^{-9})	G	giga (10^9)
p	pico (10^{-12})	T	tera ($^{10}12$)

COMMON CONVERSIONS

0.30480 m =1ft	4.448222 N = lbf
2.54 cm = 1 in	1.355818 J =1 ft·lbf
0.4535924 kg = 1 lb	0.1129848 N m = lbf·in
0.06479891g = 1gr	14.59390 N/m =1 lbf/ft
0.9463529 L = 1 qt	6894.757 Pa = 1 lbf/in^2
3600000 J = 1 kW·hr	1.609344 km/h = mph

Temperature: T $_{°C}$ = (T $_{°F}$ –32)×5/9 Temperature: T $_{°F}$ = (T $_{°C}$ ×9/5)+32

ACRONYMS SPECIFIC TO THIS DOCUMENT

APS	aerosol particle sizer	JSLSCAD	Joint Service Lightweight Standoff Chemical Agent Detector
BA	biological agent	LANL	Los Alamos National Laboratory
BAWS	Biological Aerosol Warning System	LAP	leucine aminopeptidase
BDG	bidiffractive grating	LD_{50}	Lethal Dose for 50 % of Population
BW	biological warfare	LIDAR	Light Detection and Ranging
CA	chemical agent	LLNL	Lawrence Livermore National Laboratory
CBMS	Chemical Biological Mass Spectrometer	MALDI-TOF	Matrix Assisted Laser Desorption Ionization-Time of Flight
CFU	colony forming unit	μg	microgram (0.000001 g)
CIBADS	Canadian Integrated Biological Agent Detection System	mcg	microgram
CW	chemical warfare	mg	milligram
DARPA	Defense Advanced Research Projects Agency	NASA	National Aeronautics and Space Administration
DNA	deoxyribonucleic acid	NIOSH	National Institute for Occupational Safety and Health
DoD BSK	Department of Defense Biological Sampling Kit	PCR	polymerase chain reaction
DOE	Department of Energy	PFU	plaque forming unit
ECBC	Edgewood Chemical Biological Center	PHTLAAS	Portable High-Throughput Liquid Aerosol Air Sampler System

ELISA	Enzyme-Linked Immunosorbent	PY-GC-IMS	Pyrolysis-Gas Chromatography-Ion Mobility Spectrometer
EOO	Electro Optics Organization, Inc.	QCM	Quartz crystal microbalance
FLAPS	Fluorescent Aerodynamic Particle Sizer	RNA	ribonucleic acid
FTIR	Fourier Transform Infrared	RSCAAL	Remote Sensing Chemical Agent Alarm
HHA	handheld assay	SBCCOM	Soldier, Biological, and Chemical Command
HeNe	Helium-Neon	SEB	Staphylococcal enterotoxin
HUS	hemolytic uremic syndrome	SESI	Science and Engineering Services, Inc.
HVAPS	High Volume Aerodynamic Particle Sizer	SRI	Stanford Research Institute
IAB	Interagency Board	TE	Transverse Electric
IBADS	Interim Biological Agent Detector System	TIMs	toxic industrial materials
IMS	Ionization/Ion Mobility Spectrometry	TM	Transverse Magnetic
IND	Investigational New Drug	TTP	Thrombocytopenic purpura
IR	infrared	UAV	Unmanned Aerial Vehicle
JPO-BD	Joint Program Office for Biological Defense	WMD	Weapons of Mass Destruction

GLOSSARY OF TERMS SPECIFIC TO THIS DOCUMENT

TERM	DEFINITION
ACPLA	Agent Containing Particles per Liter of Air.
Aerosol	A fine mist or spray containing minute particles.
Aflatoxins	A group of chemically related mycotoxins formed by common fungi (*Aspergillus flavus, A. parasiticus,* and *A. nominus*) found in corn, cottonseed, peanuts, and other nuts, grains, and spices. Exposure or ingestion of aflatoxins may lead to structural and functional damage of the liver, including liver cell necrosis, hemorrhage, lesions, fibrosis, and cirrhosis depending on the animal species. They have been cited as BA under weapons development.
Antibody	A biological molecule (protein) that specifically recognizes a foreign substance (antigen) as a means of natural defense; proteins used commonly in diagnostic tests.
Antigen	A substance that generates or stimulates a specific antibody immune response; a substance that is specifically bound or attracted to a given antibody molecule.
Assay	An analytical test used to measure the amount or presence of a specific substance.
Bacteriophage	A virus that infects bacteria and sometimes destroys them by cell lysis or dissolution of the cell.
Biological Agent	Toxin, bacterial or viral organism that can cause casualties when released; to be an agent, it must be infectious to humans, be capable of being produced in enough quantity to be toxic and stable through the dissemination process.
Biosensor	An analytical device composed of a biological recognition element either integrated within or intimately interfaced to a signal transducer, which together relate the concentration of an analyte to a measurable response signal.
CCD	Charged Couple Device; imaging detectors with remarkable sensitivity.
Chemi luminescence	Generation of electromagnetic radiation by the release of light from a chemical reaction.
Concatameric	Tandem repeats of the genome linked in head-to-tail configuration.
Cross reactivity	Ability of an antibody to react with or bind with an antigen that did not stimulate its production.
Degranulation	Release of secretory granule contents by fusion with the plasma membrane.
ELISA	A biochemical technique to detect the presence of an antibody or an antigen that utilizes two antibodies, one specific to the antigen and the other coupled to an enzyme. The second antibody causes a chromogenic substrate to produce a signal.
Fabs	Refers to the variable regions of an antibody that are responsible for antigen binding. The associations of heavy and light chains through a series of disulfide linkages form a Fab.
femto	An SI unit of measure, 10^{-15} or one quadrillionth. Symbol = f.
Flow Cytometry	Technique for the rapid counting and analysis of biological cells and other microscopic particles in a liquid by the use of a laser. This technique provides accuracy, speed, versatility, and excellent precision. The light source is a long-life diode laser with 635 nm wavelength. Microcyte® detects fluorescence and light scatter for counting cells or particles in the 0.4 µ to 15 µ size range. The patented optical design, where all lenses, filters, light source, detectors, and flow cell are mounted in one solid aluminum block, facilitates enhanced sensitivity and stability. For detection of scattered and fluorescent light solid-state photodetectors are used.
Fluorochromes	Compounds that absorb light (excitation) at a given wavelength and reemit at a higher wavelength (emission); a process referred to as fluorescence.

TERM	DEFINITION
Hapten	A small molecule that reacts or binds specifically to an antibody but cannot induce the formation of the antibody unless it is bound to a carrier protein or other large antigenic molecule.
Immunosensor	A biosensor that employs antibodies and antigens as biological recognition elements.
mcg	Microgram; apothecary unit of measure typically used as a dose measurement.
Monoclonal antibodies	Produced from cells known as hybridoma. Hybridoma cells are produced by fusing single antibody forming cells to tumor cells grown in culture. Each hybridoma produces relatively large quantities of identical antibody molecules. By allowing the hybridoma to multiply in culture, it is possible to produce a population of cells, each of which produces identical antibody molecules. These antibodies are called "monoclonal antibodies" because they are produced by the identical offspring of a single, cloned antibody producing cell.
Phage display	Unique way of selecting peptides and proteins with binding affinity similar to that of monoclonal antibodies. Large quantities of high affinity peptides can be produced inexpensively and in far less time, compared to monoclonal antibodies.
Phagocytosis	Process that describes the engulfing and ingestion of extracellular derived materials by phagocytic cells such as macrophages and neutrophils.
Polyclonal antibodies	Population of antibodies observed in the serum of an immunized animal that recognizes in a collective manner all the antigens to which the animal was previously exposed. Polyclonal antibodies are limited by presence of cross-reacting antibodies; they are not specific.
Plasmid	Circular, double-stranded unit of DNA that replicates within a cell independently of the chromosomal DNA. Plasmids are mostly found in bacteria and are used in recombinant DNA research to transfer genes between cells.
SELEX	Systematic Evolution of Ligands by Exponential Enrichment.
simulant	Displays similar characteristics for detection without being toxic.
Toxins	Poison produced by a living organism or its synthetic equivalent (e.g., ricin or botulinum toxins).
Viruses	Small, cellular parasites that cannot reproduce by themselves; they therefore attach to cells via specific receptors to enable their reproduction. The infected cells are ultimately destroyed because of complex biochemical disturbances accompanying the intracellular replication of the virus.

ABOUT THIS GUIDE

The Preparedness Directorate's Office of Grants and Training (G&T) Systems Support Division (SSD) of the U.S. Department of Homeland Security (DHS) is the focal point for providing support to State and local law enforcement agencies in the development of counterterrorism technology and standards, including technology needs for CBRNE defense. In recognizing the needs of State and local emergency first responders, the Office of Law Enforcement Standards (OLES) at the National Institute of Standards and Technology (NIST), supported by the U.S. Department of Homeland Security (DHS), the Technical Support Working Group (TSWG), the U.S. Army Edgewood Chemical and Biological Center (ECBC), the National Fire Protection Association (NFPA), the National Institute of Occupational Safety and Health (NIOSH), and the Interagency Board for Equipment Standardization and Interoperability (IAB), has developed CBRNE defense equipment guides. The guides focus on CBRNE equipment in areas of detection, personal protection, decontamination, and communication. This document is an update of the *Guide for the Selection of Biological Agent Detection Equipment for Emergency First Responders* (DHS Guide 101–04) published in March 2005 and was developed to assist the emergency first responder community in the evaluation and purchase of biological agent (BA) detection equipment.

The long-range plans continue to include two goals: (1) subject existing BA detection equipment to laboratory testing and evaluation against a specified protocol, and (2) conduct research leading to the development of a series of documents, including national standards, user guides, and technical reports. It is anticipated that the testing, evaluation, and research processes will take several years to complete; therefore, DHS will continue to maintain this guide for the emergency first responder community in order to facilitate their evaluation and purchase of BA detection equipment.

In conjunction with this program, additional published guides and other documents, including chemical detection equipment, explosives detection and blast mitigation equipment, portable radiological detection equipment, decontamination equipment, personal protective equipment, and communications equipment used in conjunction with protective clothing and respiratory equipment, will be periodically updated.

The information contained in this guide has been obtained through literature searches and market surveys. The vendors were contacted multiple times during the preparation of this guide to ensure data accuracy. In addition, the information is supplemented with test data obtained from other sources (e.g., Department of Defense) if available. It should also be noted that the purpose of this guide is not to provide recommendations but rather to serve as a means to provide information to the reader to compare and contrast commercially available detection equipment.

Technical comments, suggestions, and product updates are encouraged from interested parties. They may be addressed to the Office of Law Enforcement Standards, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8102, Gaithersburg, MD 20899–8102. It is anticipated that this guide will continue to be updated periodically.

Questions relating to the specific devices included in this document should be addressed directly to the proponent agencies or the equipment manufacturers. Contact information for each equipment item can be found in the equipment data sheets.

GUIDE FOR THE SELECTION OF BIOLOGICAL AGENT DETECTION EQUIPMENT FOR EMERGENCY FIRST RESPONDERS

This second edition guide includes information intended to be useful to the emergency first responder community in the selection of BA detection techniques and equipment for different applications. It includes an updated market survey of BA detection technologies and commercially available detectors known to the authors as of June 2006. Brief technical discussions are presented that consider the principles of operation of the various technologies. These may be ignored by readers who find them too technical, while those wanting additional technical information can obtain it from the extensive list of references that is included in appendix A and the equipment data sheets provided in the corresponding data sheets in the appendices.

1. INTRODUCTION

The primary purpose of the *Guide for the Selection of Biological Agent Detection Equipment for Emergency First Responders* is to provide emergency first responders with information to aid them in the selection and utilization of BA detection equipment. The guide is intended to be more practical than technical and provides information on a variety of factors to be considered when purchasing detection equipment, including, but not limited to, sensitivity, specificity, startup and response times, power requirements, cost, durability, and portability.

The remainder of this guide is divided into ten sections. Section 2 includes an introduction to BAs and discusses each category of BA in detail. Section 3 discusses the challenges of detecting BAs. Section 4 describes the components included in a biological detection system, and section 5 presents an overview of biological sampling devices. Section 6 discusses the various biological detection technologies. For each technology, a short description is provided along with pictures of specific equipment that fall within each class of technology discussed. Section 7 discusses the market survey that was conducted to identify the commercially available BA detection equipment items. Section 8 discusses the 19 characteristics and performance parameters that are used to evaluate the BA detection equipment in this guide. These characteristic and performance parameters are referred to as selection factors in the remainder of this guide. These factors were compiled by a panel of scientists and engineers with multiple years of experience in the areas of BA detection and analysis, domestic preparedness, and emergency first responder needs identification. The factors have also been shared with the emergency first responder community in order to obtain their thoughts and comments. Section 9 presents several tables that allow the reader to compare and contrast the different detection equipment utilizing the 19 selection factors. Section 10 includes the cross-references that are used throughout the guide.

Ten appendices are included within this guide. Appendix A lists the documents that were used in developing this guide. Appendix B presents a table of the potential BA detection technologies developed before 2001. Appendix C presents a table of the potential BA detection technologies developed post 2001. Appendix D lists questions that could assist emergency first responders with selecting BA detection equipment. Appendix E provides the 55 data fields that were identified for providing information relating to the equipment. Appendix F is a compendium of commercially available biological agent detection equipment and contains detailed data on 46

biological detection equipment items. Appendix G contains biological detection equipment that was identified during the market survey but not evaluated due to insufficient data. Appendix H contains limited data sheets for biological sampling equipment, and appendix I contains data sheets for biological reagent kits. Appendix J lists the vendor changes and updates to the biological detectors that are included the corresponding appendices.

2. INTRODUCTION TO BIOLOGICAL AGENTS (BAs)

The purpose of this section is to provide a description of BAs. Section 2.1 provides a historical background of the use of BAs against humanity. Section 2.2 provides an overview of BAs; section 2.3 provides a discussion of bacterial agents, including rickettsiae; section 2.4 provides a discussion of viral agents; and section 2.5 discusses biological toxins.

2.1 Historical Use of Biological Agents

The September 11, 2001 terrorist attacks against the United States, coupled with the havoc caused by the intentional dispersal of anthrax spores directed at highly visible targets, has attracted renewed attention to the potential for BAs to be used as weapons of terror.

The use of BAs and toxins to wage war and promote terror is nothing new. Throughout history, governments and individuals have used various methods to spread BAs and toxins that could cause disease and death in the opposing camp or targeted persons. Table 2–1 shows some of the well-known incidents related to BAs and toxins.

Table 2–1. Historical incidents related to biological agents and toxins*

Location	Perpetrator(s)	Disease(s)	Number of cases/deaths	Dissemination	Year
Eastern USA	Unknown	Anthrax	22/5	Mailed envelopes	2001
Texas	Individual	Dysentery	12/0	Foodborne	1996
Oregon	Rajneeshee cult	Salmonellosis	751/0	Foodborne	1984
South Africa	Apartheid regime	Several	Unknown	Various	1980s
Sverdlovsk, USSR	Escaped from a lab	Anthrax	96/64	Air	1979
London	Bulgarian authorities	Ricin toxicity	2/1	Pellet in an umbrella tip	1978
Toronto	Individual	Intestinal roundworm	4/0	Foodborne	1971
China	Japanese military	Several	Unknown	Various	1932–1944
Europe	German agents in the U.S.	Anthrax	Unknown	Infected animals destined for the Allied Forces in Europe	1915
N. America	British soldiers	Smallpox	Unknown	Distributed infected blankets	1754
Kaffa, on the Black Sea	Tartar warriors	Plague	Unknown	Catapulted infected bodies	1346
Assyria, Middle east	Assyrians	Ergotism	Unknown	Poisoned enemy wells	600 B.C.

*Modified from: Frank Sorvillo, James R. Greenwood, and Roger Detels 2003. Bioterrorism [Available Online] at http://www.oup.co.uk/pdf/0-19-263041-5_12-13.pdf, Verified on 08/06/03

2.2 Overview of Biological Agents as Weapons

Biological agents (BAs) are living organisms or infectious materials derived from them, which may intentionally be used to cause disease or death in humans, animals, and plants. Biological agents are relatively easy and inexpensive to produce and include naturally occurring viruses and bacteria that can be obtained from soil, water, clinical specimens, and research laboratories [1]. Potential biological threat agents are described in the following section.

The use of BAs as weapons is a serious threat for several reasons. In contrast to their chemical counterparts, they have the ability to multiply in the human body and significantly increase their effect. Many BAs are highly virulent and toxic; they have an incubation period (their effects are not seen for hours to days after dissemination) and some can be transmitted from person-to-person. Significant advances in the areas of molecular biology and biotechnology over the past quarter century have made the tasks of detection and treatment of BAs all the more difficult.

Several other characteristics make BAs uniquely appealing to terrorist states, groups, or individuals. Biological agents can be grown in facilities that are inexpensive to construct or facilities that resemble pharmaceutical, food, or medical production sites that provide no detectable sign that such agents are being produced. In the absence of adequate detection equipment, there is a time lag (incubation period) between infection and appearance of symptoms, which gives the perpetrators a chance to escape.

Biological agents have often been described as the "poor man's bomb." This may be due to the fact that BAs are relatively cheap to make because all that is usually involved is growing organisms that are found naturally in a lot of cases, and growing things that already exist is much more cost effective than making chemical weapons.

2.2.1 Relative Size of Biological Agents

Biological agents are often considered to be psychologically more threatening than their chemical counterparts, and therefore provide more appeal to the terrorist. Pathogenic microorganisms can quickly reproduce and cause disease in a very large number of people. Moreover, BAs have a remarkably low infectious dose; that is, the quantity of agent that is required to create the desired results (incapacitation or death) on the target population is low relative to other types of agents.

Figure 2–1 shows the approximate mass in milligrams (mg) of an agent needed to achieve the desired result compared to toxins and chemical agents. The approximate weight of a paper clip is included in this figure as a point of reference. The reader can immediately see the vast differences in effectiveness between BAs and chemical agents (CAs) based on their masses. At the extreme, some BAs are as much as 14 billion times more effective than chemical agents. The reader should also note that if a terrorist chooses to use a toxin (in order to get relatively rapid effects in a tactical situation), a much greater amount of the toxin will have to be employed than if BAs were being used. This mass of toxin agent in some cases may be equivalent to chemical agent masses.

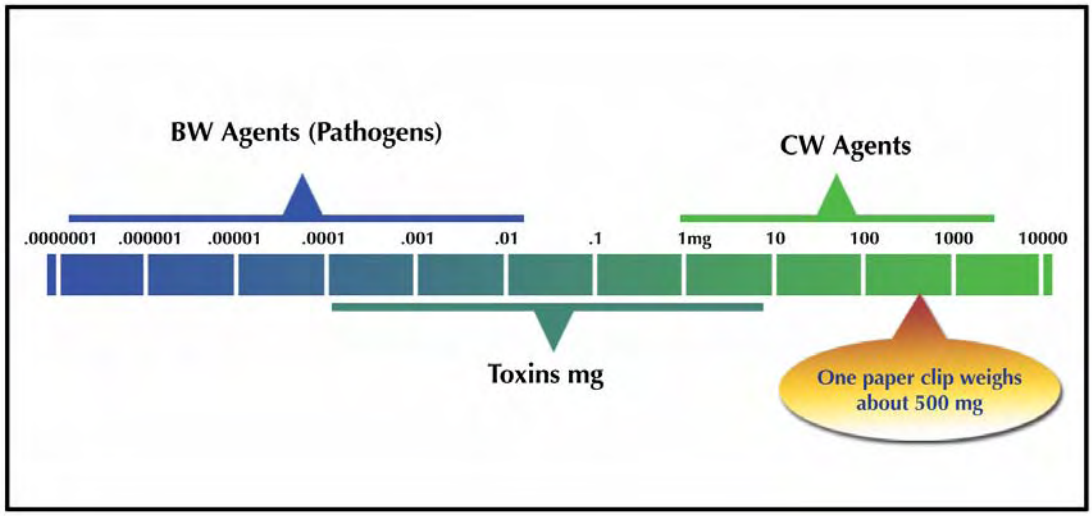

Figure 2–1. Comparative toxicity of effective doses, approximate LD_{50}, of biological agents, toxins, and chemical agents

2.2.2 Centers for Disease Control and Prevention Classification of Biological Agents

The Centers for Disease Control and Prevention (CDC) has classified potential agents of bioterrorism into three, high-priority categories.

Category A includes BAs that could easily be disseminated or transmitted from person-to-person, and may result in high mortality rates. They have the potential for a major public health impact, causing panic and social disruption that requires special action for the public health system. Category A threats include agents that cause anthrax, smallpox, botulism, plague, tularemia, and viral hemorrhagic fevers.

Category B includes BAs that are moderately easy to disseminate, result in moderate morbidity and low mortality rates, and require specific enhancements of CDC's diagnostic capacity and enhanced disease surveillance. This category consists of agents that cause brucellosis, salmonella, glanders, meliodosis, psittacosis, Q fever, typhus fever, various food and water-borne diseases, E. Coli O157:H7, ricin toxin, staphylococcal enterotoxin B (SEB), and various encephalitis viruses.

Category C includes emerging pathogens that could be engineered for mass dissemination in the future because of availability, ease of production and dissemination, potential for high morbidity and mortality rates, and major public health problems. Category C agents include various viruses that cause hemorrhagic fever, encephalitis, and influenza, among other illnesses.

2.2.3 Types of Biological Agents Likely to be Used in a Terrorist Attack

This section provides a description of the types, or grouping, of BAs likely to be used in a terrorist attack. There are three important classes of BAs under discussion: bacterial (including rickettsiae), viral, and biological toxins.

2.3 Bacterial Agents

Bacteria are the simplest and oldest life forms. They are small, single-celled organisms, most of which can be grown on solid or in liquid culture media while others are obligate intracellular parasites and can be grown in animal cells. Under special circumstances, some types of bacteria can transform into spores that are more resistant to cold, heat, drying, chemicals, and radiation than the bacterium itself. Rickettsiae are discussed in a separate section.

2.3.1 Characteristics of Bacterial Agents

Bacteria are a versatile group of microorganisms that can be found in any kind of environment, ranging from extremely cold to temperatures above the boiling point of water. They can utilize a wide range of substrates (sugar, starch, sulfur, and iron). One species of bacteria—*Deinococcus radioduran*—has been found to withstand radiation doses 1000 times greater than the lethal dose to human beings. Bacteria reproduce themselves by simple division. Most bacteria do not cause disease in human beings, but those that do cause disease act by two differing mechanisms: by invading the tissues or by producing poisons (toxins). Bacterial diseases often respond to specific therapy with antibiotics. Many bacteria, such as *Bacillus anthracis*, have the following properties that make them attractive as potential warfare agents:

- They retain potency during growth and processing to the end product (biological weapon).
- They have long “shelf life.”
- They have a slow rate of inactivation when used as an aerosol.

Table 2–2 lists some of the common bacterial agents along with possible methods of dissemination, incubation period, symptoms, and treatment.

Table 2–2. Bacterial agents

Biological Agent	*Bacillus anthracis*	*Burcella abortus, B. melitensis, B. suis, B. canis*	*Escherichia coli serotype* (O157:H7)	*Francisella tularenius*
Disease	Anthrax	Brucellosis	Diarrhea, hemolytic uremic syndrome	Tularemia
Likely Method of Dissemination	1. Spores in aerosol 2. Sabotage (food) 3. Cutaneous—contact with contaminated animal product	1. Aerosol 2. Sabotage (food)	1. Water 2. Food supply contamination	1. Aerosol 2. Water and food supply contamination 3. Ticks
Transmissible Person-to-person	No	Rare	Unknown, evidence passed person-to-person in daycare or nursing homes	No
Incubation Period	1 d to $\geq$ 43 d	1 wk to 3 wk, sometimes months	Unknown	2 d to 10 d
Duration of Illness	3 d to 5 d (usually fatal)	Unknown	5 d to 10 d (most cases)	>2 wk
Fatality Rate	Inhalation anthrax: after symptoms appear, almost always fatal, regardless of treatment Intestinal: 25 % to 60 % fatality rate Contact or cutaneous anthrax: 5 % to 20 % fatality rate	Low	Up to 15 % if develop hemolytic uremic syndrome (HUS); 5 % if develop thrombotic thrombocytopenic purpura (TTP)	In general, tularemia has a slower progression of illness and a lower case-fatality rate than anthrax; between 1985 and 1992, 1409 cases and 20 deaths were reported in the U.S., a case fatality rate of 1.4 %
Vaccine Efficacy (for aerosol exposure)/ Antitoxin	Currently no human data; however, the anthrax attack of 2001 showed that anthrax could be successfully treated	Vaccine under evaluation	No vaccine	No commercially available vaccine
Symptoms and Effects	Inhalation: Flu-like, upper-respiratory distress; fever and shock in 3 d to 5 d, followed by death Intestinal: nausea, loss of appetite, vomiting, and fever are followed by abdominal pain, vomiting of blood, and severe diarrhea Cutaneous: Ulcer with black necrotic center, followed by swollen lymph glands	Irregular prolonged fever, profuse sweating, chills, joint and muscle pain, persistent fatigue	Gastrointestinal (diarrhea, vomiting) dehydration; in severe cases, cardiac arrest and death, HUS, or TTP	Aerosol exposure: chills, sustained fever, prostration, tendency for pneumonia, enlarged, painful lymph nodes, headache, malaise, anorexia, nonproductive cough Cutaneous: ulcers on the skin or mouth, swollen and painful lymph glands, swollen and painful eyes, and a sore throat
Treatment	Antiobiotics approved for anthrax are ciprofloxacin, tetracyclines (including doxycycline), and penicillins; if exposed to anthrax, but symptom free, 60 d treatment with one of the antibiotics is given to reduce the risk or progression of disease due to inhaled anthrax	Antibiotics	Antibiotics available; most recover without antibiotics within 5 d to 10 d; do not use antidiarrheal agents	Antibiotics: parenteral antimicrobial therapy recommended A vaccine for tularemia is under review but is not currently available in the U.S.
Potential as Biological Agent	High, Iraqi and USSR biological programs worked to develop anthrax as a bio-weapon	Unknown	Unknown	High, if delivered via aerosol form (highly infectious, 90 % to 100 %)

Table 2–2. Bacterial agents–Continued

Biological Agent	*Vibrio cholerae*	*Burkholderia mallei*	*Psuedomonas pseudomallei*	*Yersinia pestis*	*Salmonella typhi*
Disease	Cholera	Glanders	Melioidosis	Plague (pneumonic and bubonic)	Typhoid fever
Likely Method of Dissemination	1. Sabotage (food and water)	1. Aerosol 2. Cutaneous	1. Food contamination (rodent feces) 2. Inhalation	1. Aerosol (pneumonic) 2. Infected fleas (bubonic and pneumonic)	1. Contact with infected person 2. Contact with contaminated substances
Transmissible Person-to-person	Rare	No	No	High (pneumonic)	High
Incubation Period	3 d to 5 d	3 d to 5 d	Days	1 d to 3 d	7 d to 14 d
Duration of Illness	>1 wk	Unknown	4 d to 20 d	1 d to 6 d (usually fatal)	Unknown
Fatality Rate	Low with fluid replacement	50 % to 70 %	Although bloodstream infection with melioidosis can be fatal, the other types of the disease are nonfatal	5 % to 10 % if treated 1. Bubonic: 30 % to 75 % if untreated 2. Pneumonic: 95 % if untreated	<1 % if treated; 10 % to 14 % if untreated
Vaccine Efficacy (for aerosol exposure)/ Antitoxin	No data on aerosol	No vaccine	No vaccine	Vaccine not available	Oral vaccine (Vivotif) and single dose injectable vaccine (capsular poly-saccharide antigen); both vaccines are equally effective and offer 65 % to 75 % protection against the disease
Symptoms and Effects	Sudden onset with nausea, vomiting, diarrhea, rapid dehydration, toxemia, and collapse	Skin lesions, ulcers in skin, mucous membranes, and viscera; if inhaled, upper respiratory tract involvement	Cough, fever, chills, muscle/joint pain, nausea, and vomiting; progressing to death	Enlarged lymph nodes in groin; septicemia (spleen, lungs, meninges affected)	Prolonged fever, lymph tissue involvement, ulceration of intestines, enlargement of spleen, rose-colored spots on skin, constipation or diarrhea
Treatment	Replenish fluids and electrolytes; a prepackaged oral rehydration solution (a mixture of sugar and salts to be dissolved in water) is available	Drug therapy (streptomycin and sulfadiazine) is somewhat effective	Antibiotics (doxycycline, chlorothenicol, tetracycline) and sulfadiazine	Antibiotics: streptomycin, or gentamicin if streptomycin not available, tetracyclines and chloramphenicol can be used	Antibiotics (amoxicillin or cotrimoxazole) shorten period of communicability and cure disease rapidly
Potential as Biological Agent	Not appropriate for aerosol delivery	Unknown	Moderate—no vaccine available	High—highly infectious, particularly pneumonic (aerosol) form; lack of stability and loss of virulence complicate its use	Not likely to be deployed via aerosol; more likely for covert contamination of water or food

2.3.2 Important Bacterial Agents

The following subsections attempt to describe the bacterial agents of highest concern:

Anthrax is a highly lethal disease caused by an infection with a gram-positive bacterium *Bacillus anthracis*. In nature, anthrax most commonly occurs in cattle, sheep, goats, and horses, but can also infect humans. There are three types of this disease: cutaneous anthrax, inhalation anthrax, and gastrointestinal anthrax. Cutaneous anthrax manifests itself as a small, elevated lesion on the skin that becomes a skin ulcer. The lymph glands near the lesion may also swell from the infection. Inhalation anthrax develops when the bacterial organism is inhaled into the lungs. Since inhalation anthrax is not diagnosed in time for treatment, it has a very high mortality rate, about 90 % to 100 %. Intentional release would presumably be through aerosols since *B. anthracis* spores are highly stable and easily aerosolized [2]. The U.S. Centers for Disease Control and Prevention (CDC) considers *B. anthracis* a Category A bioterrorism agent. Figure 2–2 shows a culture of *B. anthracis*.

Figure 2–2. Bacillus anthracis

Symptoms of anthrax usually occur within seven days after exposure. Symptoms of inhalation anthrax include fever, cough, and chest discomfort. These symptoms are sometimes followed by a brief period of improvement and then respiratory failure. Death typically occurs within 24 h to 36 h after onset of severe symptoms. Cutaneous anthrax is a less severe form and affects exposed areas of the hands, arms, or face. Its symptoms are papulae (small, solid, and raised lesions), blisters, and ulcers with black scabs known as eschar, hence the term anthrax (from the Greek word for coal). Symptoms of gastrointestinal anthrax include nausea, anorexia, vomiting, and fever, progressing to severe abdominal pain, hematemesis, and diarrhea that is almost always bloody. Death typically occurs within 2 d to 5 d of onset. Figure 2–3 shows an example of a black eschar (source CDC).

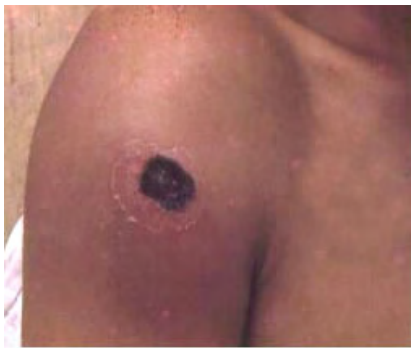

Figure 2–3. Black eschar caused by anthrax

There is no reported case of anthrax transmission from person-to-person. Early intervention with antibiotics such as ciprofloxacin, penicillin, doxycycline, and fluoroquinolones may save lives, while an anthrax vaccine could prevent infection. However, because of the stability of spores in the lungs, antibiotics would have to be administered for at least 60 d. Recent research (Sellman et al., 2001) has shown that even an advanced stage of the disease could be treated by the administration of a protective antigen.

Brucellosis is an infection caused by one of the four species of the gram-negative bacteria *Brucella:, B. melitensis, B. suis, B. canis, and B. abortus. B. melitensis, B. suis,* and *B. canis* are pathogens of goats, pigs, and dogs, respectively, while *B. abortus* is a pathogen of cattle [1]. These bacteria are small aerobic, nonmotile coccobacilli that reside quiescently in tissue and bone marrow and are extremely difficult to eradicate with antibiotics. Humans acquire these organisms through the ingestion of unpasteurized dairy products or by inhalation or aerosols generated from farms or via inoculation of skin lesions in persons in close proximity to the animals [1]. Intentional release would most likely involve aerosolization but could also involve the contamination of food products. *Brucella* species fall into Category B of the CDC's classification of BAs.

Typical symptoms of brucellosis are fever, headache, back pain, sweats, chills, generalized malaise, and in some cases depression and mental status changes. However, brucellosis has a very long incubation period and symptoms may not appear for months. Person-to-person transmission has been reported via tissue transplantation and sexual contact. No human vaccine is available against brucellosis, but the disease responds well to antibiotics such as doxycycline and rifampin. In addition, a 0.5 % hypochlorite solution can be used for environmental decontamination of brucellosis.

Plague is an infectious disease caused by the gram-negative bacterium *Yersinia pestis*. A plague infection is naturally acquired by humans through a bite (*Xenopsylla cheopis or Pulex irritans)* from a flea that had previously fed on infected rodents [2] Plague presents itself as a localized abscess with secondary formation of large fluctuant regional lymph nodes known as buboes (bubonic plague). Intentional release would involve aerosolization and transmission by inhalation. In this form, the disease develops rapidly leading to death in 2 d to 3 d. Although different forms of the disease are known, pneumonic plague represents the most serious threat because of possible aerosol dissemination by a terrorist. The CDC considers plague a Category A bioterrorism agent.

Pneumonic plague symptoms usually start after an incubation period of 1 d to 6 d and include high fever, chills, headache, malaise, vomiting, coughing, bloody sputum, respiratory failure, and circulatory collapse. The disease is often fatal. However, doxycycline, ciprofloxacin, tetracycline, and chloramphenicol are known to be effective antibiotics for plague, if administered within 24 h of the onset of the first symptom. In the United States, plague is endemic in several western states, including northern New Mexico, northern Arizona, southern Colorado, California, southern Oregon, and far western Nevada.

Cholera is caused by the bacterium *Vibrio cholerae* and acquired through the ingestion of contaminated food or water. *V.cholerae* multiplies in the small intestine and secretes an enterotoxin that causes secretory (watery) diarrhea [2]. Without treatment, severe dehydration may result leading to death. Intentional release would most probably be through the contamination of water supplies. It is unlikely to be used in its aerosol form.

2.3.3 Rickettsiae

Rickettsiae are bacteria that are obligate intracellular parasites associated with arthropods such as body lice, fleas, ticks, and mites. They are intermediate in size, between most bacteria and viruses, and possess certain characteristics common to both bacteria and viruses. Like bacteria, they have metabolic enzymes and cell membranes, use oxygen, and are susceptible to broad-spectrum antibiotics; like viruses, they grow only in living cells. Most rickettsiae are spread by the bites of arthropod vectors including insects (fleas and lice) and arachnids (ticks and mites) and are not spread through human contact.

Table 2–3 lists the common rickettsiae along with possible methods of dissemination, incubation periods, symptoms, and treatment.

Table 2–3. Rickettsiae

Biological Agent or Source	*Rickettsia typhus*	*Rickettsia prowazekii*	*Coxiella burnetii (Rickettsia burnetti)*	*Rickettsia rickettsii*
Disease	Endemic Typhus	Epidemic Typhus	Q Fever	Rocky Mountain Spotted Fever
Likely Method of Dissemination	Aerosol	Aerosol	1. Sabotage (food supply) 2. Aerosol	Aerosol
Transmissible Person-to-person	No	No	Rare	No
Incubation Period	6 d to 14 d	6 d to 15 d	14 d to 26 d	3 d to 14 d
Duration of Illness	Unknown	Unknown	Weeks	Unknown
Fatality Rate	1 %, increasing in people >50 yr old	10 % to 40 % untreated; increases with age	Very low	15 % to 20 % untreated (higher in adults); treated—death rare with specific therapy (tetracycline or chloramphenicol)
Vaccine Efficacy (for aerosol exposure)/ Antitoxin	Unknown	Vaccine confers protection of uncertain duration	94 % protection against 3500 LD_{50} in guinea pigs	No vaccine
Symptoms and Effects	Sudden onset of headache, chills, prostration, fever, pain; maculae eruption on 5th day to 6th day on upper body, spreading to all but palms, soles, or face, but milder than epidemic form	Sudden onset of headache, chills, prostration, fever, pain; maculae eruption on 5th day to 6th day on upper body, spreading to all but palms, soles, or face	Mild symptoms (chills, headaches, fever, chest pains, perspiration, loss of appetite)	Fever and joint pain, muscular pain; skin rash that spreads rapidly from ankles and wrists to legs, arms, and chest; aversion to light
Treatment	Antibiotics (tetracycline and chloramphenicol); supportive treatment and prevention of secondary infections	Antibiotics (tetracycline and chloramphenicol); supportive treatment and prevention of secondary infections	Tetracycline (500 mg/ 6 h, 5 d to 7 d) or doxycycline (100 mg/ 12 h, 5 d to 7 d) also, combined Erythromycin (500 mg/ 6 h) and rifampin (600 mg/d)	Antibiotics—tetracycline or chloramphenicol
Potential as Biological Agent	Uncertain—broad range of incubation (6 d to 14 d) period could cause infection of force deploying BA	Uncertain—broad range of incubation (6 d to 14 d) period could cause infection of force deploying BA	Highly infectious if delivered in aerosol form; dried agent is very stable; aerosol form is stable	Unknown

2.3.3.1 Characteristics of Rickettsiae

All of the rickettsiae agents that cause diseases belong to the CDC classification of Category B. However, because of the great difficulty in diagnosing such diseases and their ability to incapacitate humans, they are potentially attractive to bioterrorists.

The following subsections cover some of the rickettsiae agents of highest concern:

2.3.3.2 Important Rickettsiae Agents

Q-Fever is caused by infection with the rickettsiae organism, *Coxiella burnetii*. Its most common hosts are sheep, goats and cattle. Humans acquire the disease through inhalation of particles contaminated with the organisms [2]. Q-fever generally occurs as a self-limiting febrile illness lasting 2 d to 2 wk. A nonproductive cough and pleuritic chest pain occur in about 1/4 of patients with Q-fever pneumonia. Patients usually recover uneventfully. Intentional release would be through aerosolization and would cause disease similar to that occurring naturally. Because of its low mortality rate, it would likely be employed as an incapacitating agent.

Symptoms of Q-fever include high fevers [up to 40 °C to 40.6 °C (104 °F to 105 °F)], severe headache, feeling of bodily discomfort and fatigue, muscle pain, confusion, sore throat, chills, sweats, non-productive cough, nausea, vomiting, diarrhea, abdominal pain, and chest pain. Fever usually lasts for 1 wk to 2 wk. Thirty to fifty percent of patients with a symptomatic infection will develop pneumonia, but pulmonary syndromes are usually not prominent. Also, patients could have abnormal liver function test results indicating the possibility of developing hepatitis in some patients. In general, most patients will recover to good health within several months without any treatment. Rarely, *Coxiella burnetii* may cause a peculiar form of chronic endocarditis, which is largely responsible for the few fatal cases. Since the disease is not a clinically distinct illness, it may resemble a viral illness or other type of atypical pneumonia.

Q-fever is a generally easily treatable disease if diagnosed properly. Treatments with tetracycline (500 mg every 6 h) or doxycycline (100 mg every 12 h), and in some cases chloramphenicol, are considered very effective. An experimental, inactivated whole cell vaccine used by the U.S. Army has also been shown to be effective. Environmental decontamination can be accomplished by washing with soap and water or a 0.5 % hypochlorite solution.

Typhus is caused by different types of rickettsiae. There are three main forms of typhus.

- Epidemic typhus, known as louse-borne typhus, is transmitted by body lice, usually in overcrowded conditions, and has resulted in hundreds of thousands of deaths in times of war or famine. The epidemic typhus has an incubation time of 7 d.
- Endemic typhus, known as murine typhus, is a rare disease that can be transmitted from rats to humans by fleas. A few cases occur each year in North and Central America. The endemic typhus has an incubation time of 8 d to 16 d.
- Scrub typhus, transmitted by mites, has been reported in India and Southeast Asia and has an incubation time of 6 d to 21 d.

The agent known as *Rickettsia prowazekii* causes the epidemic typhus. In most cases, the infected lice excrete rickettsiae when feeding on the second host. Symptoms occur 1 wk to 2 wk after the initial bite. The symptoms consist of headaches, chills, prostration, high fever, coughing, and sever muscular pain. The affected persons might also be prone to agitations due to the constant pain and exhaustion they experience due to the infection. After 5 d, a red eruption (rash) starts to appear throughout the body, with the exception of the face. In severe cases of typhus, delirium and coma occur. If the disease is not treated, dangerous complications such as pneumonia or kidney failure can develop.

Typhus is often diagnosed from the symptoms, but a blood test may be necessary for confirmation. Treatment with antibiotics, such as tetracycline and chloramphenicol, is usually effective. Without treatment, the rickettsiae can lie dormant in the body for years before being reactivated and causing the disease to recur. A person cannot get typhus fever more than once.

2.4 Viral Agents

Viruses are the simplest type of microorganism and consist of a nucleocapsid containing a protein coat and genetic material, either RNA or DNA. Because viruses lack a system for their own metabolism, they require living hosts (cells of an infected organism) for replication and cannot be cultivated in synthetic nutritive solutions. However, host cells can be cultivated in synthetic nutrient solutions and then infected with a virus specific to the host cells. In addition, viruses are much smaller in size than bacteria.

2.4.1 Characteristics of Viral Agents

Viruses are attractive as BAs because many do not respond to antibiotics. However, cultivation of viruses is expensive, demanding, and time-consuming. Since their incubation periods are normally longer than for other BAs, incapacitation of victims also is delayed. Table 2–4 lists the viral agents of greatest concern along with possible methods of dissemination, incubation period, symptoms, and treatment.

Table 2–4. Viral agents

Biological Agent or Source	Filovirus		Tacaribe Virus complex Arenavirus	Phlebovirus	Variola major, Orthopoxvirus
Disease	Marburg Hemorrhagic Fever	Ebola Hemorrhagic Fever	Argentine Hemorrhagic Fever (Junin)	Rift Valley Fever	Smallpox
Likely Method of Dissemination	Aerosol	Direct contact Aerosol (BA)	Not known	Mosquito-borne; aerosols or droplets	Aerosol
Transmissible Person-to-person	Moderate	Moderate	Moderate	Unknown	High
Incubation Period	5 d to 7 d	4 d to 16 d	7 d to 16 d	2 d to 5 d	7 d to 17 d
Duration of Illness	Unknown	Death between 7 d to 16 d	16 d	2 d to 5 d	4 wk
Fatality Rate	23 % to 25 %	50 % to 90 %	18 %	<1 %	20 % to 40 % (Variola major) <1 % (Variola minor)
Vaccine Efficacy (for aerosol exposure)/ Antitoxin	No vaccine	Experimental	No vaccine	Inactivated vaccine available in limited quantities	Vaccine protects against infection within 3 d to 5 d of exposure
Symptoms and Effects	Sudden onset of fever, malaise, muscle pain, headache, and conjunctivitis, followed by sore throat, vomiting, diarrhea, rash, and both internal and external bleeding (begins 5th day); liver function may be abnormal and platelet function may be impaired	Mild febrile illness, then vomiting, diarrhea, rash, kidney and liver failure, internal and external hemorrhage (begins 5th day), and petechiae	Hemorrhagic syndrome, chills, sweating, exhaustion and stupor	Febrile illness, sometimes abdominal tenderness; rarely shock, ocular problems	Sudden onset of fever, headache, backache, vomiting, marked prostration, and delirium; small blisters form crusts which fall off 10 d to 40 d after first lesions appear
Treatment	No specific treatment exists; severe cases require intensive supportive care, as patients are frequently dehydrated and in need of intravenous fluids	No specific therapy; supportive therapy essential	No specific therapy; supportive therapy essential	No studies, but IV ribavirin (30 mg/ kg/6 h for 4 d, then 7.5 mg/kg/8 h for 6 d) should be affective	Vaccinia immune globulin (VIG) and supportive therapy
Potential as Biological Agent	High—weaponized by former Soviet Union biological program	Unknown—possibly weaponized by former Soviet Union	Unknown	Difficulties with mosquitos as vectors	Possible, especially since routine smallpox vaccination programs have been eliminated worldwide; weaponized by former Soviet Union

2–4. Viral agents–Continued

Biological Agent or Source	Flaviviruses		Nairovirus	Alphavirus
Disease	Yellow Fever Virus	Dengue Fever Virus (DEN-1, DEN-2, DEN-3, and DEN-4)	Congo-Crimean Hemorrhagic Fever Virus	Venezuelan Equine Encephalitis
Likely Method of Dissemination	Mosquito-borne Aerosol	Mosquito-borne (*Aedes aegypti*)	Insect vectors	Aerosol
Transmissible Person-to-person	Low	No	Yes	No
Incubation Period	3 d to 6 d	3 d to 15 d	7 d to 12 d	1 d to 6 d
Duration of Illness	2 wk	1 wk	9 d to 12 d	Days to weeks
Fatality Rate	10 % to 20 % death in severe cases or full recovery after 2 d to 3 d	5 % average case fatality	15 % to 20 %	<1 %
Vaccine Efficacy (for aerosol exposure)/ Antitoxin	Vaccine available; confers immunity for >10 yr	Vaccine available	No vaccine available; prophylactic ribavirin may be effective	Experimental only: TC–83 protects against 30 LD_{50} to 500 LD_{50} in hamsters
Symptoms and Effects	Sudden onset of chills, fever, prostration, aches, muscular pain, congestion, severe gastrointestinal disturbances, liver damage and jaundice; hemorrhage from skin and gums	Sudden onset of fever, chills, intense headache, pain behind eyes, joint and muscle pain, exhaustion and prostration; occasionally produces shock and hemorrhage, leading to death	Fever, easy bleeding, petechiae, hypotension and shock; flushing of face and chest, edema, vomiting, diarrhea	Sudden illness with malaise, spiking fevers, rigors, severe headache, photophobia, and myalgias
Treatment	No specific treatment; supportive treatment (bed rest and fluids) for even the mildest cases	No specific therapy; supportive therapy essential	No specific treatment	Supportive treatments only; there is a vaccine for laboratory workers
Potential as Biological Agent	High, if efficient dissemination device is employed	Unknown	Unknown	High—former U.S. and U.S.S.R. offensive biological programs weaponized both liquid and dry forms for aerosol distribution

2.4.2 Viral Agents of Greatest Concern

The viral agents of greatest concern are described in the following subsections.

Smallpox is an infection caused by variola virus, an orthopox virus with its host confined to humans. Although naturally occurring smallpox has been eradicated from the world,

monkeypox, cowpox, and vaccinia are closely related viruses that may genetically be manipulated to produce smallpox-like diseases [1]. However, known laboratory cultures of the virus are maintained under security at the CDC, Atlanta, GA, and the State Research Center of Virology and Biotechnology, Koltsovo, Russia.

Variola major (smallpox virus) is a DNA-containing virus that belongs to the genus *orthopoxvirus*. The orthopoxviruses are among the largest and most complex of all viruses. Three other members of this genus (monkeypox, vaccinia, and cowpox) can also infect humans, causing cutaneous lesions, but only smallpox is readily transmitted from person-to-person. It is possible that recombinant (artificially created) poxviruses could be developed from monkeypox, vaccinia, or cowpox, and used as biological weapons.

The incubation period for smallpox lasts for about 7 d to 17 d and symptoms include high fever, malaise, head and body aches, vomiting, and rash. Infected people are most contagious during the early rash stage and continue to be contagious until the smallpox scabs have fallen off. Before the worldwide eradication of smallpox, major epidemics, such as those that occurred in Asia, resulted in fatality rates of 30 % or higher among the unvaccinated population. According to the CDC classification, smallpox falls in the highest priority bioagents group, Category A.

The disease spreads from person-to-person, primarily by respiratory droplets or aerosols expelled from the infected persons. It can also be transmitted by direct contact with skin lesions, drainage, or contaminated objects such as clothing or bed linens. There are no known animal or insect reservoirs or vectors. As a result, the biggest threat from the use of smallpox as a bioweapon comes from its potential to reestablish as an endemic disease through the above routes of transfer. There is no specific antiviral therapy against smallpox, but prompt vaccination of exposed persons appears to be the best option. Prophylactic vaccination, when use of smallpox as a biological weapon is a distinct possibility, is one way of dealing with this threat.

Venezuelan equine encephalitis (VEE) is a mosquito-borne viral disease maintained in nature predominantly in a horse-mosquito-horse cycle. The disease is characterized by its sudden onset of symptoms following a 1 d to 5 d incubation period. The symptoms include fever, chills, sore throat, severe headache, back pain, prostration, nausea, and vomiting. In some cases, particularly in young children, the disease may progress to encephalitis, an acute inflammation of the brain caused by a viral infection. Because naturally occurring VEE has a low mortality rate, and 100 % of the human population is susceptible to it, VEE used as a BA would be considered an incapacitating agent.

Experimental vaccines are available against VEE, and environmental decontamination could be achieved with an 0.5 % hypochlorite solution or heat treatment at 80 °C (176 ºF) for 30 min. The CDC categorizes viral encephalitis, including VEE, in Category B.

2.5 Biological Toxins

Biological toxins are poisons produced by living organisms. It is the poison, and not the organism, that produces harmful effects in humans. Toxins are synthesized during the growth of some bacteria and algae and may be excreted into the surrounding medium (environment).

Toxins can also be genetically altered and/or synthetically manufactured and produced in a laboratory environment. Biological toxins are most similar to chemical agents in their dissemination and effectiveness. Table 2–5 lists the common biological toxins along with possible methods of dissemination, incubation period, symptoms, and treatment.

Table 2–5. Biological toxins

Biological Source	*Clostridium botulinum*	*Staphylococcus aureus*	Mycotoxins of the Trichothecence group	Isolated from Castor Beans	Marine dinoflagellate
Toxin/Disease	Botulinum toxin—7 antigenically different botulinum toxins (A, B, C, D, E, F, and G); Types A, B, E, and F responsible for most human cases	Staphylococcal enterotoxin B (SEB)	T-2 mycotoxins (yellow rain)	Ricin	Saxitoxin
Likely Method of Dissemination	1. Aerosol 2. Sabotage (food and water)	1. Sabotage (food supply) 2. Aerosol	1. Aerosol 2. Sabotage	1. Aerosol 2. Sabotage (food & water)	In biological scenario, inhalation or toxic projectile
Transmissible Person-to-person	No	No	No	No	No
Incubation Period	Variable (hours to days)	3 h to 12 h	2 h to 4 h	Hours to days	5 min to 1 h
Duration of Illness	Death in 24 h to 72 h; lasts months if not lethal	Hours	Days to months	Days—death within 10 d to 12 d for ingestion	Death in 2 h to 12 h
Fatality Rate	70 %, untreated <5 % treated	For aerosol exposures the ED_{50} is 0.0004 mcg/kg, and the LD_{50} is 0.02 mcg/kg	Moderate	100 %, without treatment LD_{50}, 30 mcg/kg (gastrointestinal) LD_{50}, 3 mcg/kg (aerosol) LD_{50} similar to aerosol (parenteral)	High without respiratory support
Vaccine Efficacy (for aerosol exposure)/ Antitoxin	Botulism antitoxin (IND) Prophylaxis toxoid (IND) Toxolide	No vaccine	No vaccine	No vaccine	No vaccine

Table 2–5. Biological toxins–Continued

Biological Source	*Clostridium botulinum*	*Staphylococcus aureus*	Mycotoxins of the Trichothecence group	Isolated from Castor Beans	Marine dinoflagellate
Symptoms and Effects	Ptosis; weakness, dizziness, dry mouth and throat, blurred vision and diplopia, flaccid paralysis	Sudden chills, fever, headache, myalgia, nonproductive cough, nausea, vomiting, and diarrhea	Skin—pain, pruritis, redness and vesicles, sloughing of epidermis; respiratory—nose and throat pain, discharge, sneezing, coughing, chest pain, hemoptysis	Aerosol—Weakness, fever, cough, pulmonary edema, severe respiratory distress Parenteral—local necrosis of muscle and regional lymph nodes with organ involvement and death Gastrointestinal—severe gastroenteritis, GI hemorrhage, and hepatic, splenic, and renal necrosis; death may occur secondary to circulatory collapse	Light-headedness, tingling of extremities, visual disturbances, memory loss, respiratory distress, death
Treatment	Antitoxin with respiratory support (ventilation)	Pain relievers and cough suppressants for mild cases; for severe cases, may need mechanical breathing and fluid replenishment	No specific antidote or therapeutic regimen is available; supportive and symptomatic care	Oxygen, plus drugs to reduce inflammation and support cardiac and circulatory functions; if ingested, empty the stomach and intestines; replace lost fluids	Induce vomiting, provide respiratory care, including artificial respiration
Potential as Biological Agent	Not very toxic via aerosol route; extremely lethal if delivered orally	Moderate—could be used in food and limited amounts of water (for example, at salad bars); LD_{50} is sufficiently small to prevent detection	High—used in aerosol form ("yellow rain") in Laos, Kampuchea and Afghanistan (through 1981)	Has been used in 1978—Markov murder (see app. B, ref. 7); included on prohibited Schedule I chemicals list for Chemical Weapons Convention; high potential for use in aerosol form	Moderate, aerosol form is highly toxic

2.5.1 Characteristics of Biological Toxins

Biological toxins have very distinct characteristics that differentiate them from the chemical agents. Unlike chemical agents, biological toxins are not manmade or volatile; they are generally much more toxic per weight than chemical agents. With the exception of mycotoxins, biological toxins are not dermally active. Biological toxins can cause significant illness at concentrations much lower than the level required for lethality. As a result, they are highly appealing as weapons of bioterrorism not only for their lethality, but also because of their ability to incapacitate humans.

2.5.2 Biological Toxins of Greatest Concern

Botulinum toxins are a group of seven toxins (A-G) produced by the anaerobic bacterium *Clostridium botulinum*. The toxins are formed in canned foods and subsequently ingested [1]. However, spores may gain access to the body through wounds or the gastrointestinal tract before germinating and producing toxin. Botulinum toxins, which are proteins with molecular weights of about 150000 daltons, act by blocking acetylcholine release at the neuromuscular junction and in the central and peripheral nervous systems [2] Intentional release would be through aerosolization of the preformed toxin or deliberate contamination of foods. Botulinum toxin is a CDC category A, delayed-action, lethal toxin.

The very first symptoms of botulinum toxin poisoning may be observed as early as 1 h after exposure or as late as 8 d after the exposure, with average incubation period between 12 h and 22 h. Symptoms include dizziness, sore throat, and difficulty speaking and swallowing. Muscular paralysis of the eyes, diarrhea, and vomiting is observed after a duration of time. In the worst case scenario, a complete paralysis of the respiratory musculature may occur, leading to death by suffocation.

The botulinum toxin is considered to be a stable toxin because it retains its integrity up to 7 d when protected from light and heat. If exposed to light and heat, it decomposes within 12 h in the air, but could stay stable for a week if placed in stagnant water. The toxin remains stable for up to a year when stored as a suspension or lyophilized powder between -0.4 ºF to 32 ºF (-18 ºC to 0 ºC).

Saxitoxin is the parent compound of a family of chemically related neurotoxins. In nature, they are predominantly produced by marine dinoflagellates, although they have also been identified in association with such diverse organisms as blue-green algae, crabs, and the blue-ringed octopus [2]. Human exposure is mainly due to ingestion of bivalve mollusks that have accumulated dinoflagellates. Intoxication results in a life threatening illness known as paralytic shellfish poisoning (PSP) that requires immediate medical intervention. Intentional exposure would be through inhalation of aerosols or as a toxic projectile or contamination of water supplies.[9]

Staphylococcal Enterotoxin B. (SEB), produced by *Staphylococcus aureus*, is a toxin that causes food poisoning when ingested. After 1 h to 6 h of exposure, the disease begins with sudden fever, headache myalgia, and nonproductive cough. In many patients, nausea, vomiting, and diarrhea also occurs. Intentional release of SEB would be through aerosolization, which would cause significant morbidity and potential mortality [2].

Tricothecene mycotoxicosis are a large group of low molecular weight toxins produced by several species of filamentous fungi [1] They are potent inhibitors of protein synthesis, impair DNA synthesis, alter cell membrane structure and function, and inhibit mitochondrial respiration. Naturally occurring trichothecenes have been identified in agricultural products and have been implicated in a disease of animals known as moldy corn toxicosis or poisoning. It presents itself as alimentary toxic aleukia, a lethal condition related to consumption of moldy grains. T-2 is one of the most stable of these toxins and therefore a likely candidate for intentional exposure [2].

Aerosolization or the deliberate contamination of food would be the most likely mode of intentional exposure.

Ricin is a glycoprotein toxin found in the seed of the castor plant. Ricin blocks protein synthesis in cells by altering the rRNA thereby killing it. Its symptoms after ingestion include nausea, vomiting, abdominal cramps, and severe diarrhea with vascular collapse. Death usually occurs on the third day. The exact cause of death is unknown and probably varies with route of intoxication [2]. High doses by inhalation appear to produce severe enough pulmonary damage to cause death. Ricin is a significant biological warfare agent due to its ease of production worldwide and its extreme pulmonary toxicity when inhaled.

Clostridium perfringens toxins are produced by an anaerobic bacterium, *Clostridium perfringens,* associated with three distinct disease syndromes, namely gas gangrene (or clostridial myonecrosis), enteritis necroticans (pig-bel), and clostridium food poisoning. Most *Clostridia* species produce large amounts of CO_2 and hydrogen that cause intense swelling, hence the term "gas" gangrene, resulting in gas in the soft tissues and the emission of foul-smelling gas from the wound [2]. Specific requirements for delivering inocula of *C. perfringens* to specific sites to induce disease are necessary, making it difficult for the spores or vegetative organisms of *Clostridium perfringens* to be used as a biological warfare agent. However, there are at least 12 toxins elaborated; one of these could be produced, concentrated, and used as a weapon. An example is the alpha toxin which would be lethal as an aerosol. Other toxins from the organism might be co-weaponized and enhance effectiveness. For example, the epsilon toxin is neurotoxic in laboratory animals.

3. CHALLENGES OF BIOLOGICAL AGENT DETECTION

Biological agents are infectious in very low doses. Therefore, BA detection systems need to exhibit high **sensitivity** (i.e., be able to *detect* very small amounts of BAs). The complex and rapidly changing environmental background also requires these detection systems to exhibit a high degree of **specificity** (i.e., be able to *discriminate* BAs from other harmless biological and nonbiological material present in the environment). A third challenge that needs to be addressed is **speed** or **response time**. **Ease of use** of a biological detection system (i.e., sample preparation requirements) is a fourth challenge needing attention. These combined requirements provide a significant technical challenge.

The purpose of this section is to identify some of the major challenges associated with BA detection. Specifically, section 3.1 addresses challenges associated with the ambient environment, section 3.2 discusses challenges with specificity, section 3.3 discusses challenges with sensitivity, and section 3.4 addresses challenges with sampling.

3.1 The Ambient Environment

The environment is an extremely complex and dynamic medium. The meteorological, physical, chemical, and biological constituents of a "normal" atmospheric environment all affect the ability to detect BAs. In order to understand the complex effect that the ambient environment can have on BA detection, the remainder of this section discusses specifics of the particulate background, the biological background, and the optical background, respectively.

3.1.1 The Particulate Background

Particulates in the atmosphere originate from a number of sources. Dust, dirt, pollen, and fog are all examples of naturally occurring particulates found in the air. Manmade particulates such as engine exhaust, tire rubber, smoke, and industrial effluents (smokestacks) also contribute significantly to the environmental particulate background. Therefore, the particulate background can be defined as the combination of natural and manmade particles in the atmosphere that are, for the most part, nonpathogenic (does not cause disease) in nature. Biological agents (not including toxins) consist of particulates of pathogenic (disease-causing) organisms. The particulate background can change on a minute-by-minute basis depending on the meteorological conditions at the time. For example, the particulate background next to a road will change dramatically depending on whether there is traffic on the road disturbing the dust and producing combustion products, or if the road is empty. Likewise, if there is little wind, not many particulates will be widely disseminated; however, when the wind begins to blow, particulates can be carried long distances. The challenge for a biological detection system is to be able to discriminate between all of the naturally occurring particulates and the BA particulates.

Particle counters can be used to monitor changes in the particulate background on a real-time basis because these systems see particles in the air and can count them. If the number of particles increases rapidly, it is possible that BAs are being used; however, it must be stressed that particle counters cannot determine if the particulates are dust, pollen, engine exhaust, or BAs. Other, more sensitive and selective tests must be performed on the particulates to determine if BAs are present. Particle counters are best used in a detection system where the

particle counter activates a sampler that collects a sample of the particles for a more detailed analysis.

3.1.2 The Biological Background

The environment is filled with living creatures that form a large and complex biological background from which BAs must be identified. The challenge for a BA detection system is to be able to identify a specific signal from the BA while rejecting, or at best minimizing, any signals originating from the nonpathogenic (nontoxic) biological background. This is a significant challenge given the amount of biological particulates in the environment. Research has identified a variety of potential bioaerosol sources (e.g., adjoining crop fields that are fertilized with "night soil," garbage incinerators, landfills, industrial areas, and dairy farms). Studies have shown that the concentration of bioaerosols depends on the location of the measurement. In Oregon, a study showed that the concentration of bioaerosol in an urban setting was six times greater than near the sea coast and almost three times greater than in a rural setting.

Data shown in figure 3–1 suggest that not only do biological aerosols vary by location, they also vary significantly by time of day.

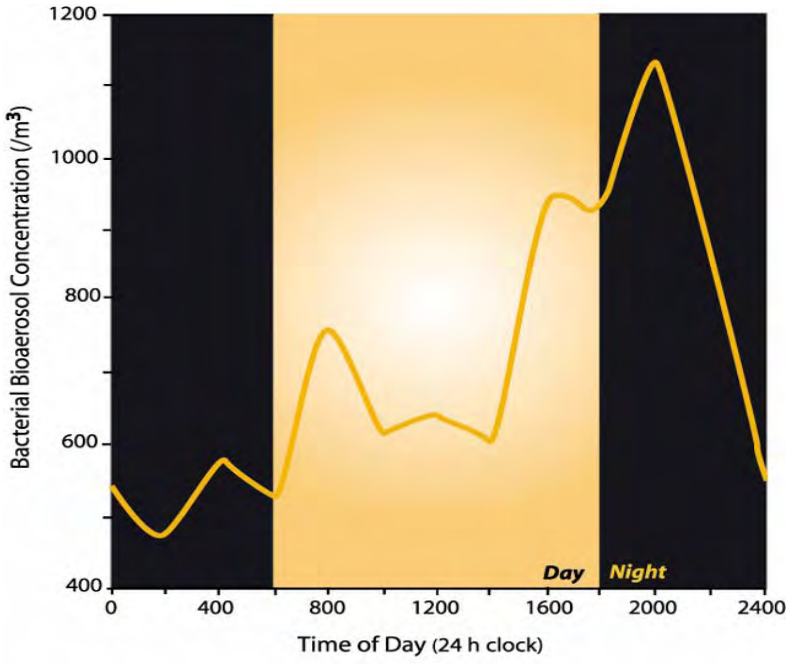

Figure 3–1. Airborne bacterial concentration fluctuation in a single day[5]

[5] Aerosolized bacterial concentration fluctuation over a 24 h period. The vertical (y) axis is bacterial concentration per cubic meter of air. The horizontal (x) axis is the time of day; shaded regions represent nighttime hours, and the clear region is daytime hours. The graph shows that airborne bacterial concentration exhibits a peak at 8:00 a.m., decreases throughout the morning and then increases during the afternoon, reaching a daytime maximum at 4:00 p.m. The bacterial concentration continues to rise, reaching a daily maximum at 10:00 p.m.

3.1.3 The Optical Background

Systems such as laser or passive infrared (IR) systems rely on optical properties for detection of BAs. They can be affected by micron-range particulates, as well as by other obstructions to visibility such as rain, fog, snow, and dust. Aerosols and precipitation may act like mirrors, reflecting and diffusing the light energy to and from the detector, and in the case of some aerosols, return false signatures (e.g., fluorescence from engine exhaust and pollens may confuse some ultraviolet [UV]-based systems). Consequently, different standoff systems are affected to different degrees by precipitation and aerosols. Infrared-based systems, as a rule, tend to be less affected by atmospheric clarity than UV-based systems.

3.2 Specificity of the Detection System

Detection systems must exhibit a high degree of specificity for BAs. The specificity of a detection system can be defined as its ability to discriminate between the target agent and the environmental interferents. The degree to which the specificity of a system is affected by interferents depends on the type of measurement being conducted. For example, dust and pollen can be considered interferents for a particle counter, while water vapor and fog are interferents for standoff IR detection systems. For BA monitoring, the most difficult interferents originate from the biological background (i.e., live, non-pathogenic organisms). Generally, the more selective systems require more sample processing and multiple detectors. A single system that exhibits high specificity for detection of BAs in the environment currently does not exist as a commercially available item. The systems currently developed by the military are limited to detection of a small number of agents and are prohibitively expensive.

3.3 Sensitivity of the Detection System

Detection systems must exhibit high sensitivity for the BAs because of the agent's low infectious doses. Sensitivity can be defined as the smallest amount of target agent that gives a reproducible detector response above the system noise. The system noise can be defined as the random fluctuation of the detector response and is generally associated with small variations in electronic output. Other noise that lowers the sensitivity is caused by interferents in the environment. In a perfect detection system, the system is sensitive enough to detect and identify the agent of concern and the system sensitivity (only dependent on the electronic noise) defines how much of the target agent can be detected. Interferents cause the sensitivity to decrease because the system needs more of the target agent to distinguish it from potential interferents.

3.4 Sampling

When first responders arrive at a potential biological agent exposure, they need to keep in mind that while inhalation exposure tends to be the biggest concern for the military, civilians can be exposed through aerosols, food contamination, and water contamination. It may be critical for the emergency first responders to conduct environmental (soil/water) sampling, and air and swipe tests, to corroborate the occurrence of a biological attack and to determine if the BA is still present.

Since sampling is a key issue for all analytical devices, the way a sample is taken and how it is handled will affect the outcome of the analysis. In a point collection/detection scenario, sampling for BA particulates in the air is especially difficult due to the limited quantity of these agents that can be present and still constitute a threat. To sample BAs effectively, some samplers pass large volumes of air through a sampler, where the particulates in the air are concentrated into a small volume of water. By concentrating the biological particulates, current detection systems have more sample to work with. However, the water and air filters also concentrate other particulates that may interfere with the detection of the agents of concern. Many other samplers deposit the air directly on filters, which are periodically removed and assayed.

4. BIOLOGICAL DETECTION SYSTEM COMPONENTS

The utility of BA detection equipment to the emergency first responders will depend on the characteristics of the detection equipment, the type and quantity of BA to be detected, the environment in which the sampling takes place, skill levels, and the objective of the emergency first responder unit. In addition, the quality of analytical results from the various analyzers will depend on the ability to effectively sample the environment and deliver the BA to the analyzer.

Reviews of the current status of chemical and biological detection equipment showed that biological detectors lag far behind their chemical counterparts. As a result, there are many biological detection systems that are currently in the research stage or in the early development stages. A limited number of biological detectors are commercially available. However, because of the highly complex and transient nature of the BAs, these devices still have limited utility (respond only to a small number of agents or give excessive false negative/positive results) and are generally high-cost items. It is, therefore, strongly recommended that first responders be very careful when considering the purchase of any device that claims to detect BAs and toxins.

The purpose of this section is to discuss the overall configuration of a biological detection system (sec. 4.1) and to discuss each component separately (sec. 4.2).

4.1 Configuration of a Biological Detection System

As has already been stated, the main reason for the limited availability of biological detection equipment is that BAs, compared to chemical agents, are very complex systems of molecules. This makes them much more difficult to identify. For example, ionization/ion mobility spectrometry (IMS), an excellent (though expensive) system for collection, detection, and identification of chemical agents, cannot detect or discriminate between BAs and other biological organisms in its present form. Another reason for the limited availability of biological detection equipment is that detection of BAs requires an extremely high sensitivity (because of the very low doses needed to cause infection) and a significantly high degree of specificity (because of the large and diverse biological background in the environment).

Because of the need for high-efficiency collection and concentration of the sample, and high specificity and sensitivity during detection and identification, biological detection systems are necessarily complex devices consisting of various subunits. Each subunit performs a specific collection, detection, and signal transduction task. As a result, in its truest form, a biological detection system consists of a sampler, a probe (detection), and a signal transducer.

The effective detection of BAs in the environment requires a multicomponent analysis system because of the complexity of the environment. Other variables contributing to the effectiveness of detection of BAs include the detection process itself and the efficient use of consumables in the field. Biological agent detection systems generally consist of four components: the trigger/cue, the collector, the detector, and the identifier. Figure 4–1 shows a flow diagram for a typical point detection automated architecture system. The function of these components is described in the remainder of this section, while section 5 will provide representative examples of each component.

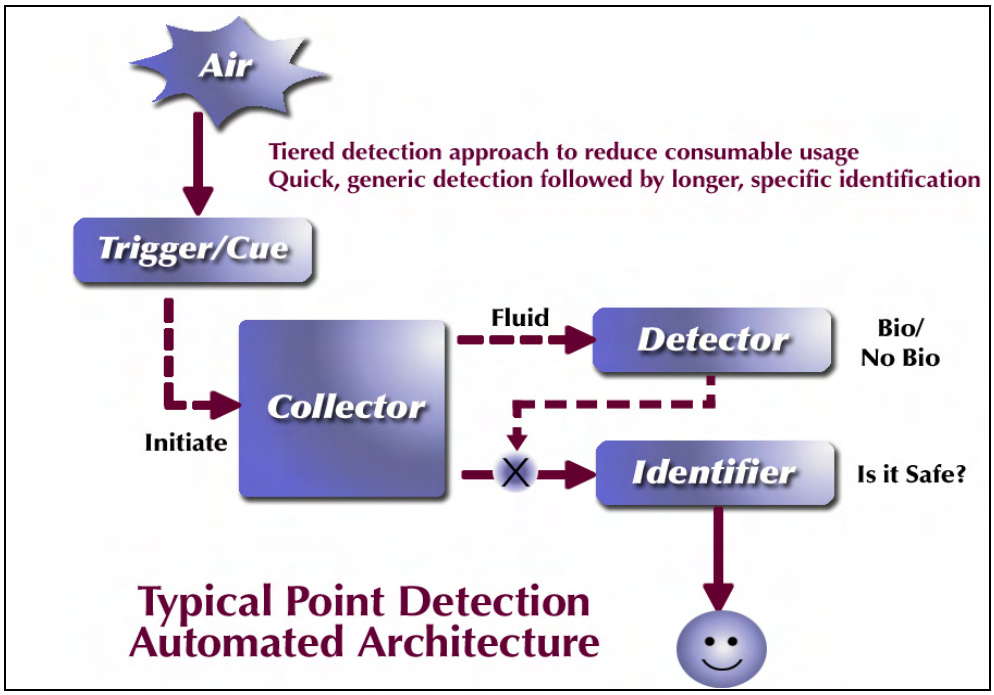

Figure 4–1. Typical point detection automated architecture (with a combined trigger/cue)

4.2 Subunits of a Point Detection System

Trigger/Cue. Trigger technology is the first level of detection that determines any change in the particulate background at the sensor, indicating a possible introduction of BAs. Detection of an increase in the particulate concentration by the trigger causes the remaining components of the detection system to begin operation. The trigger function typically provides a means of continuously monitoring the air without unnecessary use of consumables, thus keeping the logistical burden of BA detection low.

To reduce false positives (alarm activates in the presence of no BA) and false negatives (no alarm in the presence of agent), many detection systems combine trigger technology with a second detector technology (such as fluorescence that provides more specificity) into a single technology known as cueing. Most effective cueing technologies can detect airborne particulates in near real-time and can discriminate between BA aerosol particles and other particles in air, avoiding unnecessary system activation. For example, a cueing device monitors the air for particulates as does any other trigger device. When the particulate concentration increases, the cue determines if the particulates are biological in nature. The cue device generally uses a fluorescence detector to make this determination. If the particulates are found to be biological, the cue device activates the collector for sample collection.

Collector. The infectious dose for some agents is extremely small; therefore, highly efficient collection devices must be employed. One type of collector pumps large volumes of air through a chamber where the air mixes with water. The water scrubs all the particulates from the air, resulting in a sample containing particulates suspended in water. Once collected in the water, the

sample is further concentrated by evaporation of a portion of the water. After concentration, the sample moves into the analytical section of the BA detection system.

Detector. Once a sample has been collected/concentrated, it must be determined if the particulates are biological or inorganic in origin. To accomplish this, the sample is passed to a generic detection component that analyzes the aerosol particles. This component may also classify the suspect aerosol by broad category (e.g., spore, bacterium, toxin/macromolecule, or virus). In its simplest form, the detector acts as a "gateway" for further analysis. If the sample exhibits characteristics of biological particles, it is passed through to the next level of analysis. If the sample does not exhibit such characteristics, it is not passed to the next level of analysis, thereby conserving analytical consumables.

It is important to note that detection has traditionally taken place after the trigger function. For example, an aerosol particle sizer (APS) triggers, then a detector (e.g., flow cytometer) examines the aerosol for biological content. Many of the newer detection technologies combine the trigger and detection functionalities into a single instrument, creating a cueing instrument. As described in section 4.1, the cue first detects a rise in particulates then determines if the particulates are of biological origin. If the sample is biological, the collector gathers a sample and passes it directly to the identifier.

Identifier. An identifier is a device that specifically identifies the type of BA collected by the system. Identifiers are generally limited to a preselected set of agents and cannot identify agents outside of this set without the addition of new identifier chemistry/equipment or pre-programming. Because the identifier performs the final and highest level of agent detection, it is the most critical component of the detection architecture and has the widest variety of technologies and equipment available. The information obtained from the identifier is then used to determine protection requirements.

5. SAMPLING EQUIPMENT

Environmental sampling is the first critical step in determining the nature and scope of the threat from a BA. Although sampling devices were considered when conducting the market survey for BA detection equipment, several items were identified that were considered appropriate for these purposes.

Sampling refers to the collection and transfer of the material to be tested to the detector/analyzer. Since sampling is a key issue for biological detection, the way a sample is taken and how it is handled will affect the outcome of the analysis.

5.1 General Considerations

The decision to sample should be based on the extent and location of any suspected contamination, the potential for the contaminant to migrate, the matrix to be sampled (air, water, or soil), the direction and speed of prevailing winds, and other factors. For example, in a point collection/detection scenario, sampling for BA particulates in the air is especially difficult due to the low effective doses of these agents. To sample BAs effectively, samplers are used that pass large volumes of air through the sampler, dispersing the small amount of agent contained in the large volume of air into a small volume of water or other liquid reagent, thereby forming a concentrated mixture of particulates. By concentrating the biological particulates, current detection systems that are not able to detect BAs at very low levels can detect these agents in the concentrated mixture.

Microbiological considerations and human factors are covered in this section.

5.1.1 Microbiological Considerations

In general, understanding the four cardinal premises in environmental microbiology, to a large extent determines the quality of sampling and ultimately the reliability of the results from detection and identification systems. These premises are as follows: 1) Most microbes do not survive well outside of their natural environment or growth site. Therefore, one should find a significantly lower number of microbes in an environment that is not typical for the specific organism. It should be noted, however, once these organisms get a favorable environment (e.g., human tissue), they may grow rapidly. However as mentioned before, one does not need large concentrations of agents to infect individuals. 2) Microbes are ubiquitous (found everywhere). As a result, environmental samples could be rich in nontarget organisms that could add to the sampling and analytical burden or complicate the entire effort. 3) Microbes are not uniformly distributed in the environment. Consequently, one would find greater numbers of microbes close to the source of release, along the wind direction, and under favorable conditions for microbial growth. 4) Each environment has a characteristic bioburden and can be considered a separate biosphere. Therefore, in order to correctly interpret the analytical results, the bioburden (bioload) of each environment to be sampled needs to be properly identified.

5.1.2 Human Factors

Training of personnel involved in sample collection, handling, and analysis is important for assuring the reliability of results from sample analysis. As a result, proper training in sampling methods, handling of biological samples and data, and rudimentary understanding of the effects of biological and environmental factors on analytical results should be part of the emergency first responder's preparedness program.

Personnel safety is also paramount to the first responders. The National Institute for Occupational Safety and Health (NIOSH) interim recommendations for personal protective equipment calls for the following: 1) use of a NIOSH-approved, pressure-demand self-contained breathing apparatus (SCBA) in conjunction with a level A protective suit when information on the BA is unknown or the event is uncontrolled; 2) use of a level B protective suit with an exposed or enclosed NIOSH-approved pressure-demand SCBA if the suspected BA is no longer being released and/or other conditions may present a splash hazard; and 3) use of a full face-piece respirator with a P100 filter or powered air-purifying respirator (PAPR) with high efficiency particulate air (HEPA) filters when it can be determined that an aerosol-generating device was not used to create high airborne concentration, or dissemination was by a letter or package that can be easily bagged. In addition, care should be taken when bagging letters and packages to minimize creating a puff of air that could spread pathogens. It is also important to decontaminate the outside of the bag containing specimens to be tested. This protects anyone who touches it without protective equipment and also prevents contamination of the surroundings in which the specimen may be kept. The NIOSH also recommends use of disposable hooded coveralls, gloves, and foot coverings instead of wearing standard firefighter turnout gear when responding to reports of potential biological threats.

Decontamination. Sampling equipment and tools should be effectively decontaminated or properly disposed of after use. Moreover, depending on the size of the affected area and environmental conditions, it may be necessary to isolate and control access to the area to prevent the spread of the BAs. After taking off the protective gear, first responders should shower using copious quantities of soap and water. Decontamination of protective equipment and clothing is done using soap and water, and 0.5 % hypochlorite solution (one part household bleach to 10 parts water).

Record keeping and chain of custody. Proper sampling of BAs should be accompanied by a comprehensive documentation of sampling procedures, sample identity, personnel involved, and environmental conditions during sampling. A typical sample record would have sample ID, sample type, sample location, time and date of sample collection, name(s) of person(s) collecting sample, description of the surrounding environment, weather conditions, and other factors deemed relevant. In addition to the detailed sample records, maps, photographs, recordings, and sketches could also be used as supplemental information. This information is vital for assuring the integrity of samples, interpreting the data, and meeting forensic and other requirements, to include the safety of first responders and the general population.

In order to further maintain sample accountability and integrity, strict chain-of-custody procedures should be followed and documented. Chain-of-custody procedures are used to

establish the traceability of samples from the time of collection through the time of analysis. For this purpose, chain-of-custody forms are prepared in duplicate and accompany the sample from collection to the data compilation. The form should be dated, legible, and contain accurate and complete documentation of the activities of personnel involved at each step. The records should then be reviewed by a peer to ensure that all information is correct, witnessed, and signed. In addition to the sample records discussed above, the chain-of-custody form should also include a detailed description of the analytical procedures and any deviations from these procedures that may have occurred.

5.2 Sampling Procedures

Choosing a given sampling strategy depends on the purpose of the analysis to be performed, including screening, confirmatory, and basic research. In general, however, the number of samples should be sufficient to be representative of the target area. Sampling methods may vary, but it is a good idea to follow the NIOSH Method 0800. Although this method is intended for indoor air sampling, the general principles from this and other similar methods can be applied to any type of sampling. These principles include, but are not limited to the following:

- Triplicate sampling from affected/complaint area and a similar, but not affected (noncompliant) area.
- Sampling for 10 min before moving to the next site.
- Using one set of sampling media in each sampler to serve as field blanks.
- Collecting another complete set of samples and blanks on the following day.

5.3 Sampling Equipment

Sampling equipment is as varied as the nature of the threat and the number of equipment vendors. The following list represents some examples of available sampling equipment but it is not intended to be exhaustive. Some of the equipment items may not be relevant for the first responder's use or the detection equipment already used by the first responders may have integrated sampling mechanisms. The five sampling techniques that are commonly used include the following:

- Air sampling.
- Liquid sampling.
- Solid sampling.
- Surface sampling.
- Bulk material sampling.

5.3.1 Air Sampling

Since the most likely scenario of a bioterrorist attack appears to be through aerosolization of the bioagents, emergency first responders would more likely utilize air sampling than any other media. It is also likely, though, that most of the initial aerosol would have settled by the time emergency first responders arrive on the scene of an incident, which does not lessen the possibility of infection of the first responders by reaersolization of the agent, but requires that the

emergency first responders take more than just air samples for analysis. The emergency first responders should conduct environmental (soil/water) sampling and air and swipe tests to corroborate the occurrence of a biological attack and to determine if the BA is still present.

Most aerosol sampling devices use techniques that separate particles from the air stream and collect them in or on a pre-selected medium. The three common sampling techniques used to separate and collect the bioaerosol are impaction, filtration, and impingement. Each of these methods pulls a measured volume of air with the aid of an electric or battery-powered pump. The air is then directed through a chamber (or a series of chambers), guiding the bioaerosols on a specific trajectory to a solid agar disc or adhesive medium (impactor samplers), a liquid buffer (impinger samplers), or a filter (filtration samplers). Several air sampling equipment items are discussed in the remainder of this section.

The **Dry Filter Unit (DFU)** is a biological sample collection system developed by the Joint Program Office for Biological Defense (JPO-BD) and available for the emergency first responder community. The unit consists of a high-flow air sampling pump that collects airborne spores on 47-mm polyester filters (PEF-1 filters).

The DFU is a portable device that operates on ac or dc power and draws air through 1 micron polyester felt filter. It weighs approximately 14.5 kg (32 lb) and measures 33 cm x 33 cm x 38 cm (13 in x 13 in x 15 in). A single filter unit (SFU) and a 3-filter unit are available. Figure 5–1 shows the DFU with the inlet stack on top and the air outlet on the left. Figure 5–2 is the DFU with the lid open to expose the internal pump and filter assemble. It is easy to see the muffler that is stored in the lid.

Figure 5–1. Dry Filter Unit (DFU)

Figure 5–2. DFU showing accessories

After collection, each filter may be transferred into a 50 mL conical tube or may be left in the sample filter holder and transferred into a 50 mL conical tube in the laboratory. In the laboratory, the sample is prepared in a manner that will yield a suspension. Aliquots of the

suspension may be assayed by different microbiological techniques depending on the sensitivity needed. Figure 5–3 shows 50 mL conical tubes.

Figure 5–3. Conical tubes

The **Biocapture BT-550**, MesoSystems Technology, Inc., is an example of several self-contained, battery operated, portable units. It pulls an air sample through a solution that can be run through a PCR-type instrument or can be used with colorimetric test strips and spectrophotometric readers. The BioCapture™ is also compatible with other detection methodologies such as PCR, GC Mass Spectrometry, and traditional microbiological culturing. See figure 5–4 for a picture of the BioCapture BT-550.

Figure 5–4. BioCapture BT-550, MesoSystems Technology, Inc.

Cascade Impactors, Thermo Electron Corporation, have classification stages consisting of a series of nozzles and an impaction surface. At each stage an aerosol stream passes through the nozzles and impinges upon the surface. Particles in the aerosol stream with a large enough inertia will impact upon the plate, smaller particles passing as aerosols onto the next stage. By designing stages with higher aerosol velocities in the nozzles, smaller diameter particles are collected at each stage. Particles too small to be collected on the first stage are collected on a subsequent filter. Figure 5–5 presents the picture of a Cascade Impactor.

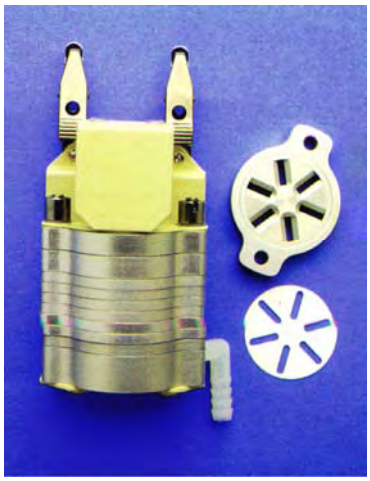

Figure 5–5. Cascade Impactor, Thermo Electron Corporation

The **BioSampler**, SKC, Inc., has an inlet design that limits the collection of airborne particles to those that would pass through the human nose. The sampler is normally used with a liquid that swirls upward on the inner wall of the sampler and removes collected particles. This gentle swirling motion generates very few bubbles, thus minimizing reaerosolization of collected particles. The design also reduces particle-bounce off the inner wall helping to ensure bioaerosol viability. The BioSampler can be used with collection liquids that have a viscosity much higher than water, such as ViaTrap®, which is a special mineral oil for sampling bioaerosols. When used with ViaTrap, the BioSampler's collection efficiency stays constant over an 8 h sampling period.

The BioSampler is designed to operate with a sonic flow pump, and no orifice is needed for operation. The three tangential nozzles of the BioSampler act as critical or sonic orifices, each permitting 4.2 L/min of ambient air to pass through. Once sonic flow is established, a flow rate of approximately 12.5 L/min is achieved. Figure 5–6 shows a picture of the BioSampler.

Figure 5–6. BioSampler, SKC, Inc.

5.3.2 Liquid Sampling

Liquids tend to be more homogeneous than other media. However, an attempt should still be made to get as representative a sample as possible. This may involve shaking or mixing by inversion to assure a uniform suspension of nondissolved fractions.

Similar precautions are needed for liquid sampling as required for bulk sampling. It is mandatory that the sample collection unit is leak-proof for liquid samples. Sampling kits or Teflon bottles can be used for liquid sampling.

The DIO-SIBCA**,** Sampling and Identification Kit of Biological and Chemical Agents, is manufactured by DIOMED Defense Systems Technologies and provides all the necessary material to detect chemical and biological warfare agents and take samples from air, water, soil, and surfaces suspected of being contaminated by these agents. It contains both motor-driven and manual vacuum pumps that enable easy and rapid sampling of air and water. With the help of these pumps, the air is passed through the sampling tubes and water is passed through special sampling filters. Figure 5–7 shows the DIO-SIBCA.

Figure 5–7. DIO-SIBCA, DIOMED Defense Systems Technologies

5.3.3 Solid Sampling

Sampling of solids represents a considerable challenge since getting a representative sample out of solids is a significantly difficult task. The most likely solid to be sampled for BAs is soil. The removal and containment of specific loose or compacted soil for laboratory analysis could either be manual, done by wearing gloves and collecting the soil sample in a sterile container, or instrumental. There are a variety of instruments for soil sample collection.

The **Bio-HAZ™ Kit** from EAI Corporation is a portable field system designed for use by emergency response personnel at incidents where biological materials may be present and sample collection and analysis are needed. The system contains all the materials needed to collect liquid and solid samples, as well as air sampling media for on-site biological analysis and also provides detailed instructions to ensure sample integrity. Step-by-step instructions starting with preparation for entry into the hot zone through sample splits, sample analysis, and sample

transfer to law enforcement are included. The Bio-HAZ is packaged in rugged, portable, watertight containers with each sample collection kit and sample processing kit marked for easy locating and use. All sampling/processing kits and other individual components are designed to be disposable and replaceable.

Sample screening is conducted by fluorometry, luminescence, or colorimetry, and sample specific analyses are performed through the use of sensitive membrane antigen rapid tests. Figure 5–8 shows a picture of the Bio-HAZ™ Kit.

Figure 5–8. Bio-HAZ™ Kit, EAI Corporation

5.3.4 Surface Sampling

Surface sampling may include swabs, tape lifts, or vacuuming for sampling collection. Carpet is listed as one of nine potential sources of BAs in an occupied space by the American Conference of Governmental Industrial Hygienists [(ACGIH)—Bioaerosols: Assessment and Control, 1999]. The difficulties in assessing carpet contamination arise from the porous nature of the material, lack of standardized sampling methods, and obscurity of data interpretation.

Surface samples are collected by wiping or swabbing a moistened, absorptive medium across a nonporous surface. If the samples are sent to a lab for analysis, the absorptive media, wetting agent, and bags used to transport samples should be selected in consultation with the laboratory personnel who will be analyzing the samples to ensure that collection procedures are compatible with the analytical procedures of the laboratory. Although there are several absorptive media available, noncotton (rayon, polyester, etc.) wipes or swabs are usually preferred. Swabs are best used for smooth small surface areas that do not have a large accumulation of dust. A larger surface area [>98 cm^2 (15.5 in^2)] can generally be sampled with wipe materials. The collection media must also be sterile and used with a sterile wetting agent such as sterile water, a sterile saline solution, or a sterile phosphate-buffered solution.

Sampling with the **CarpetChek™ System,** from Aerotech Laboratories, Inc., includes collecting carpet dust by vacuuming relatively large areas of carpet [65.6 cm x 279.4 cm (1 ft 2 in x 9 ft 2 in)], based on the amount of dust present with a high-volume pump and a dust cassette. Any three piece cassette fitted with an 0.8 µmicron polycarbonate filter is sufficient. The area of carpet sampled is inconsequential as the microbes are analyzed on a per gram basis. The

sampling technique, however, should be consistent, working the inlet tube as deep as possible into the carpet to collect a representative sample. Approximately 1 g (0.035 oz) of dust should be collected. See figure 5–9 for a picture of the CarpetChek cassette.

Figure 5–9. CarpetChek™, Aerotech Laboratories, Inc.

5.3.5 Bulk Material Sampling

Bulk material sampling refers to the random or specific sampling and scientific collection of water, soil, air, and building materials for laboratory analysis.

Bulk material sampling presents a significant challenge because of the possibility of secondary spreading of bioagents from contaminated bulk samples. Moreover, the extraction of bioagents from bulk samples can pose exposure concerns for laboratory personnel. As a result, appropriate precautions (such as double-bagging of samples) should be taken to prevent secondary exposure. In addition, bulk samples should be sent to at least a B-level laboratory with biosafety level 3 (BSL-3) facilities and should only be removed within a biological safety cabinet or glove box. ASTM E2458–06 Standard has been developed to address the practices for bulk sampling and collection of powders suspected of being biological agents [3].

The **Chemical-Biological Sampling Kit**, from QuickSilver Analytics, Inc., was developed by the U.S. Army Soldier Biological Chemical Command (SBCCOM) Forensic Analysis Center's Rapid Prototyping Team as a field adaptable sampling collection kit. The device was designed, developed, fabricated, and utilized so that environmental samples, including potentially toxic samples and forensic evidence samples, could be collected by kits. These kits are provided to government and commercial clients by QuickSilver, under a Cooperative Research and Development Agreement with SBCCOM.

The Chemical-Biological Sampling Kit, FAC™ Model 102, see figure 5–10, contains all required components in one handy "backpack" configuration designed to take up to six wipe, solid, and/or liquid samples.

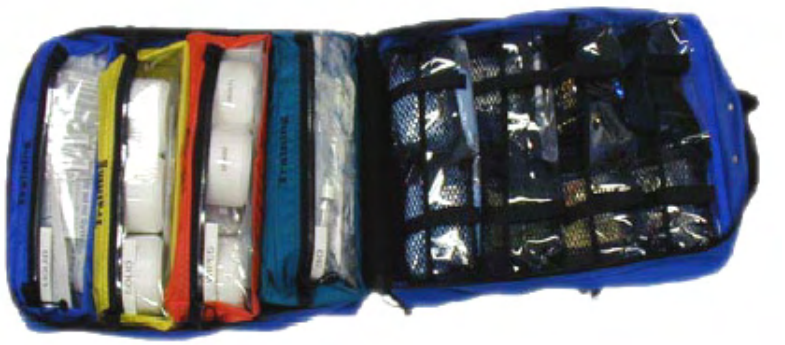

Figure 5–10. Chemical-Biological Sampling Kit, FAC™ Model 102, QuickSilver Analytics, Inc.

6. BIOLOGICAL DETECTION TECHNOLOGIES

Many technologies are currently being used or being explored for detection of BAs and toxins. Section 6.1 presents a discussion of potential BA detection technologies developed prior to 2001 and post 2001. Section 6.2 provides descriptions of technologies that were identified through the combined experience of an expert panel and first responders, through available literature searches, and through a market survey of biological detection equipment.

6.1 Potential BA Detection Technologies

Prior to the terrorist attacks of September 11, 2001, research and development activities for BAs could be considered insignificant. However, immediately after the attacks, a significant increase in BA technology reports and commercial product development occurred. A comparison of the BA technologies reported before and after 2001 is depicted in figure 6–1. Some of the detection technologies developed before 2001 are discussed in section 6.1.1 and those developed after 2001 are discussed in section 6.1.2.

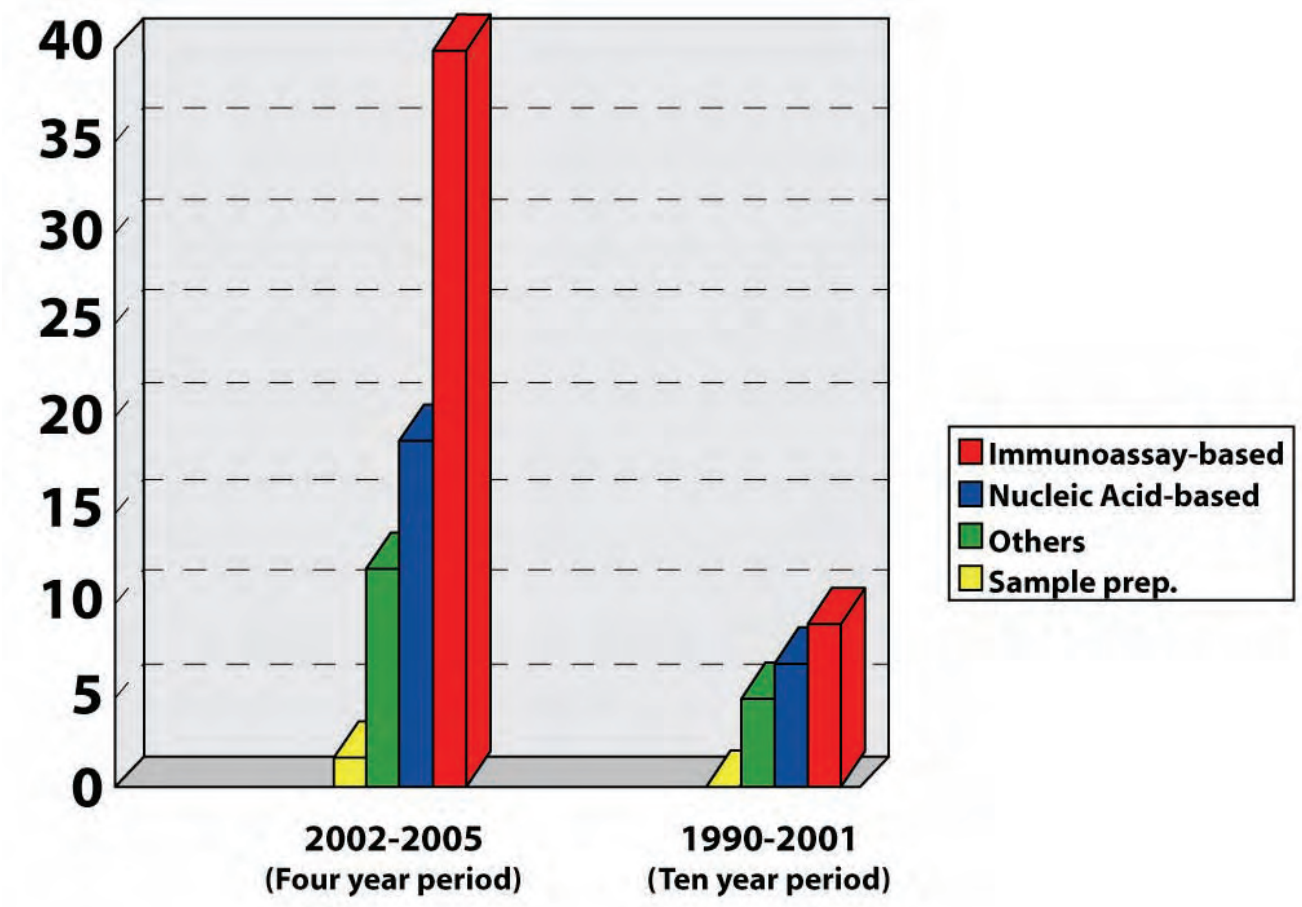

Figure 6–1. Comparison of BA technologies reported before and after the year 2001

6.1.1 Technologies Developed Before 2001

The detection technologies reported before 2001 are broadly categorized as immunoassay based, nucleic acid-based, and mass spectroscopy based technologies. These three technologies are described in the remainder of this section. See appendix B for a more detailed listing of the technologies developed prior to 2001.

6.1.1.1 Immunoassay-Based Technologies

Immunoassay based detection with antibodies is perhaps the only technology that has been successfully employed for detection of bacterial cells, spores, viruses and toxins alike [4]. Antibodies specific to virtually any compound can be produced so long as the compound of interest is able to trigger an immunological response. Most immunological techniques target surface antigens, which obviates the need for cell lysis or antigen purification prior to performing the assay. Both monoclonal and polyclonal antibodies have been used to develop immunoassays with the former selected for assays that are more specific, but at the expense of sensitivity and binding affinity [4].

Several immunoassay techniques have been reported for the detection of BA with electrochemical [5], CCD camera [6], and impedance spectroscopy [7] detection. Carlson *et al* [8] developed a hand-held, self-contained, automated immunoaffinity fluorometric biosensor for detecting and quantifying aflatoxins, a family of fungi-produced carcinogens that have been cited as BA under development. The biosensor requires no special storage and can perform more than 100 measurements before refurbishment is required. The design and fabrication of biosensors able to distinguish multiple analytes is a major research goal, especially for the detection of BA in the field. However, several of the reported biosensors describe the method for multianalyte sensing but only demonstrate the detection of a single analyte. Uithoven *et al [9]* developed a flow-through immunofiltration-enzyme assay system with leucine aminopeptidase (LAP) for the detection of *B. subtilus*. The instrument has been incorporated into the Department of Defense's Biological Integrated Detection System (BIDS). It can assay up to eight agents simultaneously within a total assay time of 15 min and with a 3×10^3 colony forming units per mL (cfu/mL) limit of detection. Section 6.2.7.6 has a brief discussion of the BIDS.

In another approach, Koch *et al* [10] developed an automated multichannel capillary ELISA for the detection of SEB, bacteriophage M13 and *E. coli* that employs different capture molecules placed on different capillary channels. In another study, Lee *et al* [11] combined discrete sensing formats to detect SEB, *B. melitensis*, soman, and sarin. The biosensor utilizes biotin streptavidin filtration capture onto a nitrocellulose membrane with a silicon-based light addressable potentiometric sensor (LAPS). The biosensor was adaptable for immunoassays as well as nucleic acid hybridization assays for the detection of SEB and *B. melitensis* and enzyme inhibition assays for the detection of sarin and soman. In an effort to address the challenges encountered in design of biosensors for multianalyte sensing, Rowe *et al* [12] developed an array biosensor using a single sensor substrate with a single detection step to test multiple samples for the presence of several analytes of different classes (viral, bacterial, and protein). The designed

sensor could detect *B. globigii*, MS2 bacteriphage, and SEB within 14 min with sensitivities comparable to standard ELISA.

Flow cytometry is based on the flow of a fluid stream carrying a low density of biological particles past an illuminating laser and target molecules quantified according to their fluorescence. It can be combined with fluorescently labeled monoclonal antibodies to create a powerful immunological detection technique that affords rapid and sensitive detection. Megerle [13] developed a patented immunoassay technique based on flow cytometry for the detection and subsequent removal of BA from water supplies. In another study, a miniaturized (hand-held) flow cytometer for the detection of SEB with a response time of 2 min is described [14]. While flow cytometry techniques find widespread application in the clinical laboratory, the transition into field-portable instruments has been hindered by the requirement for high-power laser systems.

Copalis™ a homogenous ligand binding detection technology was developed by Sienna Biotech. It measures particle size using high-resolution optical sizing to distinguish between monomers from larger aggregates. Since molecular recognition from nucleic acid, antibody-antigen, receptor-hormone interactions involve coupling into larger aggregates, assays utilizing Copalis™ technology can be readily developed. Although this technology is reported for the detection of Cytomegalovirus (CMV) [4] in an immunoassay, it can find potential use in the detection of BA utilizing both nucleic acid interactions and immunoassays. For DNA analysis, the probes can be immobilized onto latex particles, either directly or indirectly via proteins. Hybridization of the amplified sequences with DNA probes immobilized on the latex particles would then result in detectable aggregation [15].

6.1.1.2 Nucleic Acid-Based Detection Technologies

Nucleic acid-based detection technologies are generally more sensitive and specific than immunological-based detection technologies. These remarkable sensitivities are only achieved where amplification procedures such as PCR are employed. PCR has been coupled to a majority of nucleic acid-based detection system resulting in significant improvements in assay sensitivity. Several PCR-based technologies have been reported for the detection of *B. anthracis* [4,16,17,18,19], *F. tularensis* [20], *Brucella* sp [20], *B. cereus* [4], *B. thuringiensis* [4], *Y. pesti*s [21]. However, nucleic acid-based techniques coupled with pre- and post-amplification procedures are not adaptable to field applications since they are time intensive and require highly trained personnel. Therefore, there has been a need to develop assay techniques that are rapid, can purify the target nucleic acid, and can remove inhibitors from the sample. In this regard, Iqbal *et al* developed a fluorogenic assay for the detection of *Y. pestis* utilizing the *Taqman* assay, which eliminates the need for post-PCR separation step and significantly reduces the assay time [22]. In another study that requires no post PCR procedures, Edelstein *et al* developed a Bead ARray Counter (BARC) biosensor that uses DNA hybridization, magnetic microbeads, and giant magnetoresistive (GMR) sensors to simultaneously detect and identify *B. anthracis, Y. pestis, B. suis, F. tularensis, V. cholerae, C. botulinum, C. jejuni* and vacinni virus [19]. In an effort to reduce the number of false positives and negatives, they employed magnetic fields to discriminate between specifically and non-specifically bound magnetic microbeads. GMR sensors were used to detect the remaining beads with the intensity and location of the signal

indicating the concentration and identity of the pathogens. DNA was detected at 100 fM using optical detection. Detection of the GMR sensor signal is expected to improve assay sensitivity.

For optimal PCR-based analyses, the nucleic acids must be made available to the reaction components. For example, *B. anthracis* spores contain an outer cortex that is extremely resistant to harsh physical and chemical treatments, making the process of spore lysis a major constraint in PCR analysis. Belgrader *et al* have developed a mini-sonicator that rapidly disrupts bacillus spores in 30 s making the total time of spore disruption and detection using a microchip PCR instrument less than 15 min [23].

The most characteristic molecules used in nucleic acid-based techniques are DNA or RNA. However, ribosomal RNA (rRNA), present in many thousands of copies per cell, obviates the need for amplification using PCR [14]. Nucleic acid-based techniques that employ the natively amplified rRNA would dramatically reduce the time required for such assays. Researchers from Argonne National Laboratory have developed the Bacillus Chip, a two-dimensional array of complimentary rRNA probes immobilized within a 10 µm x 60 µm gel pad. Detection is achieved by allowing the target oligonucleotides to flow over the chip, and after hybridization between the immobilized probes and the target oligonucleotides fluorescence of the individual pads is measured. The chip has the potential to distinguish organisms that have a single base pair mismatch [14].

6.1.1.3 Mass Spectroscopy-Based Technologies

Three mass spectroscopy based technologies were reported prior to 2001. The Block I Chemical and Biological Mass Spectrometer (CBMS) [24] was used to detect aerosolized *B. globigii*. The detection strategy involves liberation of *B. globigii* biomarkers by thermolysis-methylation, followed by direct sampling ion mass spectrometry. A detection of 50 agent-containing particles per liter of air (ACPLA) was achieved. The Block II CBMS [25] (fig. 6–2) resulted in an improved detection limit of 25 ACPLA. Donlon and Jackman [14] reported the use of MALDI to detect Staphylococcus enterotoxin B with a remarkable detection limit of 1×10^{-18} M. MS techniques possess impressive analytical characteristics such as short response times and minimal sample preparation (aerosols) and would be suitable for point detection of BA agents. However, the interpretation of mass spectra requires highly trained personnel; furthermore, significant effort is still required for the development of spectral signals for each of the BAs. In addition, MS instruments are bulky with high power requirements and therefore could be better suited for confirmatory analysis following initial screening of BAs using either immunoassays or nucleic acid-based technologies.

Figure 6–2. Block II Chemical and Biological Mass Spectrometer (CBMS)

6.1.2 Technologies Developed Post 2001

The events of September 11, 2001 and thereafter led to a significant increase in the development of BA detection and other technologies related to homeland security. Over the past five years, technologies have been developed or adapted to the challenges posed by BAs leading to improved limits of detection and shorter assay times. The development of fully automated fieldable or point-detection technologies has also increased significantly. At the same time, assay systems that are reliable, robust, accurate, simple to use, and inexpensive have also seen increased production. Improved reagents and detection equipment has led to dramatic improvements in the sensitivity and specificity of the molecular recognition (e.g., immunoassays and nucleic acid-based assays) techniques that find application in a majority of the developed technologies. In the remainder of this section, potential BA technologies reported in literature, beyond 2001 are presented. See appendix C for a more detailed listing of the technologies developed after 2001.

6.1.2.1 Immunological Technology

Significant progress has been made in the past five years in the development of devices that employ immunological technology for the detection of BA. Consequently, immunoassays are now the most widely used analytical technique for bioassays. Recent improvements in antibody production, and the fact that immunoassays are inherently specific, selective, require minimal sample processing, and are readily adaptable to fieldable devices, have led to the quantitation and identification of a wide range of analytes including BAs. Immunological techniques reported for the detection of BA employ both monoclonal and polyclonal antibodies that target surface antigens. Unlike nucleic-based detection technologies, this eliminates the need for cell lysis or antigen purification prior to performing the assay, which is advantageous for the detection of intact bacterial spores such as *B. anthracis* whose spores are not easily disrupted. Therefore, detection technologies that adopt immunological techniques are inherently rapid since minimal sample preparation is required. Several sensitive laboratory based immunoassays have been developed for BA detection with fluorescent covalent microsphere immunoassays (FCMIA) [26,27] and bead-based assays with electrochemical detection [28], time resolved fluorescence (TRF) [29], integrated metal clad leaky waveguide sensor [30], and ion channel switch array biosensor (ICS) [31], among others (see appendix C).

The advances in immunological techniques have been matched by improvements in complimentary technology such as automated analyzers, microarrays for multianalyte detection, reporter systems, and microchip-based technologies. New developments and improvements in handheld and portable immunoassay systems have been reported with remarkable sensitivity and specificity. Most of these technologies employ lateral flow immunoassay formats since these are rapid, simple, and require minimal time to perform, usually between 15 min to 60 min. Recently, a portable semi-automated immunoassay system with limit of detection of 700 cells/mL of pathogenic bacteria and 0.1 ng/mL for toxins and proteins was reported [32]. The sensitivity of the system was greatly enhanced by the use of a dual enzyme amplification system, while the detection system utilized low-cost disposable microfluidic cartridges. A microfluidic cartridge was used to house the reagent reservoirs, the antibody labeling and concentration chamber, and a screen-printed electrochemical sensor reducing the total assay time to less than 60 min. In another study, Song *et al* [33] employed a biochip system based on complimentary metal oxide semiconductor (CMOS) technology with enzyme amplification and fluorescence detection to develop a device with the potential for single-bacteria detection. The limit of detection achieved was < 1 cell of *B. globigii*.[6] . The excellent sensitivity of the assay was attributed to the combination of the laser induced fluorescence and enzyme amplification. Several other portable immunological based technologies have been reported with chemiluminescence based detection [34], portable surface plasmon resonance (SPR) Spreeta®SPR [35,36], compact biochip detection systems [37], immunofiltration membranes with amperometric detection [38], and the reagentless optical biosensor (ROB) [39], among others (appendix C).

Protein microarrays have recently been employed in the detection and quantification of proteins in solution. Microarrays have the advantage of portability, low rate of false positives, shortened assay times, and the ability to analyze multiple analytes in a single assay. These characteristics must be considered when developing sensors for BA to be used for multiple analyte detection. Ligler and co-workers [40,41,42] employed arrayed antibodies in a microfluidic format for the fluorescent identification of microorganisms and toxins using a sandwich immunoassay for the detection of cholera, tetanus toxin, botulinum toxin, ricin, and SEB. The result of this research is the Multi-Analyte Array Biosensor (MAAB) that simultaneously detects multiple analytes in a complex sample in less than 15 min [43]. At Lawrence Livermore National Laboratory, McBride and co-workers [44,45], developed liquid array-multiplex immunoassays for rapid, sensitive, specific, and simultaneous detection of BAs. The immunoassays were developed in a commercially available flow cytometer, the Luminex LX-100, integrated into the autonomous pathogen detection system (APDS). The APDS (fig. 6–3) is a podium sized fully automated instrument for the continuous monitoring of air for aerosolized BAs. It performs sample preparation and detection of 11 biological agents including *B. anthracis, Y. pestis, B. globigii,* and botulinum toxoid using multiplexed immunoassay followed by confirmatory PCR using real time *TaqMan* assays. Prior to PCR analysis, sample preparation is performed by sequential injection analysis (SIA) that extracts the DNA and eliminates the PCR-inhibitor. Immunoassay combined with confirmatory PCR was employed to minimize the probability of reporting false positives.

[6] Experimental results showed 0.31 cells of *B. globigii*.

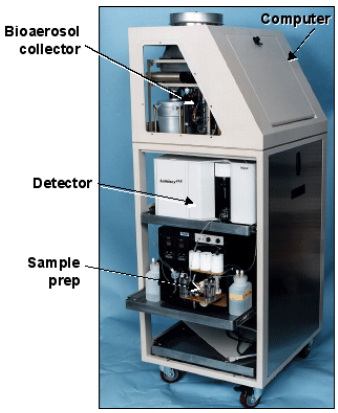

Figure 6–3. Autonomous Pathogen Detection System (APDS)

Several multiarray sensors have been employed in the classification of bacterial species. The rapid detection of bacterial species is important in many practical applications ranging from medical diagnosis to homeland security. In one study, Ertl *et al* [46] employed an electrochemical screen-printed biosensor array for the rapid identification of *E. coli* subspecies (*E. coli* B, *E. coli* Neotype, *E. coli* JM105, and *E. coli* HB101). Selective recognition was accomplished by using ten lectins, immobilized onto porous membranes, which bind to cell surface lipopolysaccharides. Coulometric transduction of non-native external oxidants was used to monitor the respiratory cycle activity in the lectin-bound cells. The use of this technology requires no prior knowledge or assumption of the identity of the analyte. In another bacterial classification study, Karasinski *et al* [47,48] employed a fully autonomous electrochemical multiarray sensor with pattern recognition for the real time detection and classification of bacteria at subspecies and strain levels. They employed a 96 well-type electrode array (DOX-dissolved oxygen sensor) system with principal component analysis for rapid detection and classification of bacteria species. The DOX-96 is an automated potentiostat prototype, produced by Daikin Industries Ltd., Japan, that was designed to measure cell respiratory activity via their consumption of dissolved oxygen in bacteria cultures. The classification was based on the hypothesis that various bacteria consume oxygen at different rates in the presence of different antibiotics. Therefore, the response of the individual electrode in an array is altered compared to that of cells growing in a medium without antibiotics.

Development of immunoassay reporter systems with optical detectors to address the shortcoming of the current technologies has recently become an active area of research. Reporter systems such as fluorescence, phosphorescence, or luminescence are routinely used because of their high sensitivity and capability for simultaneous use as multiple optical reporters with different spectral characteristics (multiplexing). Hampl *et al* [49] recently developed a new class of labels with the unique ability to convert low energy (IR) radiation to high energy (visible) light by a multiphoton absorption process and subsequent phosphorescence emission. These upconverting phosphors (UCP) are lanthanide containing submicron-sized ceramic particles that can absorb infra red light and emit visible light. Multiple spectrally unique phosphor colors exist so each spectrally unique phosphor can be attached to different detection probes (e.g., antibodies or nucleic acid oligomers) to allow multiplexing. Due to the upconverting process, there is no background phosphorescence from the carrier fluid and no interference from common assay interferents such as hemoglobin. As a result, UCP assays are currently 10 fold to 100 fold more sensitive than assays using conventional colored beads [49,50]. Although UCP labels have not

been employed in BA detection assays, they have the potential to greatly improve the sensitivities of the current technologies since they can be used for quantitation of analytes in complex environments and be employed for multiplexing.

6.1.2.2 Nucleic Acid-Based Techniques

To date, detection and identification strategies based on nucleic acid-based techniques remain the most common for BA because of their sensitivity and specificity. However, these techniques are generally not adaptable to field applications since they are time intensive and require highly trained personnel to perform the prehybridization sample preparation. However, since the advent of real-time PCR, the time frame of these assays has significantly been reduced from several hours to a few minutes. Invnitski *et al* [51] gives a comprehensive review on potential PCR-based technologies for the detection of BAs.

Current research trends in the development of BA nucleic acid-based detection technologies are geared towards handheld systems that include prehybridization sample preparation techniques and employ homogenous hybridization assays involving single reaction multianalyte detection that obviates the separation steps, which would be rather difficult under field conditions [3]. The results have been rapid, sensitive detection methods that are potentially adaptable for field applications. Researchers at Lawrence Livermore National laboratories have developed a hand-held, four-chamber, battery operated instrument referred to as the Handheld Advanced Nucleic Acid Analyzer (HANAA) [51,52]. The HANAA system, which employs TaqMan®-based PCR assay, is highly automated, capable of automatically preparing samples, and simultaneously tests four different samples for two different DNA sequences in about 30 min. It is about the size of a brick, weighs less than 1 kg, and, in principle, can detect as few as 10 individual bacteria including *B anthracis* (fig. 6–4).

Figure 6–4. Handheld Nucleic Acid Analyzer (HANAA)

Smiths Detection-Edgewood, Inc. has commercialized the production of HANAA. The updated redesigned version is referred to as BioSeeq® and is capable of detecting 1 CFU of bacterial pathogens in less than 30 min [53]. An integrated sample preparation cartridge allows samples to be taken in the field and tests run on the spot. See section 6.2.1.1.2, figure 6–11 for a picture of the BioSeeq Handheld PCR Detector from Smiths Detections.

Another automated PCR-based system is the Ruggedized Advanced Pathogen Identification Device (R.A.P.I.D.®) developed by Idaho Technology [51]. R.A.P.I.D.® is based on the Light Cycler® PCR technology with a fluorescence detection system. The principle behind the Light Cycler® system is based on hybridization probes. Two probes hybridize to the specific target in a head-to-tail arrangement that bring the two different fluorophores into close proximity, which in turn leads to fluorescence energy transfer. R.A.P.I.D.® is capable of amplifying and analyzing up to 32 test samples within 40 min. The basic instrument weighs less than 25 kg and can automatically collect data interpret test and report the results. See section 6.2.1.1.2, figure 6–10 for a picture of the R.A.P.I.D.® System (7200) from Idaho Technology, Inc.

In another study, Intergrated Nano-Technologies (INT) developed a novel biosensor technology that rapidly and accurately provides DNA-based field detection and identification of pathogenic organisms [54]. The sensor is capable of detecting the binding of a single molecule of DNA or RNA, therefore does not require PCR amplification. The biosensor consists of oligonucleotides probes attached to multiple pairs of interdigitated electrodes on a microchip. Hybridization of target DNA to the DNA capture probes that are bound to the electrodes forms a DNA bridge connecting the two electrodes. Chemical treatment of the DNA bridge coats it with metal converting it to a conductive wire. Formation of the one metalized DNA bridge reduces the electrical resistance of the sensor 1000-fold, enabling the detection of a single molecule of DNA. INT is currently developing the BioDetect™ analyzer with the biosensor technology incorporated into a single-use disposable BioDetect™ test card. The test cartridges will perform the sample preparation, cell/spore disruption, filtration, DNA shearing, and the electronic detection. Figure 6–5 presents a schematic of the BioDetect™ Sensor System.

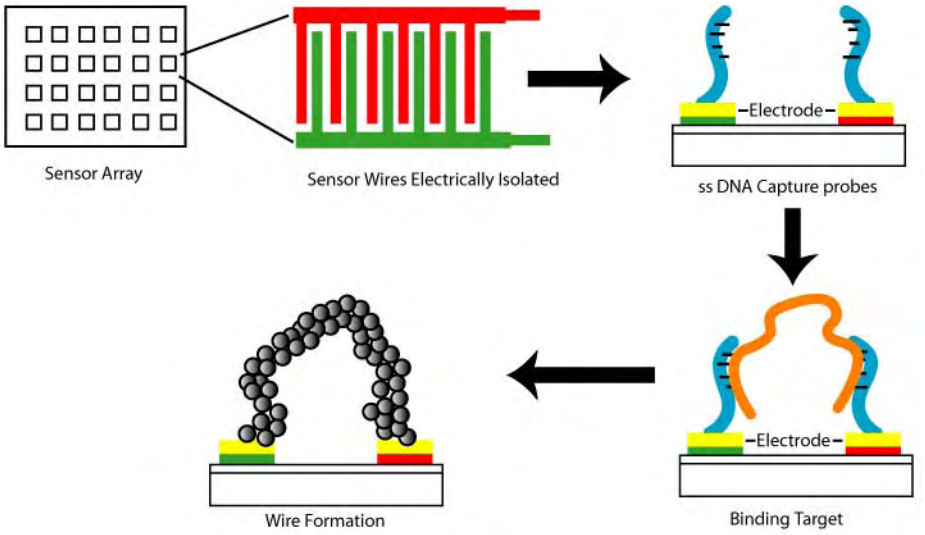

Figure 6–5. Schematic presentation of the BioDetect™ Sensor System [55]

There have been several other reports on the development of nucleic acid biosensors with various amplification procedures and transduction principles. Among the reported systems with the potential for BA detection are quartz crystal microbalance (QCM) based DNA biosensor [56],

simple membrane-strip-based biosensor [57], and integrated capillary fluorescence DNA biosensor [58], among others.[7]

The complexity of BAs requires sample preparation procedures such as cell lysis, selective cell isolation, and nucleic acid extraction to reduce their complexity for accurate detection. Current research trends are geared towards automation with the integration of sample preparation procedures, PCR amplification, and detection into a single microchip or instrument for rapid assays with minimal user intervention. Breadmore *et al* [59] have developed a rapid microchip solid-phase extraction method for purification of DNA from biological samples. DNA from human blood was purified in about 15 min with the only sample preparation being the mixing of blood with the loading buffer. In another study, Huang *et al* [60] demonstrates the extraction of three BAs from blood using a miniaturized dielectrophoresis (DEP) device. The device has the potential to reduce the complexity of BAs collected in the field. In another study, Liu *et al* [61] developed a fully automated biochip device that includes sample preparation, PCR amplification, hybridization, and electrochemical detection. The device is fully self-contained and requires no external sample manipulations such as external pumps, thereby eliminating the possibility of sample contamination.

In the development of a fully automated system, two bottlenecks are usually encountered. One occurs during sample extraction since most systems are designed to detect threat agents in specific matrices (e.g., aerosols) but may not necessarily be optimal for other matrices. The second is the potential of false positives and false negatives since most of the available systems use either PCR or immunoassay techniques. However, not all agents can be detected by the same molecular recognition technique. For example, a PCR-based detection technique may not be effective for the detection of a toxin such as ricin [62]. In an effort to address the need for a high throughput system for rapid, accurate, and cost-effective analysis, DOD has initiated the development of the Automated Biological Agent Testing System (ABATS) [62]. Although ABATS is a laboratory based technology not suitable for first responders, the need to have a back-up lab system is still necessary since most portable BA detection may not be suitable for the large variety of matrices in which BA may be encountered in the field. The ABATS was designed to be versatile and detect biological threat agents within multiple matrices, such as air, soil, water, and on surfaces. The DOD approach was to design a system that is highly automated with the flexibility to detect multiple biological molecules such as DNA, RNA, and protein (antibodies) for use with a wide range of potential BAs. The current ABATS consists of two ABI 7900 PCR thermocyclers, an M series M8 ECL analyzer, an Abgene piercer and plate sealer, multi-drop liquid dispenser, heat block, shaking platform, pipette tip lift, storage carousel, and a Biomek FX liquid handler all linked via a master computer control. Figure 6–6 shows the Automated Biological Agent Testing System (ABATS).

[10] Appendix D—Potential Biological Agent Detection Technologies Developed Post 2001

Figure 6–6. Automated Biological Agent Testing System (ABATS)

6.1.3 Discussion

The most common BA detection systems are nucleic acid-based and immunoassay detection. These have been integrated with various detection technologies, including PCR-amplification for nucleic acid-based assays, electrochemiluminescence (ECL), and lateral flow assays for handheld immunoassay based detection technologies. Remarkable improvements in the technologies have been achieved with the most notable one being the development of real-time PCR and PCR extraction. The manual extraction of bacterial samples prior to PCR that required a 5 h germination step in which bacteria was grown in culture media and induced to shed the bacterial spore coat has been replaced by a 30 min bead beating step [62].

Despite the major improvements in BA detection technologies, limitations pertaining to their performance are still imminent. First, a majority of the BA technologies are designed to detect BAs in specific matrices with a lot of emphasis on aerosol samples (the method of choice for the intentional dispersal of *B. anthracis*). However, a detection method for one sample matrix (e.g., air from a filter) may not be optimal for another matrix such as a swab or soil sample. Furthermore, some of these technologies have been adopted from systems previously employed for medical diagnosis or pharmaceutical drug discovery that were optimized for specific matrices such as blood samples or highly purified conditions. BAs on the other hand are found in widely variable backgrounds and, therefore, require a system that can discern the bioagent in a background that is full of other biological interferents. Secondly, most of the current technologies use nucleic acid-based detection systems or immunoassay based technologies exclusively. Therefore, they assume the inherent limitations associated with these techniques in terms of sensitivity, specificity, speed, false positives, and cost. Until a fundamentally new technology is developed, process enhancements will be the best solution to these limitations. The use of orthogonal methods, such as PCR technology coupled with immunological-based technology, could provide the greatest levels of confidence in the developed technologies.

Future successes or failures in BA detection technologies will greatly depend on developments in the affinity and specificity of molecular recognition elements and the ability to efficiently extract their targets from real samples. Continued research to improve molecular recognition elements (i.e., antibody, DNA, RNA, receptor, aptamers, etc.) and sample extraction/preparation

techniques will, therefore, remain crucial in the development of BWA detection technologies of the future.

6.2 Technology Descriptions

Technologies identified during the development of this guide include molecular recognition technologies, immunological detection techniques, physical techniques, ligand-based techniques, microscopic techniques, and standard culture applications. Screening equipment and reagent kits are discussed in section 6.2.8 and section 6.2.9, respectively. While not all of these technologies are applicable or available for the first responder community, the information is designed to provide background material for making sound decisions. Currently, the predominant detection methods that are being used by the first responder community are molecular (real-time polymerase chain reaction [PCR]), immunochemical (lateral flow immunochromatography [LFIC]), and screening (Fourier transform infrared [FTIR] spectrometry), and are thought to be the most appropriate systems at this stage. Each of these technologies is discussed in the remainder of this section.

6.2.1 Molecular Recognition Technologies

Molecular recognition assays can be developed for virtually any organism on the basis of its unique nucleic acid sequence, either deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) with the identification of nucleic acid sequences unique to that particular organism. Prions are an exception since they have no nucleic acid associated with them [63]. Nucleic acid-based assays can be classified into two broad categories, those that rely on nucleic acid hybridization followed by signal amplification, and those that rely on target DNA replication (amplification) by means of PCR. Those that rely on nucleic acid hybridization require larger amounts of genomic DNA and are less sensitive than those that rely on target DNA replication (amplification). For this guide, molecular recognition technologies have been classified into three major categories, polymerase chain reaction (PCR), molecular hybrid techniques, and molecular array techniques.

6.2.1.1 Polymerase Chain Reaction (PCR)

PCR is the most commonly used molecular technique for identification and detection of biologicals. PCR can be coupled to virtually any nucleic acid-based detection system resulting in a significant increase in the sensitivity of the assay. There are several variations of PCR including standard PCR, real-time PCR, and reverse transcriptase PCR. These are discussed in the following sections.

6.2.1.1.1 Standard Polymerase Chain Reaction

PCR amplification is an *in vitro* technique that uses the enzyme DNA polymerase and short single-stranded DNA primers to produce large quantities of identical copies of a specified DNA sequence. The primers are usually 18 nucleotides to 22 nucleotides in length and are complimentary in sequence to the ends of the DNA sequence to be amplified. In standard PCR, double-stranded DNA is denatured, either chemically or at high temperatures (approximately 95 ºC or 205 ºF), to form the single-stranded DNA templates. The DNA primers are used to

initiate the DNA synthesis by annealing to the template at the region of interest. The newly synthesized strand, starting at the primer, extends beyond the position of the primer on the template strand so that both the synthesized strand and the primer both contain new primer binding sites for further replication. Each cycle consists of three steps: DNA denaturing, primer annealing, and primer extension (or DNA synthesis). Standard PCR requires post-PCR processing to separate the DNA (gel electrophoresis) and visualize using a chemical stain (ethidium bromide). Figure 6–7 presents a schematic of standard PCR.

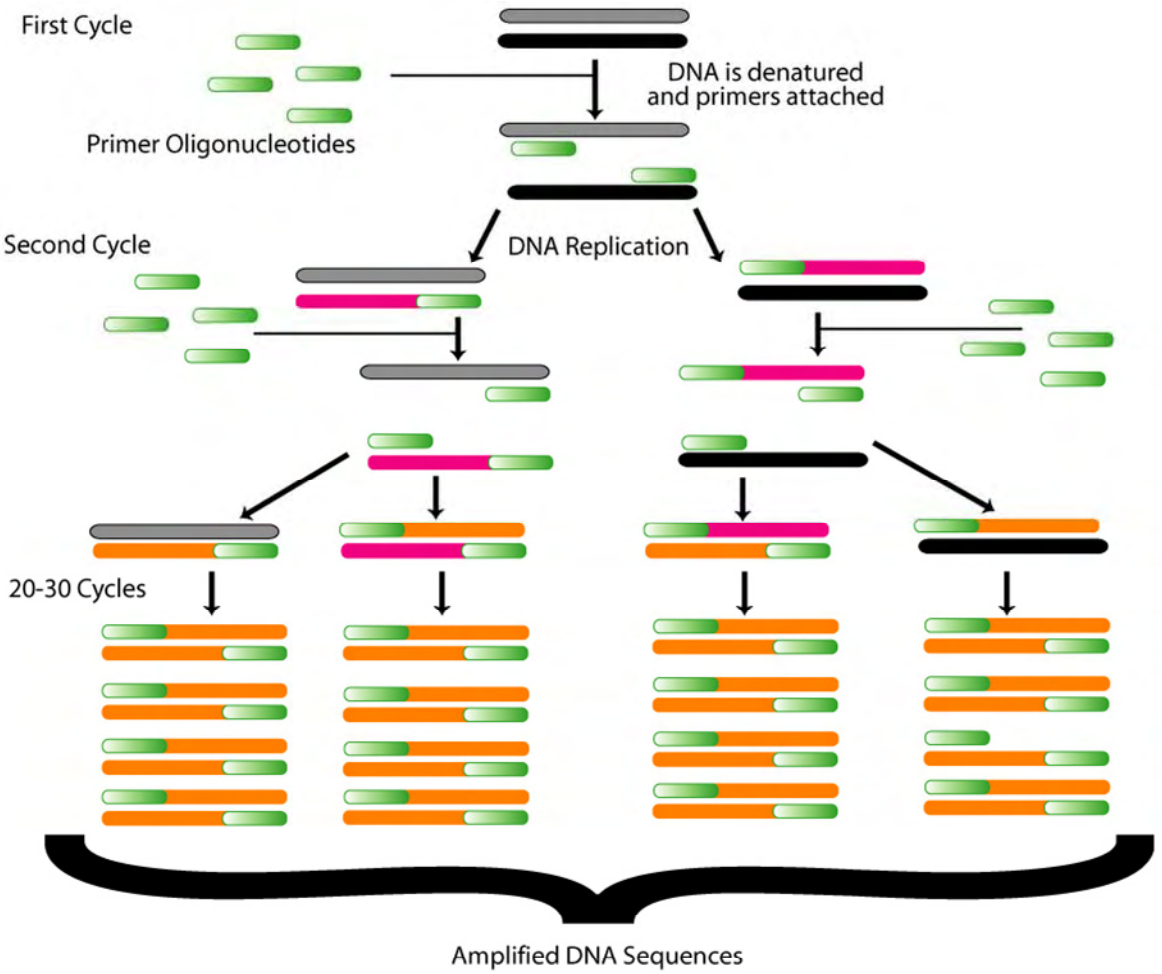

Figure 6–7. Polymerase Chain Reaction (PCR) [64]

A picture of the BAX system manufactured by DuPont Qualicon is presented in figure 6–8 and the iCycler™ Thermal Cycler from Bio-Rad Laboratories is pictured in figure 6–9.

Figure 6–8. BAX System, DuPont Qualicon

Figure 6–9. iCycler™ Thermal Cycler, Bio-Rad Laboratories

6.2.1.1.2 Real-Time Polymerase Chain Reaction

Real-time PCR is the most sensitive nucleic acid detection technique. In contrast to standard PCR that requires post-PCR processing, real-time PCR detects and quantifies the nucleic acid amplification product as it is being produced. The assays are performed using PCR primers and an internal probe containing fluorescent reporter and quencher molecules. Appropriate genomic or plasmid clone DNA controls are used to generate a standard curve in order to determine an approximate number of plasmid DNA copies of a plasmid-borne gene that are present [65]. The progress of the reaction is followed on a cycle-to-cycle basis by measuring the increasing fluorescence, using a real-time PCR instrument. The instruments consist of a thermal cycler, computer with data acquisition and analysis software, and optics for fluorescence excitation.

There are several technical variations of real-time PCR. One format uses the double-stranded DNA-specific dye SYBR® Green molecular probe. Although this technique is relatively inexpensive, it is not highly specific since SYBR Green will bind to any double-stranded DNA in the reaction. Two other techniques are TaqMan® and molecular beacons, which are both hybridization techniques that rely on fluorescence resonance energy transfer (FRET) for quantification.

Real-time PCR requires an instrumentation platform that consists of a thermal cycler, computer, optics for fluorescence excitation, and data acquisition and analysis software. These machines, available from several manufacturers, differ in sample capacity (some are 96-well standard format, others process fewer samples or require specialized glass capillary tubes), method of excitation (some use lasers, others broad-spectrum light sources with tunable filters), and overall sensitivity. There are also platform-specific differences in how the software processes data. Two examples include the R.A.P.I.D.® System (7200) from Idaho Technology, Inc., (fig. 6–10), and the BioSeeq Handheld PCR Detector, from Smiths Detection (fig. 6–11).

Figure 6–10. R.A.P.I.D.® System (7200), Idaho Technology, Inc.

Figure 6–11. BioSeeq Handheld PCR Detector, Smiths Detection

6.2.1.1.3 Reverse Transcriptase PCR

PCR has been applied in the development of detection systems for large number of bacteria and viruses. However, for a virus whose genome is RNA based, an initial reverse transcription step is required. Reverse transcription employs the enzyme rTth DNA polymerase (recombinant thermostable DNA polymerase isolated from the bacterium *Thermus thermophilus)* to transcribe RNA to DNA prior to amplification by standard or real-time PCR techniques.

6.2.1.2 Molecular Hybrid Techniques

Molecular hybrid techniques utilize multiple biochemistry processes to complete the target amplification and identification. These hybrid technologies include Branched Chain Amplification, Invader Assay, Ligase Chain Reaction, Q-Beta Replicase, Rolling Circle Amplification (RCA), and Strand Displacement Amplification. Each requires specific reagents and sophisticated processing, generally starting with purified DNA or RNA from samples. Molecular hybrid techniques are generally used for laboratory and diagnostic purposes rather than first responder applications.

6.2.1.2.1 Branched Chain DNA Signal Amplification (bDNA)

Branched chain DNA (bDNA) signal amplification is a non-PCR based method of analysis that resembles the well-established enzyme-linked immunosorbent assay (ELISA) [66]. In (bDNA), the sample is lysed and synthetic oligonucleotides hybridize the target nucleic acid to a microtiter plate. Additional probes that bind the bDNA for target detection consist of additional branched nucleotide sequences that can bind multiple copies of enzyme labeled molecules to the hybridized complex [66]. Detection is similar to that of an indirect ELISA, where an enzyme (e.g., alkaline phosphatase) is conjugated to an oligonucleotide (label probe) that hybridizes to the branches of the bDNA molecules. Addition of the enzyme substrate dioxetane produces a chemiluminescent signal that is measured. The bDNA assay amplifies the hybridization of a single DNA molecule such that the signal generated is proportional to the amount of DNA input into the system. This allows for increased efficiency and reproducibility. However, the

methodology has lower sensitivity compared to PCR based techniques that amplify the target DNA molecule.

6.2.1.2.2 Invader Assay

The invader assay detects single nucleotide polymorphisms (SNPs) by use of cleavase enzyme and a fluorescence resonance energy transfer (FRET) based method without target (non-PCR) amplification. Single-nucleotide polymorphisms are the most frequently found polymorphisms in any genome and have been touted as the genetic markers of choice for the study of complex genetic traits [67]. In the assay (fig. 6–12), a signal probe with a fluorescently labeled flap and an invader probe are used to hybridize in tandem to a specific region of genomic DNA. When the oligonucleotides of the probe is overlapped by at least one base pair, it is recognized and cut by the cleavase enzyme. Only a perfect match between the invader probe and the DNA target leads to cleavage. The signal probe dissociates and a new one anneals to the sequence. The process repeats several times producing a linear amplification of the signal.

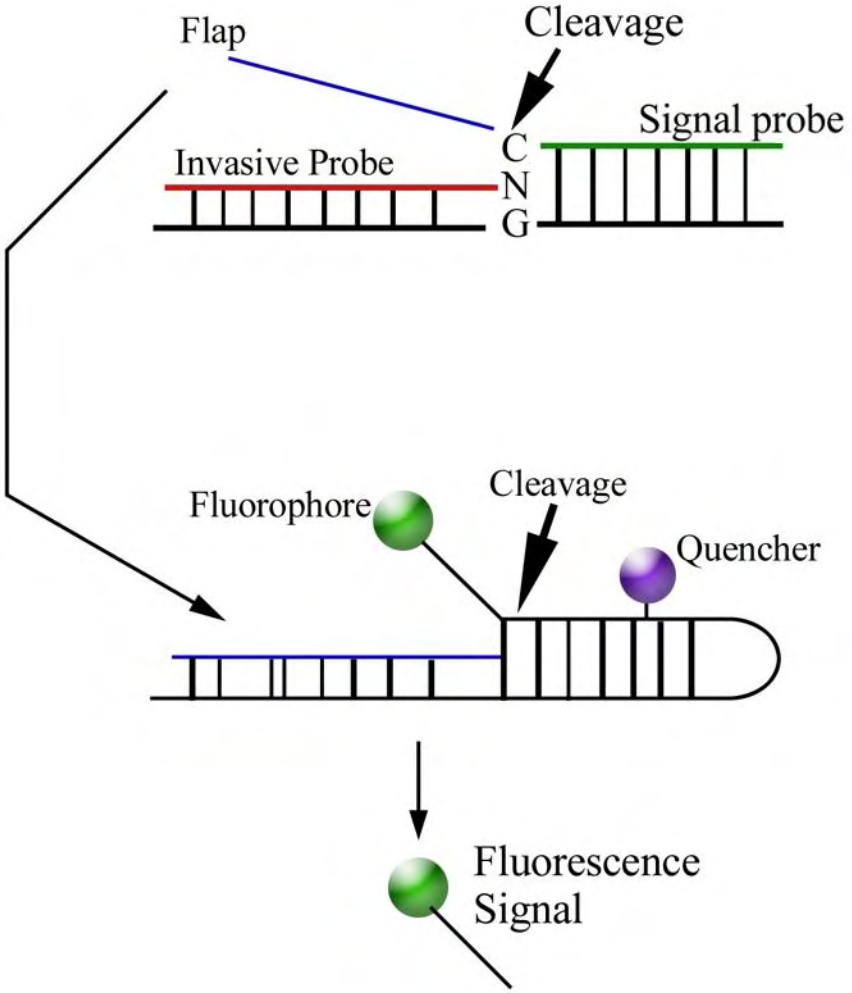

Figure 6–12. Schematic representation of the invader assay **[68]**

6.2.1.2.3 Rolling-Circle Amplification (RCA)

Rolling-circle amplification (RCA) has been used for sensitivity enhancement in DNA quantitation, DNA mutation detection, and array-based sandwich immunoassays. In RCA, a circle of DNA, a short DNA primer (complimentary to a portion of the circle), and an enzyme catalyst convert deoxyribonucleotides into a single-stranded concatameric DNA molecule composed of thousands of tandemly repeated copies of the circle. Unlike other amplification procedures, RCA produces a single amplified product that remains linked to the DNA primer. Therefore, RCA is suited for solid phase formats such as microarrays because it allows the generation of localized signals at specific microarray locations. This feature also allows simultaneous (multiplexing) assays that can be performed without interference. RCA being an isothermal process overcomes the need for costly and cumbersome equipment required for temperature cycling [69]. Figure 6–13 shows the Gen-Probe 450i, manufactured by Gen-Probe, that uses rolling circle amplification.

Figure 6–13. Gen-Probe Leader 450i, Gen-Probe

6.2.1.2.4 Q-Beta Replicase

Q-beta replicase assay uses Q-beta replicase, an RNA-directed RNA polymerase of bacteriophage Q-beta, to exponentially amplify certain RNA, genomic RNA, and RQ RNA *in vitro*. The replication of bacteriophage Q-beta RNA by Q-beta replicase is a two-step process involving the end-to-end synthesis of a single-stranded, complementary minus strand, which in turn serves as a template for the synthesis of more Q-beta plus strand RNA [70]. The natural source of RQ RNA is Q-beta phage-infected *E. coli* cells where they are formed by recombination from viral and cellular RNA and propagated. However, Q-beta replicase does not amplify most RNA including any tested cellular RNA or genomic RNA of other viruses [71]. The replication of the Q-beta replicase strand requires RNA-protein interactions both at internal sequences of the template. Figure 6–14 shows the DNA Engine Opticon™ Continuous Fluorescence Detection System, from MJ Research, Inc., that uses Q-Beta Replicase technique.

Figure 6–14. DNA Engine Opticon™ Continuous Fluorescence Detection System, MJ Research, Inc.

6.2.1.2.5 Ligase Chain Reaction

Ligase chain reaction (LCR) is a DNA amplification method similar to PCR. It requires a thermal cycler to run the reaction and each amplification cycle produces a doubling of the target nucleic acid molecule. However, in LCR, the probe molecule is amplified as opposed to the target strand as in PCR. In addition, LCR uses two primers per DNA template strand, which are ligated together to form a single probe segment. LCR uses both a DNA polymerase enzyme and a DNA ligase enzyme to drive the reaction. Ligase offers better specificity than PCR and can be coupled to PCR to take advantage of the latter's sensitivity.

6.2.1.2.6 Strand Displacement Amplification

Strand displacement amplification (SDA) is based on the primer-directed nicking activity of a restriction enzyme and an exonuclease-deficient DNA polymerase that is capable of initiating synthesis at a nick and displacing the downstream strand. The technique exploits the ability of several restriction enzymes to create a nick on one DNA strand. As a result of repeated nicking, strand displacement and priming of displaced strands, DNA is exponentially amplified. A schematic representation of SDA is presented in figure 6–15.

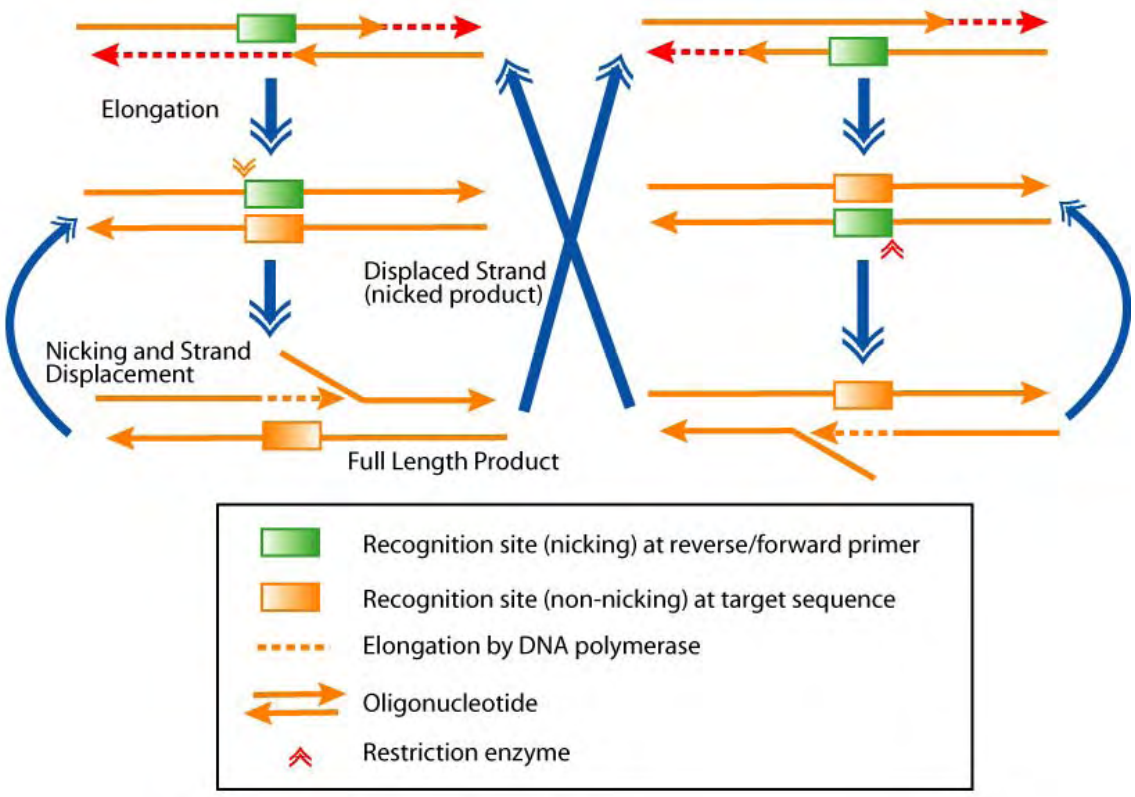

Figure 6–15. Schematic presentation of Strand Displacement Amplification **[72]**

An advantage of SDA is the heightened production of single-stranded DNA by asymmetric SDA (use of two different primers). This is important especially with respect to use as fluorescent probes for microarrays or single-nucleotide polymorphisms. Figure 6–16 shows the On-Chip Amplification Workstation from Nanogene that uses strand displacement amplification.

Figure 6–16. On-Chip Amplification Workstation, Nanogen

6.2.1.3 Molecular Array

Molecular array techniques are based on base pairing rules (A-T or A-U and G-C), where known DNA sequences (probe) are matched to unknown DNA sequences (target). The technique identifies the expression profiles of genes by the simultaneous measurement of numerous DNA

or messenger RNA species. In majority microarray systems, DNA (cDNA or oligonucleotides of known sequence complimentary to the genes of interest) are immobilized onto specific regions of a solid support. The immobilized DNA is exposed to fluorescently labeled DNA to which it binds, unbound material is washed off and fluorescence detects the bound material. The specific area of sample binding on the slide identifies the DNA sequence of the immobilized sample. This technique requires the amplification of the target RNA or DNA prior to binding to the immobilized complementary sequences.

The GeneTAC Biochip System, manufactured by Genomic Solutions, (fig. 6–17) uses the microarray technique. It consists of a GeneChip Hybridization Oven 320, an HP GeneArray Scanner, and a GeneChip Fluidics Station, and utilizes the patented Affymetrix GeneChip® process.

Figure 6–17. GeneTAC Biochip System, Genomic Solutions

6.2.2 Immunological Detection Techniques

Immunological detection technologies, i.e., immunoassays, are based on the detection of specific signals that arise from the molecular recognition of labeled antibodies to their target antigen. Immunoassays are some of the most selective methods in analytical biochemistry [9]. Immunoassays are primarily used in clinical chemistry to detect hormones, drugs, antibodies, tumor markers, and other biologically relevant substances such as bacteria, cells, spores, viruses, and toxins. They are also applied in environmental analysis for monitoring air, soil, and water for biological and chemical hazards. Any chemical or biological compound can serve as an antigen or hapten as long as it can trigger an immune response [73]. Antibodies for large BWAs can be produced by immunizing animals with the antigen. For small molecular weight BWAs compounds (or haptens) the analyte must be conjugated to another large molecule before injecting into the animal. The major disadvantages of immunoassays include strong dependence on the availability of the antibody, short-term stability of the immunoreagents, binary responses or cross-reactivity, and the need for a large number of target cells to produce a measurable positive reading [74,75]. Immunological assays can be broadly categorized as lateral flow immunochromatography (LFI), immunomagnetic separation and electrochemiluminescence (ECL), enzyme-linked immunosorbent assay (ELISA), and time-resolved fluorescence (TRF), which are schematically presented in figure 6–18.

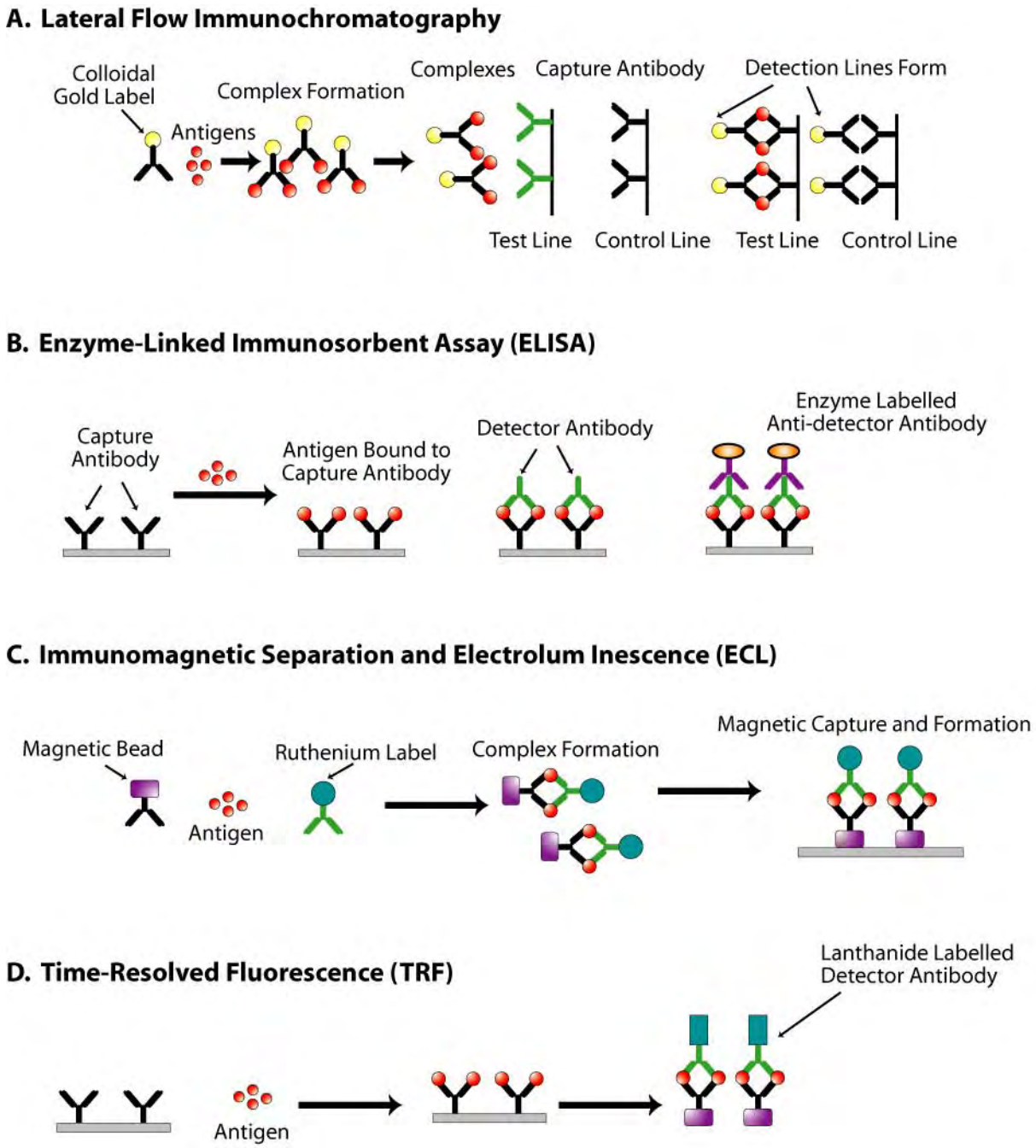

***Figure 6–18. Schematic presentation of the four primary immunological assays (A) LFI, (B) ELISA, (C) ECL, and (D) TRF* [76]**

For this guide, immunochemical detection techniques have been classified into four major categories: optical detection, electrochemical detection, enhanced immunoassay technologies, and adenosine triphopsphate bioluminescence (ATPB).

6.2.2.1 Optical Detection

6.2.2.1.1 Enzyme-Linked Immunosorbent Assay (ELISA)

Enzyme-linked Immunosorbent Assay (ELISA) is considered the "gold standard" for immunological analytical techniques. In an ELISA, an antibody (primary) specific to an antigen (or target species) is immobilized onto a solid support such as a polystyrene microwell plate. The antigen (or target species) specifically binds to the capture antibody. A labeled second antibody (secondary) specifically recognizes another epitope on the antigen (or a site on the target). The secondary antibody is conjugated to an enzyme and doubles up as the detection antibody. The final step of the assay is amplification, which is made possible by the addition of a substrate upon which the enzyme acts with a very high turnover rate giving a detectable product. The end point of the enzymatic reaction typically leads to a colored product that is detected spectrophotometrically. The absorbance is used to quantify the amount of antigen or target species present in the sample.

An example of a product that uses ELISA technology is the Staphylococcal Enterotoxin (SET) Visual Immunoassay (VIA™) from TECRA International Pty Ltd. (fig. 6–19).

Figure 6–19. Staphylococcal Enterotoxin (SET) Visual Immunoassay (VIA™), TECRA International Pty Ltd.

6.2.2.1.2 Capillary ELISA

In capillary ELISA, the capillary serves as the test tube for immobilization of reagents, immunochemical reaction vial and the waveguide for the generation and transportation of the signal. Once the capillary is coated with a specific antibody, the sample to be analyzed is introduced into the capillary and left to react with the immobilized reagents. Once the immunoreaction is complete, the immobilized reagents are detected by a fluorescent-tagged antibody. The fluorescent bands formed in the internal wall of the capillary are quantified by scanning the capillary with a light beam of appropriate wavelength for excitation of the fluorescent label. The photons emitted at angles smaller than the critical angle are trapped in the capillary walls and waveguided towards its ends. A light detector, placed near one of the capillary ends, collects the waveguided photons and feeds them to appropriate analog to digital processing electronics [77]. Capillary ELISA offers several advantages over the standard ELISA. The reduced surface area to volume ratio in the capillary and limited mass transport

kinetics are improved [78]; therefore, incubation times and reagent consumption are reduced. Capillary ELISA is also more amenable to field applications.

6.2.2.1.3 Lateral Flow Immunoassay (Immunochromatography)

Lateral flow immunoassay (LFIA) is an analytical technique that combines immune reactions and chromatographic separation techniques. LFIA are designed as simple, robust immunoassays for specific semi-quantitative detection assays that require low-cost instrumentation and reduced assay times compared to microtiter plate immunoassays. In LFIA colloidal particles, which are conjugated to analyte-specific antibodies, serve as labels for the immunoassay and the lateral flow membrane serves as the basis for the separation of the antibody bound analyte. The analyte, usually a liquid, is loaded onto one end of a test strip is bound by colloid-antibody and migrates along the lateral flow membrane. A capture zone impregnated with anti-antigen antibodies captures any free colloid-antibody and forms a visibly distinct color zone.

Two examples of detection devices that use lateral flow chromatography are the BADD™ BioWarfare Agent Detection Devices manufactured by ADVNT Biotechnologies (fig. 6–20) and the BioThreat Alert™ Bio Threat Test Strips, from Tetracore, Inc., (fig. 6–21).

Figure 6–20. BADD™ BioWarfare Agent Detection Devices, ADVNT Biotechnologies

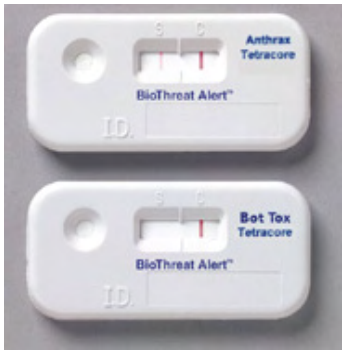

Figure 6–21. BioThreat Alert™ Bio Threat Test Strips, Tetracore, Inc.

6.2.2.1.4 Biosensors (Optical Detection)

A biosensor is defined as an analytical device composed of a biological recognition element directly interfaced to a signal transducer, which together relate the concentration of an analyte (or group of related analytes) to a measurable response [1,79]. Due to the reliability of optical methods, a large number of optical transduction techniques have been used for biosensor development. Some of the optical techniques employed include fluorescence, phosphorescence, polarization, rotation, interference, second harmonic generation, and surface plasmon resonance biosensors (see sec. 6.2.4).

Optical transduction techniques offer the advantage of speed and reproducibility of the measurements. However, most of these techniques require expensive equipment and are generally larger than is practical for field measurements.

6.2.2.2 Electrochemical Detection

Electrochemical detection techniques include electrochemical immunosensors (or biosensors) and electrochemical ELISA.

6.2.2.2.1 Biosensors (Electrochemical Detection)

Electrochemical immunosensors (or biosensors) have generated a lot of interest in the recent years. These electrochemical systems are robust, economical (since they require low-cost instrumentation), can achieve excellent detection limits and selectivity, and have minimal space and power requirements [73] Unlike spectroscopic based techniques, electrochemical methods are not affected by sample turbidity, quenching, or interference from absorbing and fluorescing compounds commonly found in biological samples. Furthermore, the required instrumentation is relatively simple and can be miniaturized easily to circuit board level with low power requirements, facilitating the development of disposable devices and methodologies for ultrasmall sample amounts [80].

Electrochemical immunosensors are based on antibody-antigen recognition processes that occur in close proximity to the electrochemical transducer. Electrochemical immunoassays can be performed in direct or indirect formats. In the direct format, changes in the electrochemical signals do not require auxiliary reactions, while in indirect formats, the binding reaction is indicated via an auxiliary reaction with a labeling compound, usually an enzyme. It can catalyze a reaction to generate an electroactive product. Depending on the electrochemical property to be measured, electrochemical immunosensors can further be classified into amperometric, capacitative (or impedance) conductimetric, and potentiometric immunosensors. Amperometry is based on measurement of the current arising from the electrochemical oxidation or reduction of an electroactive species at a constant applied potential. Capacitative immunosensors are based on the increase in the dielectric constant (capacitance) when the antibody-antigen binding occurs. Conductimetric immunosensors measure the changes in conductance of biological component arising between a pair of metal electrodes. Potentiometric measurements involve determination of the potential difference between a reference electrode and a working (or indictor) electrode.

6.2.2.2.2 Electrochemical ELISA

Electrochemical ELISA combines the antigen-antibody recognition with electrochemical detection of the product resulting from the reaction of the enzyme label with the substrate. The sensitivities of electrochemical ELISAs are favored by the fact that adequate amplification occurs during the accumulation of the enzyme-substrate product and that most of these products are electroactive. Furthermore, unlike spectroscopic-based techniques, electrochemical methods are not affected by sample turbidity, quenching, or interference from absorbing and fluorescing compounds commonly found in biological samples [80].

6.2.2.3 Enhanced Immunoassay

Enhanced immunoassay technologies include various techniques such as magnetic bead based, electrochemical luminescence (ECL), and time-resolved fluorescence immunoassays.

6.2.2.3.1 Magnetic Bead based Techniques

Magnetic bead-based techniques are used to either separate an agent of interest from a mixture as in sample preparation (immunomagnetic separation) or as a probe in an immunoassay. In immunomagnetic separation (IMS), antibodies are immobilized onto spherical, microsized paramagnetic beads. The antibody coated beads are used to trap the target nucleic acids (or bacteria) from liquid media, e.g., whole blood. The small size and shape of the beads allow for their even dispersion in the sample leading to accelerated interaction between the antibody coated beads and the target. The beads are manipulated under the influence of a magnetic field facilitating the collection and concentration of the target. After removing the supernatant, subsequent washing and elution of the target molecule from the beads yields an isolated/purified molecule that can be further processed for identification by PCR. Magnetic bead assays have favorable characteristics that reduce assay time and streamline analytical procedures allowing for higher sample throughput and automation [81].

Magnetic bead-based techniques are usually coupled with electrochemical luminescence (ECL) detection or time-resolved fluorescence detection (TRF). ECL is based on the repression of luminescence caused by antibody-antigen binding of the electroluminescence labels. The change in luminescence is related to the antigen concentration. The electrochemical reaction allows the time and position of the luminescence to be controlled. Several labels such as (2,2'-bipyridyl) ruthenium II (Ru(bpy)3 2+), luminol, hemin, and acridinum have been employed in ECL.

In Time-R Fluorescence, detection of the fluorescent label is delayed until that background signal has decayed. Both ECL and TRF detection techniques can achieve femtomolar detection limits. However, ECL labels do not require an excitation source and therefore require simpler, low cost instrumentation [82]. M-SERIES® M1M Analyzer, from BioVeris Corporation (see fig. 6–22), is an example of an instrument based on ECL technology.

6.2.2.3.2 Multianalyte and Multiphoton

Multianalyte and multiphoton equipment items are grouped with immunochemical technologies. Multianalyte bioassay detection systems can be used for immunoassays, nucleic acid research, enzymatic research, and receptor-ligand studies; the MultiPhoton Detection (MPD) is an enhanced immunoassay system developed under NIST grant support. The MPD-based BW Detector (P-chip/MPD/2004), from BioTraces, Inc., is pictured in figure 6–23.

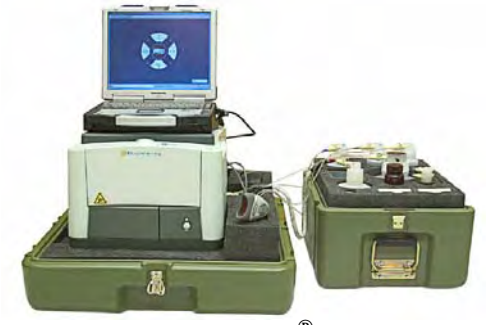

Figure 6–22. M-SERIES® M1M Analyzer, BioVeris Corporation

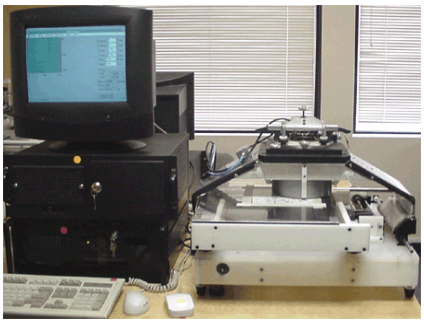

Figure 6–23. MPD-based BW Detector (P-chip/MPD/2004), BioTraces, Inc.

6.2.2.4 Adenosine Triphosphate Bioluminescence

Adenosine triphosphate bioluminescence (ATPB) assays serve as rapid techniques to detect the presence of bacteria but cannot identify specific bacteria. Compared to standard microbial techniques that take up to 5 d to complete, ATPB assays take only 24 h to perform. In some cases to increase sensitivity, it may be necessary to culture the bacteria, thus increasing the overall assay time. In these assays, microbial ATP is measured with a luminometer after the addition of luciferase and luciferin. The amount of luminescence produced is correlated with the amount of ATP in the sample and measured as Relative Light Units (RLU). Nonmicrobial (somatic) ATP is selectively extracted to ensure specificity for bacterial detection. ATPB assays depend on cell viability since ATP is rapidly lost in nonviable cells, which reduces the sensitivity of the assays. However, the lack of sensitivity can be compensated by introducing a cell culture step to amplify cell numbers, but this may reduce the value of ATPB assay as truly rapid assays. Figure 6–24 shows the PROFILE® 1 (Model 3560), manufactured by New Horizons Diagnostics Corporation, is an example of a bioluminometer.

Figure 6–24. PROFILE® 1 (Model 3560), New Horizons Diagnostics Corporation

6.2.3 Physical Techniques

Physical techniques are based on the physical properties of materials being assayed. For this bioguide, physical techniques have been classified into four categories: flow cytometry, fiber optics, sample preparation, and fluorescence.

6.2.3.1 Flow Cytometry

Flow cytometry is a technology that takes advantage of laser light scattering and fluorescence excitation of fluorochromes associated with cells, bacteria, and other biological particles. Using fluorescence detection, flow cytometry allows rapid single cell analysis of large numbers of cells (10000 cells or more) within a very short period. Cell suspensions, in a continuous single cell stream, are rapidly passed (300 cells/s to 100 cells/s) through a laser beam, where each cell scatters some laser light and emits fluorescence light resulting from the excitation by the laser light. One unique feature of flow cytometry is that it measures fluorescence per cell or particle. This contrasts with spectrophotometry in which the percent absorption and transmission of specific wavelengths of light is measured for a bulk volume of sample. The rapid analysis of

statistically large numbers of cells permits the quantitative detection of cells present in less than 2 % abundance in a sample. Figure 6–25 shows a simplified illustration of flow cytometry.

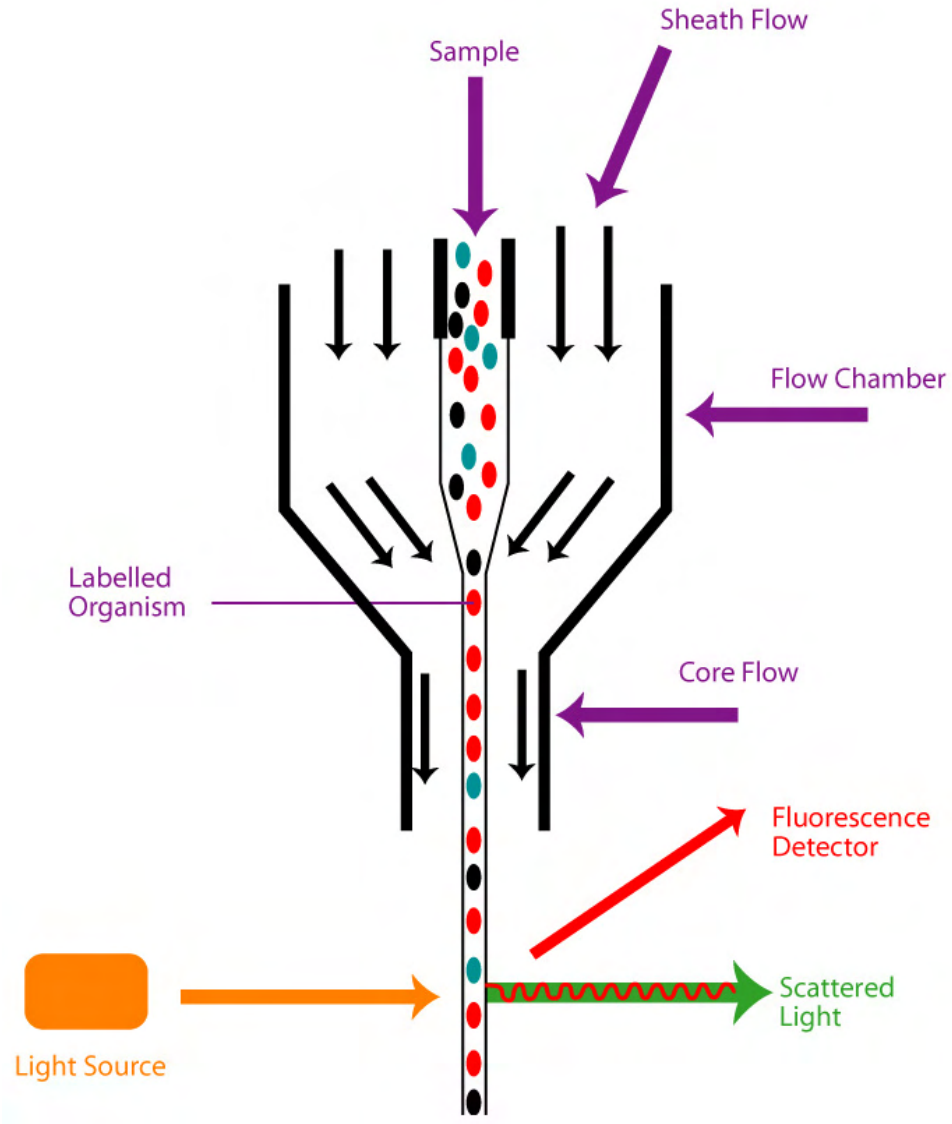

Figure 6–25. Simplified illustration of flow cytometry

Forward angle (0.5° to 2°) light scatter (FALS), is used as an approximate indicator of cell size, which permits for example distinction of erythrocytes from lymphocytes in human peripheral blood [83]. FALS is also used to distinguish viable cells from dead cell, which usually show low FALS. An increase or decrease in orthogonal (90°) intensity is used to measure phagocytosis of particles or degranulation of cells respectively. For fluorescence measurements, the choice of fluorochrome is dictated by the desired parameter to be measured and the type of laser in the flow cytometer. Many fluorochromes are chemically conjugated to proteins (antibodies, cytokines or other ligands) that convey the specificity of interaction with a cell or other biomolecules [83]. Figure 6–26 shows the BD FACSCount, from BD Biosciences Immunocytometry Systems.

Figure 6–26. BD FACSCount, BD Biosciences Immunocytometry Systems

6.2.3.2 Fiber Optics

Optical waveguide is a technique that uses fiber optic cables to guide a light wave along a specific path by constraining it with total internal reflection. A typical planar optical waveguide consists of a substrate and a thin top layer (waveguide layer) with refractive index larger than that of the substrate; the covering material (clad) is usually air. The electric field associated with light wave propagating in the waveguide layer is very strong at the surface of the optical waveguide; therefore, highly sensitive optical monitoring can be performed for biochemical or chemical species at the optical waveguide surface on the basis of absorption and scattering of the guided light [84]. By covering the inner surface with antibodies or biological receptors, fiber optic cables have been used to identify target agents. Typically, the probes are bound to a glass optical fiber and immersed into a capillary tube containing an aqueous solution of the sample. The sample is tagged with another fluorescently labeled antibody that binds to the target antigen resulting in antibody-antigen binding with the immobilized antibody. Light from the near infrared diode laser becomes constrained by the fiber and excites the fluorescent tag on the antibody, emitting fluorophores that are detected by a photodetector. Figure 6–27 shows a representation of optical waveguide technology.

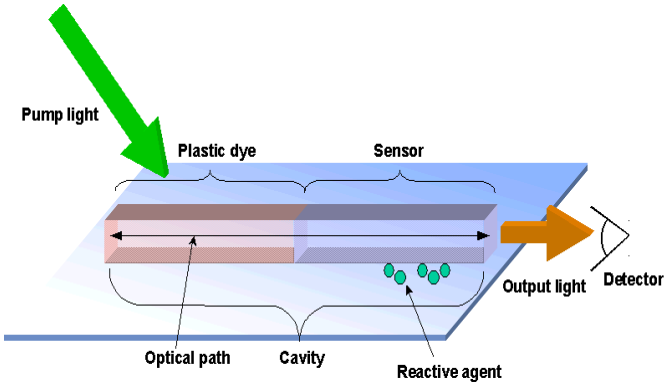

Figure 6–27. Representation of Optical Waveguide Technology

Two equipment items that use optical waveguide technology are the Analyte 2000 Biowarfare Detection (Fiber Optic Fluorometer), shown in figure 6–28, and the RAPTOR Plus, pictured in figure 6–29, both from Research International.

Figure 6–28. Analyte 2000 Biowarfare Detection (Fiber Optic Fluorometer), Research International

Figure 6–29. RAPTOR Plus, Research International

6.2.3.3 Fluorescence

Instruments that detect biological molecules on the basis of their inherent fluorescent properties serve as screening and advanced warning devices but cannot identify the suspect BA.

The Biological Aerosol Warning System (BAWS) is a UV-fluorescence-based bioaerosol detection system that was developed for the U.S. Military. The BAWS is an array of point biological aerosol detectors networked to detect BAs. The system is intended for a remote, early detection capability for biological attack and for perimeter monitoring of key areas and high-value assets. Comprised of a network of Remote Detection Stations, a Base Control Station, and a PC Analysis Workstation, BAWS provides an overall picture of a developing biological attack with detection, wind-speed and direction, and location data. In addition, BAWS is configured to allow easy integration with other types of sensors (i.e., motion detectors, IR sensors, etc.) in order to create a customized overall perimeter monitoring system. Figure 6–30 shows an example of the BAWS Remote Station, developed by Lockheed Martin.

Figure 6–30. BAWS Remote Station, Lockheed Martin

6.2.4 Ligand-Based Techniques

A ligand is a substance capable of binding specifically and reversibly with a binder. When the binder is an antibody, a ligand is termed an antigen. Ligands may be small or large, specific to a

particular microbial serotype or common to related groups, and bind with varying degrees of affinity. Ligand-based techniques rely on the principle that every cell has cell-surface proteins that bind other specific molecules.

Surface plasmon resonance is an optical transduction method [see sec. 6.2.2.1.4, Biosensors (Optical Detection)] that uses ligand-based techniques. Surface plasmon refers to the evanescent electromagnetic field that is generated at the surface of a silver or gold metal conductor that has been excited by incident light (light coming directly from the source onto the object) of appropriate wavelength. Any physical phenomena at the surface that alters the refractive surface (i.e., modifying the metal surface with organic thin films and subsequently biomolecules such as proteins, ligands, and DNA) will trigger a response that can be monitored and used to detect both the extent and the rate of the binding by means of an optical photodetector. The changes are measured continuously to form a sensorgram, which provides a complete record of the progress of association or dissociation of the interactants. Any pair of molecules that exhibit specific binding can be adapted to surface plasmon resonance (SPR) measurements. These may be an antigen and antibody, a DNA probe and complementary DNA strand, and enzyme and its substrate. Figure 6–31 presents the Biacore 2000, from Biacore, Inc., that uses surface plasmon resonance technology.

Figure 6–31. Biacore 2000, Biacore, Inc.

6.2.5 Microscopy

Microscopy is a technique to view microorganisms including whole cells, as well as sub-cellular organelles, supramolecular assemblies, and individual protein molecules. The major advantage of this technique is that it provides a direct image of the object of interest. The presence of some agents may be indicated by a light microscope if properly stained (with a Gram Stain kit, for example). Other techniques involve an abstract representation (e.g., a diffraction pattern, a spectroscopic signal, or some other physical measurement) that must be decoded or interpreted to produce a practical image.

There are several types of microscopic methods used in microbiology, including standard light microscopy, fluorescent microscopy, confocal microscopy (CFM), phase contrast, transmission electron microscopy (TEM), and scanning electron microscopy (SEM). A brief description of these different techniques follows:

- Light microscopy uses a two-dimensional microscope with high magnification and low resolution.
- Fluorescent microscopy uses high-intensity light to illuminate the sample. The light excites fluorescence in the sample, which causes it to emit light of a different wavelength. It has high magnification but low resolution.
- Confocal microscopy is like fluorescent microscopy, but with the added benefit of being able to reflect out-of-focus fluorescent light.
- Phase contrast microscopy is used when high magnification (400x to 1000x) is needed, and the specimen is colorless, or so fine that color does not show up very well.
- Transmission electron microscopy (TEM) is a two-dimensional electron illumination microscope with high magnification and high resolution. Thin slices of the sample are taken and then electrons are passed through it.
- Scanning electron microscopy (SEM) is a three-dimensional electron illumination microscope with high magnification and high resolution. The sample is coated in gold and is seen as electrons bounce off of its exterior.

Pictured in figure 6–32 and figure 6–33 are the RTM 3 from Richardson Technologies, and the Swift FM-31 LWD Field Microscope from C. Farr Optics (Scientific Instruments Division). They are both light microscopes. The market assessment identified three detection equipment items that utilize the microscopy.

Figure 6–32. RTM 3, Richardson Technologies

Figure 6–33. Swift FM-31 LWD Field Microscope, C. Farr Optics (Scientific Instruments Division)

6.2.6 Standard Culture

Standard cell culture allows the study of cultural, morphological, and physiological characteristics of individual species in a controlled experimental environment. Standard culture normally involves the use of growth media that contains a carbon source, a nitrogen source, and other nutrients (sulfur, phosphorus, trace elements, and vitamins). Microorganisms are either grown directly in artificial growth media, or if they cannot be grown in artificial growth media, they are cultured in host cells that could grow in these media. Streak plating, pour plating, or

spread plating cells on a culture agar medium are three procedures for isolating colonies of a single species of bacteria for identification purposes. Once the microorganism is isolated, it can be grown in cell culture media. Such cell cultures require a sterile environment protected from other contaminating organisms, particularly bacteria, since the culture media required by eukaryotic cells is an ideal media for bacterial growth.

Viruses have traditionally been detected by cell culture methods. Viruses are isolated from living cells and collected by enzymatic or mechanical disruption of tissues. Because of the consumables, support equipment, and sterile conditions that are needed for culturing live organisms, standard culture is not typically thought of as a biological detection method for the first responder community. No standard culture techniques were identified by the market survey.

6.2.7 Hybrid Equipment

In hybrid technologies, there is no clear division of sampler, detector, and transducer functions. Examples of hybrid techniques include mass spectrometry, capillary electrophoresis, high performance liquid chromatography, flame spectrophotometry, and gas chromatography. Many of these systems are considered analytical instruments, which have sensitivities that are extremely high. The techniques are considered reliable and accurate, but to achieve these characteristics requires that only very pure reagents be used and strict procedures and protocols be followed. In addition, many require sophisticated sample preparation, have power requirements that are not compatible with field work (i.e., 110 V or 220 V), are large and cumbersome, and have components that must remain stationary. This typically precludes their use outside of a laboratory environment. However, some instruments have been developed for field applications (i.e., air monitoring and preliminary sample screening).

Generally, hybrid-based technologies can be considered fixed-site detection systems, fixed-site analytical systems, or standoff detector systems (require vehicle transport and special setup). Applications include air monitoring.

For the purposes of this guide, hybrid techniques can be grouped into six major categories: mass spectrometry (MS), capillary electrophoresis (CE), high performance liquid chromatography (HPLC), flame spectrophotometry, gas chromatography (GC), and a biological detection suite. Descriptions of the hybrid techniques, along with their applicability for first responders, are provided in the remainder of this section.

6.2.7.1 Mass Spectrometry

Mass spectrometry is a highly sensitive detection technique that can positively identify agents at very low concentration. Mass spectrometry is used for obtaining characteristic information on the structure and molecular weight of a few nanograms of material by utilizing ionizing radiation to break up the material into characteristic fragments, which are separated on the basis of their mass-to-charge ratio (equivalent to mass for the singly charged ions usually observed). The Chemical-Biological Mass Spectrometer, developed by Oak Ridge National Laboratory, uses MS technology for biological detection. The instrument is considered a standoff detector and is used to monitor the air for BAs or CAs, or to reconnoiter the boundaries of a biological contamination. Airborne BAs are isolated, concentrated, and delivered to a pyrotube by a

bioconcentrator module. The bioparticles are then processed and transferred to the mass spectrometer by a mode select valve, transfer line, and capillary interface, where the particles are then identified.

Matrix Assisted Laser/Desorption Ionization Mass Spectrometry (MALDI-MS) has been shown to detect a single bacterial species from an environmental sample. Currently, the MALDI-MS is being utilized in the field for biological detection. The MALDI-MS is able to conduct mass spectrometry on whole bacteria, which give a unique mass signal. The capture and detection of bacterial agents is conducted by using immobilized antibodies. Polyclonal antibodies specific for the biological warfare agent of interest are immobilized on glass plates by incubating the plates overnight in a solution of antibodies. After incubation, the glass plates are thoroughly washed to remove nonspecific materials. The glass plates are secured to a MALDI probe and subjected to mass analysis.

Although these instruments are generally not considered for first responder use, there is an ongoing effort to develop a portable, fully automatic MS system and a library of bioagent "signatures." Figure 6–34 shows the Chemical-Biological Mass Spectrometer (CB-MS), developed by Oak Ridge National Laboratory. Figure 6–35 shows the Aerosol Time of Flight Mass Spectrometer (ATOFMS), from TSI, Inc.

Figure 6–34. Chemical-Biological Mass Spectrometer (CB-MS), Oak Ridge National Laboratory

Figure 6–35. Aerosol Time of Flight Mass Spectrometer (ATOFMS), TSI, Inc.

6.2.7.2 Capillary Electrophoresis

Electrophoresis is the separation of charged molecules using their different rates of migration in an electrical field. Capillary electrophoresis is a family of related separation techniques that use narrow-bore fused-silica capillaries to separate a complex array of large and small molecules. Separation is based on differences in the charge-to-mass ratio of the analytes. The CE instruments can be equipped with a variety of detectors such as ultraviolet, diode array, fluorescence, and laser-induced fluorescence. The CE systems can be used for the separation and detection (qualitative and quantitative) of oligonucleotides, proteins, peptides, and amino acids, consequently, for the identification of living organisms. One item that utilizes this technology is the Agilent 2100 Bioanalyzer from Agilent Technologies (fig. 6–36). Two limitations to the fielding of CEs are the need for power requirements (120 V house current) and

for small quantities of high purity water and chemical reagents. The market assessment identified two detection equipment items that utilize capillary electrophoresis.

Figure 6–36. Agilent 2100 Bioanalyzer, Agilent Technologies

6.2.7.3 High Performance Liquid Chromatography

High performance liquid chromatography is useful for analyzing BAs that are not easily volatilized for GC analysis. In general, a solution of the sample (which may require sample preparation, such as extraction from a matrix) is injected into, and passed through, a column at high pressure; the species are separated based on their differential affinity to the stationary phase of the column. The HPLC instruments can be equipped with a variety of detectors such as ultraviolet-visible (UV-Vis) spectrometers, mass spectrometers, fluorescence spectrometers, and electrochemical detectors for subsequent identification of biologicals. Limitations to the use of HPLC in the field include the need for a 120 V ac source, the need for high purity solvents, the size of the instruments, and the requirement for sample cleanup prior to introducing it to the column. The HPLC instrumentation is available from a variety of vendors. Figure 6–37 shows the HPLC Diode Array Detector 20/20, Groton Biosystems. Because of the aforementioned limitations, HPLC is not considered applicable for first responder use. The market assessment identified two detection equipment items that utilize this technology.

Figure 6–37. HPLC Diode Array Detector 20/20, Groton Biosystems

6.2.7.4 Flame Spectrophotometry

When ambient air is burned with hydrogen gas, the flame decomposes any substance present in the air, and substances that contain phosphorus and sulfur produce hydrogen, phosphorus, and oxygen (HPO), and elemental sulfur (S), respectively. At the high flame temperature, the phosphorus and sulfur emit light of specific wavelengths. A set of optical filters is used to selectively transmit only the light emitted from the presence of phosphorus and sulfur to a photo-multiplier tube that produces an analog signal related to the concentration of the phosphorus- and sulfur-containing compounds in the air. Since living organisms contain phosphorus and sulfur, they are detected by this technology. Figure 6–38 shows the Biological Alarm Monitor (MAB) from Proengin USA that uses flame spectrophotometry technology. It is especially adapted to the rigors of a military defense.

Figure 6–38. Biological Alarm Monitor (MAB), Proengin USA

6.2.7.5 Gas Chromatography

Gas chromatography separates analytes in a mixture for subsequent detection. An inert gas (mobile phase) is used to transport a volatile multi-component sample traveling through a long chromatographic column packed or coated with a stationary phase. As the sample travels through the column, the various components of the sample partition between the mobile and stationary phases at different rates depending on their identity or affinity for the stationary phase. The time spent (retention time) for each component of a mixture to traverse the column length will differ depending on the respective affinities of the component, resulting in separation of the sample into discrete components. The biological material then passes through a detector, such as a flame photometer or mass spectrometer, generating a signal proportional to the concentration. Identification of biological substances is generally determined by comparison of a chromatographic retention time (RT) of the substance to that of a known standard, or to chromatographic retention indices for a series of known compounds using a standard set of chromatographic conditions. Although the level of detection, or sensitivity, of these instruments is extremely low, many biological samples require sample preparation for BA identification before they can be presented to the instrument. Derivitization or extraction may be used for this process, which may be time-consuming and require supplies. The one instrument identified by the market assessment that utilizes this technique is the Agilent 6850, from Agilent Technologies, shown in figure 6–39.

Figure 6–39. Agilent 6850, Agilent Technologies

6.2.7.6 Biological Detection Suite

Both the Biological Integrated Detection System (X-BIDS) and the Biological Detection Suite (BIDS) are multifaceted systems that link aerodynamic particle sizing, bioluminescence/ flourescence, flow cytometry, mass spectrometry, and immunoassay technologies in a complementary, layered manner to increase detection and identification confidence. The BIDS consists of a shelter mounted on a dedicated vehicle, equipped with a biological detection suite employing complementary technologies. The BIDS was developed and produced at ECBC (formally the U.S. Army Soldier and Biological Chemical Command), Aberdeen Proving Ground, Maryland. Figure 6–40 shows a picture of the Biological Integrated Detection System (X-BIDS), developed by EAI Corporation.

Figure 6–40. Biological Integrated Detection System (X-BIDS), EAI Corporation

6.2.8 Screening Equipment

Screening devices may be used to safeguard or monitor the environment for hazardous materials. Although screening was not considered when conducting the market assessment for BA detection and identification equipment, several devices were identified that were considered appropriate for screening purposes. Items identified for screening utilized infrared (IR) techniques or immunochemistry techniques.

Infrared (IR) spectrometry is based on the identification of a molecule's chemical bonds. The atoms in a molecule vibrate in relation to each other, and the frequency of the vibrations is

primarily dependent on the weight of the atoms and the strength of the bond between them. Vibration frequencies of molecules lie in the infrared portion of the electromagnetic spectrum. If infrared radiation of a certain frequency hits a sample of bonds with the same inherent frequency, the molecules will absorb the radiation and their energy will increase. The absorbed radiation at different frequencies and the obtained spectra, like a fingerprint, reveal the identity of the specific molecule.

In Fourier Transform Infrared (FTIR) spectrometry, the radiation intensity variation with optical path difference (interferogram) is the Fourier transform of the (broadband) incident radiation. The radiation absorption spectrum can be obtained by measuring an interferogram with and without a sample in the beam and transforming the interferograms into spectra. The method of FTIR is fast and overcomes the disadvantage of the measurements of one resolution element at a time. However, for biological applications, FTIR spectrometry is not considered a reliable method for the identification of biological species; nevertheless, if a sample is not biological, the nature of the chemical carrier or dispersal agent can quickly and easily be identified by this technique. In the case of a credible threat, a biological specific testing tool, such as a HHA or PCR test kit, would be used in conjunction with the FTIR technology. For monitoring applications, FTIR provides detection of the substance and confirms the presence or lack of protein material, making it an easy to use and powerful tool for first responders. Infrared instruments can also be used for standoff, or remote, monitoring applications.

The IlluminatIR ML Package (006–2019), from Smiths Detection Danbury, uses FTIR mid infrared micro-spectroscopy as its core technology (fig. 6–41). The BioCheck™ Powder Screening Test Kit, 20/20 GeneSystems, Inc., (fig. 6–42) is screening equipment based on chemical methods.

Figure 6–41. IlluminatIR ML Package (006–2019), Smiths Detection Danbury

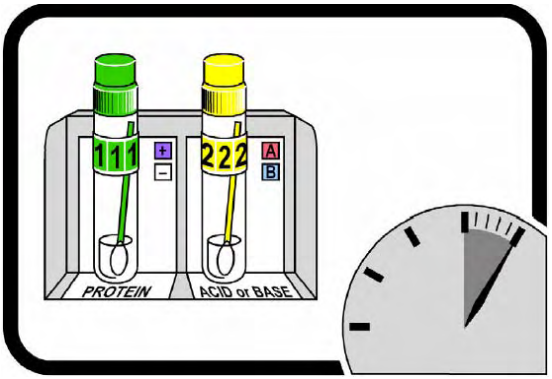

Figure 6–42. BioCheck™ Powder Screening Test Kit, 20/20 GeneSystems, Inc.

6.2.9 Reagent Kits

Reagent kits can be purchased from various manufacturers. Kits that contain the necessary reagents for particular methods can either be specific, to be used with the manufacturer's equipment, or can be generic and can be used with other manufacturers' equipment. Although reagents can be freshly prepared by following precise recipes, the ingredients would have to be purchased separately and would require additional storage and upfront time to prepare the reagents. Most kits available are used by scientific research labs, diagnostic labs, and hospitals,

and are not considered applicable for the first responder community. Figure 6–43 is the Access RT PCR System (A1280) 500 Reactions, from Promega North, and is an example of a reagent kit that uses reverse transcription followed by PCR.

Figure 6–43. Access RT PCR System (A1280) 500 Reactions, Promega North

6.3 Selecting Appropriate Detection Technologies for BA

In general, the analytical process is divided into five steps: sampling; sample preparation; separation; detection; and, data analysis. Over 80 % of analysis time is spent on the sampling and sample-preparation steps. Furthermore, the quality of these steps is a key factor in determining the success of analysis from complex matrices, such as biological samples. Therefore, the choice of an appropriate sample preparation method greatly influences the reliability and accuracy of the analysis [85].
The detection method and the reagents mentioned in most of the BA technology descriptions are target driven. It is difficult to formulate specific rules on the technology to use for a given analyte. The user must decide on what level the detection will be performed.

To help in the selection of appropriate BA detection equipment, a flow chart (fig. 6–44) is provided that can be used as a guideline in the selection of the appropriate technology for different analytes. In addition, appendix D provides a list of questions that should be posed to manufacturers of BA detection equipment.

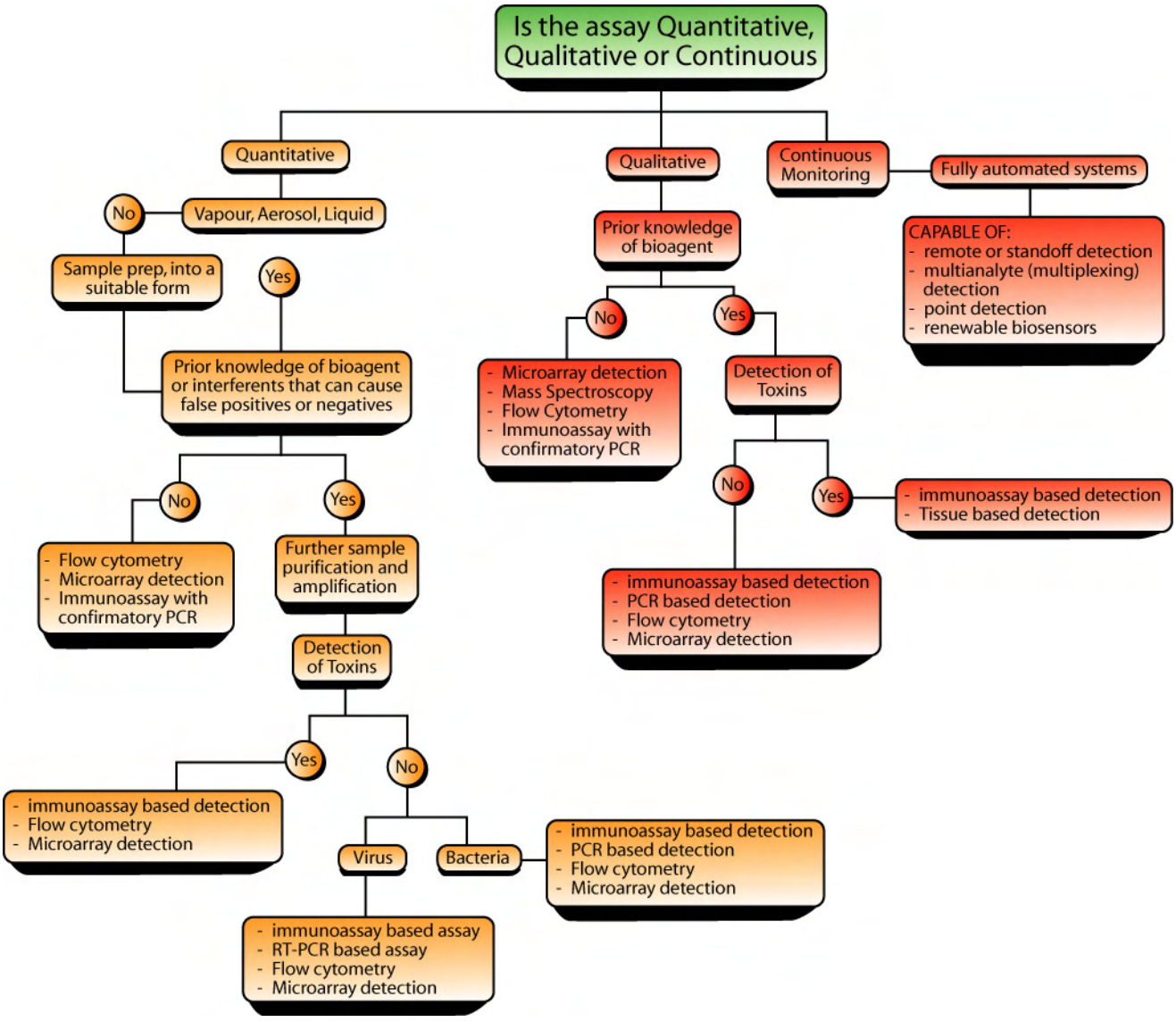

Figure 6–44. Flow chart for the selection of appropriated BA detection equipment

7. MARKET SURVEY

An extensive market survey was conducted to identify commercially available BA detection equipment. The market survey consisted of a solicitation of manufacturers, the review of previously conducted market surveys, literature searches, and consultation with subject matter experts (SMEs). Section 7.1 provides a summary of the assessment of previous market surveys. Section 7.2 provides the identification of biological equipment, and section 7.3 provides a summary of information obtained through interfacing with the vendors. In order to provide detailed information on each biological detector, 55 data fields, to correspond to the vendor questionnaire, were identified. These data fields were developed by SMEs and approved for distribution by the government. Definitions for the biological detector data fields are provided in appendix E.

7.1 Past Market Surveys

Several previously conducted market surveys were reviewed during the development of this guide. However, three specific sources proved to be the most valuable in the market survey conducted for this guide. These documents are as follows:

- *An Introduction to Biological Agent Detection Equipment for Emergency First Responders (NIJ Guide 101–00).*
- *Guide for the Selection of Biological Agent Detection Equipment for Emergency First Responders (DHS Guide 101–04), March 2005.*
- *U.S. EPA Environmental Response Team (ERT) Technical Bulletin 2001–4 Bio-Detector Assessment Final Report, March 2002.*
- *Chemical and Biological Terrorism Research and Development to Improve Civilian Medical Response NAP 1999. Chapter 6. Detection and Measurement of Biological Agents.*

Detailed references are provided for each of these market surveys in appendix A.

An Introduction to Biological Agent Detection Equipment for Emergency First Responders (NIJ Guide 101–00) was published in December 2001 and serves as an information source intended to aid the emergency first responder community in their selection and utilization of biological agent detection equipment. It includes information on the nature of biological agents (BAs), challenges of detecting BAs, components of biological detection equipment, and some basic technologies used in BA detection equipment.

The *Guide for the Selection of Biological Agent Detection Equipment for Emergency First Responders (DHS Guide 101–04)* was published in March 2005. The guide includes information on 109 biological detection equipment items as well as 26 biological samplers and nine biological reagent kits.

The *U.S. EPA Environmental Response Team (ERT) Technical Bulletin 2001–4 Bio-Detector Assessment Final Report* was published in March 2002. The objective of the ERT Bio-Detector assessment was to evaluate available biological detection and identification devices for their

potential to meet EPA program needs and to recommend the best candidate(s) for further testing. The basic recommended approach was to screen with a generic detector, then use an immunoassay device in tandem with a nucleic acid analysis technique for identification.

Chemical and Biological Terrorism Research and Development to Improve Civilian Medical Response NAP 1999, Chapter 6, Detection and Measurement of Biological Agents examines the application and utility of available and potential technologies in the detection of BAs in the environment. It considers the detection of BAs as a two-stage process involving a probe and a transducer. Accordingly, the probe technology deals with how the assay or detection device recognizes the particular target microbe. The transducer technology deals with how the assay or detection device communicates the activity of the probe to the observer.

7.2 Identification of Biological Detection Equipment

A variety of techniques were utilized to identify commercially available biological detection equipment. These techniques included the distribution of Federal Business Opportunities (FedBizOpps) and NBC Industry Group Announcements, literature searches, database searches, Internet searches, and technical contacts. These techniques resulted in the identification of 144 BA detection equipment items.

7.3 Vendor Contact

Vendors were contacted numerous times between January 2003 and January 2007 in order to obtain additional equipment information, as well as to update and to finalize their specific equipment data for inclusion in the guide.

The vendor-supplied data, along with an index identifying each of the BA detection equipment items, can be found in appendix F through appendix I.

8. SELECTION FACTORS

Section 8 provides a discussion of 19 selection factors that are recommended for consideration by the emergency first responder community when selecting and purchasing BA detection equipment. These selection factors were compiled by a panel of scientists and engineers with multiple years of experience and relevant expertise in the areas of BA detection, identification, and analysis, domestic preparedness, and identification of emergency first responder needs. The factors have also been shared with the emergency first responder community in order to obtain their thoughts and comments. It is anticipated that, as additional input is received from the emergency first responder community, additional factors may be added or existing factors may be modified.

These factors were developed to allow for a quick comparison of commercially available BA detection equipment. ***It is important to note that the evaluation conducted using the 19 selection factors was based upon vendor-supplied data and no independent evaluation of equipment was conducted in the development of this guide.*** The results of the evaluation of the detection equipment are provided in section 9. The remainder of this section defines each of the selection factors. Details on the manner in which the selection factor was used to assess the BA detection equipment are included within the selection factor definition.

8.1 Start-Up Time

Start-Up Time refers to the length of time required for assembling the equipment in preparation for operation. This includes preparing the equipment for use, and may include warm-up or calibration time after the equipment is functional.

Start-Up Time	
●	Less than 30 s
◕	Between 31 s and 60 s
◑	Between 61 s and 5 mi
◔	Between 5 min and 30 min
○	More than 30 min
⊗	Not specified

8.2 Response Time

Response Time indicates the time lapse between sample introduction and appearance of an output signal (detection).

Response Time	
●	Less than 10 s
◕	Between 11 s and 30 s
◑	Between 31 s and 60 s
◔	Between 61 s and 5 min
○	More than 5 min
⊗	Not specified

8.3 Sensitivity

Sensitivity is the lowest level at which the BA can be detected by the detector or methodology. This may include the minimum amount of BA that would need to be present for detection. A detector's sensitivity is often referred to as the detection limit or limit of detection (LOD).

Sensitivity	
●	Detects at significantly 1ow orders of magnitude below the infective dose
◕	Detects at 1 order of magnitude less than the infective dose
◑	Detection limit is equal to the infective dose
○	Detection limit is above the infective dose
⊗	Not specified

8.4 Specificity

Specificity refers to the ability of the equipment to differentiate between biological and non-biological particles, or an ability to selectively detect individual species and strains.

Selectivity/Specificity	
●	Differentiates bio from nonbioagents, no cross reactivity, and strain level detection
◑	Differentiates bio from nonbioagents, no cross reactivity, and no strain level detection
◔	Differentiates bio from nonbioagents, cross reactivity, no strain level detection
○	Does not differentiate bio from nonbioagents, cross reactivity, no strain level detection
⊗	Not specified

8.5 Forms Detected

Forms Detected indicates the different forms of BAs (sporulated, vegetative, or biological toxin) a device can detect.

Forms Detected	
●	Detects sporulated, vegetative, and biological toxins
◕	Detects sporulated and vegetative forms
◑	Detects only vegetative forms or biological toxins
◔	Detects bio in general
○	Does not differentiate bio from non-bioagents
⊗	Not specified

8.6 Type of Output

Type of Output indicates the format or way in which data is presented to the system operator. Results can include 1) delayed or real-time, 2) yes or no (+ or -), and/or 3) qualitative or quantitative.

Type of Output	
●	Real-time and quantitative in nature
◕	Real-time and qualitative in nature
◑	Delayed and quantitative in nature
○	Delayed and qualitative in nature
⊗	Not specified

8.7 Data Interpretation

Data Interpretation refers to the amount of effort needed to translate the data results after completion of the analysis. This field indicates the level of skill and training needed to determine the final result.

Data Interpretation	
●	No skill and training needed
◑	Some skill and training needed
◔	Formal training needed
○	Special skills and training needed
⊗	Not specified

8.8 Ease of Use

Ease of Use indicates the number of steps and complexity of the procedures involved in the entire detection and identification process for that system.

Ease of Use	
●	No steps or procedures involved
◕	Few steps and no procedures involved
◑	Some steps and procedures involved
○	Several steps and procedures involved
⊗	Not specified

8.9 Sample Preparation

Sample Preparation includes the number of steps and the complexity required to prepare samples for analysis. Some systems require no sample preparation, while other detection systems may involve very sophisticated procedures.

Sample Preparation	
●	No sample preparation needed
◕	One step sample preparation needed
◑	A few steps of sample preparation needed
○	Complex sample preparation needed
⊗	Not specified

8.10 Support Equipment Needed

Support Equipment Needed includes the total number and type of accessories or items needed to support the primary screening or detection and identification device. This would include equipment needed for sample preparation or data interpretation.

Support Equipment Needed	
●	Support equipment not needed
◕	Support equipment is optional
◑	Support equipment needed for sample preparation
○	Additional equipment needed for sample preparation and data interpretation
⊗	Not specified

8.11 Alarm Capability

Alarm Capability can be audible, visible, or both.

Alarm Capability	
●	Audible and visible alarm
◕	Audible alarm only
◑	Visible alarm only
○	Does not have alarm capability
⊗	Not specified

8.12 Portability

Portability is the ability of the equipment to be transported, including any support equipment required to operate the device. Two important things to consider regarding portability are the equipment dimensions and its weight. They determine if a single person can transport the equipment or if multiple people or vehicular transport is needed to move the equipment.

Portability	
●	< 2 lb and hand held
◕	Between 2 lb and 5 lb and hand held
◑	Between 5 lb and 10 lb
◔	Between 10 lb and 50 lb
○	> 50 lb
⊗	Not specified

8.13 Durability

Durability describes the ruggedness of the equipment, or how well the equipment can withstand rough handling and still operate and give reliable results.

Durability	
●	Able to operate with rough handling
◕	Can withstand some rough handling
◑	Can withstand rough handling only when stationary
○	Must remain stationary and does not withstand rough handling
⊗	Not specified

8.14 Power Requirements

Power Requirements indicate whether the specific equipment can operate on a battery and/or ac electrical power. In addition, if the equipment uses battery power, the number of batteries required and longevity of the batteries should also be considered.

Power Requirements	
●	Battery or ac powered
◕	Battery powered
◑	Vehicle or ac powered
◔	ac powered
○	Unique power requirements
⊗	Not specified

8.15 Environmental Requirements

Environmental Requirements are the ideal ranges of climate and surrounding factors required for the equipment to operate optimally. These factors include temperature extremes, humidity, pH, environmental particulate levels, and other conditions. For first responders, the greater the operation range, the better the equipment.

Environmental Requirements	
●	Operates under all expected environmental conditions
◕	Operates under most environmental conditions
◑	Needs 1 optimal environmental condition
◔	Needs up to 3 optimal environmental conditions
○	Has strict requirements for most environmental conditions
⊗	Not specified

8.16 Skill Level

Skill Level is the suggested level of education and training required by an operator to properly use the equipment or system.

Skill Level	
●	No special training required
◑	Some training required
◔	Special training required
○	Highly specialized training required
⊗	Not specified

8.17 Availability

Availability indicates the lead-time required when purchasing the equipment. Is the equipment available "off the shelf" or is there a significant amount of time between purchase and delivery? Availability is important when purchasing the detection equipment, reagents, and consumables.

Availability	
●	Equipment, reagents, and consumables readily available off the shelf
◕	Equipment, reagents, and consumables available, but only from the manufacturer
◑	Equipment, reagents, or consumables require special order
○	Equipment, reagents, and consumables are not readily available to purchase
⊗	Not specified

8.18 Cost

Cost is the price of the unit or system and includes the costs associated with purchasing the reagents and consumables to make the unit functional.

Cost	
●	Less than $3K, including reagents and consumables
◕	Between $3K and $6K, including reagents and consumables
◑	Between $6K and $15K, including reagents and consumables
◔	Between $15K and $25K, including reagents and consumables
○	More than $25K, including reagents and consumables
⊗	Not specified

8.19 Technical Support and Warranty

Technical Support and Warranty not only indicates whether trouble shooting expertise is available, but includes the type of support available (i.e., on-site support, 24 h phone support, and loaner options) and indicates whether the support is provided by the manufacturer or by the authorized dealer of the equipment. Warranty information will also be included in this data field since these two categories (at least initially) are closely related.

Technical Support and Warranty	
●	24/7 technical support, including loaner option
◕	24/7 technical support, but no loaner option
◑	Limited support and warranty
○	No technical support or warranty
⊗	Not specified

9. EQUIPMENT EVALUATION

Based on vendor information following the final vendor contact in January 2007 a number of changes were made to the *Guide for the Selection of Biological Agent Detection Equipment for Emergency First Responders,* dated March 2005. These changes included removing several discontinued biological detectors from appendix F and appendix G, moving other biological detectors from appendix G to appendix F, adding new biological detection equipment items to appendix F, and updating all entries with current vendor information. The changes are presented in tabular form in appendix J of this guide.

The market survey conducted for BA detection equipment identified 143 different pieces of biological detection and sampling equipment. The details of the market survey, with detailed data on 44 equipment items, are provided in appendix F of this guide. Information for the remaining 63 equipment items with limited vendor data, including names, manufacturers, and contact information, is presented in appendix G. Section 9.1 defines the equipment usage categories and section 9.2 discusses the evaluation results.

Although biological samplers and biological reagent kits are not considered to be biological detection equipment, they are important for the first responder to consider when preparing for a biological incident. Samplers effectively increase sensitivity of the testing procedure, for example, by concentrating airborne particles into a relatively small liquid suitable for analysis. It is important to note that biological samplers and biological reagent kits are not evaluated with the selection factors in this guide; however, data sheets for 26 biological samplers and 10 biological detection kits are included in appendix H and appendix I, respectively.

9.1 Equipment Usage Categories

In order to display the evaluation results in a meaningful format, the detection equipment items were grouped into four categories based on the prospective manner of usage by the emergency first responder community. It is important to note that many of the equipment items could be grouped into one of several usage categories, but an attempt was made to group them on the basis of intended use by the first responder community. These usage categories include the following:

- Handheld detection equipment.
- Mobile laboratory detection equipment.
- Fixed-site detection systems.
- Standoff detection systems.

The definitions for the four usage categories were extracted from the *Final Report on Biological Detection Equipment Market Survey for Emergency Responders*. (See detailed reference in appendix A.) The definitions for each of the usage categories are provided in the following sections.

9.1.1 Handheld Detection Equipment

Handheld detection equipment is defined as being human portable for mobile operations in the field. The instrument is light enough to be carried by an emergency first responder and operated while moving through a building.

9.1.2 Mobile Laboratory Detection Equipment

Mobile laboratory detection equipment is defined as being transportable for stationary operations. The instrument is light enough to be carried by an emergency first responder or in a vehicle but is operated while stationary.

9.1.3 Fixed-Site Detection Systems

Fixed-site detection systems are specifically designed to operate inside a building or inside a specially designed vehicle. This equipment generally requires a trained technical operator. The duration of operation for these instruments is indefinite, and the power requirements are met through the building infrastructure or generators. Consumables required for continuous operation of the detection instruments (e.g., compressed gas cylinders) would need to be provided by building management.

9.1.4 Standoff Detection Systems

Standoff detection systems are specifically designed to remotely monitor the presence of BAs that may be present in the atmosphere up to three miles away. These systems typically require one or two individuals for monitoring operations. Depending on the technique employed and the environmental conditions, these detectors can have high or low specificity. Standoff detectors can be mounted directly on a vehicle, or at least require vehicle transport and special assembly.

9.2 Evaluation Results

One hundred forty-three biological detection items were identified at the time of writing this guide. Ninety-seven of these items are considered for biological detection and identification applications, ten are considered for biological screening purposes, and the remaining are either biological samplers (26 items) or biological reagent kits (10 items). Only equipment with vendor supplied information were included in the equipment analysis.

Table 9–1 presents the number of biological detection items that were considered most likely to meet the needs of the emergency first responder, i.e., handheld detectors and mobile laboratory detectors, as well as biological screening equipment. These items are further grouped according to the equipment technology. In addition, the table includes the number of items with sufficient data for equipment evaluation versus the number of items with insufficient or too little data for equipment evaluation. Data sheets for the 35 evaluated biological detection equipment items are included in appendix F.

Table 9–1. Detection equipment usage categories (evaluated equipment)

Detection Type	Technology	Biological Detection Equipment			
		Evaluated	Not Evaluated	Subtotal Identified	Total Identified
Handheld Detection Equipment	Molecular	2	1	3	25
	Immunochemical	8	10	18	
	Optical	2	—	2	
	Screening*	2	—	2	
Mobile Laboratory Equipment	Molecular	3	2	5	33
	Immunochemical	6	3	9	
	Optical	4	3	7	
	Physical	2	—	2	
	Ligand	—	1	1	
	Hybrid	1	2	3	
	Screening*	5	1	6	
Fixed-Site Detection Systems	Screening*	1		1	1
Detection Equipment Subtotal		**36**	**23**	**59**	**59**

*See table 9–5 for evaluation results.

Evaluation results for the BA detection equipment are presented in tabular format for the 36 detectors identified with completed vendor supplied information. Separate evaluation tables are presented for the handheld and mobile laboratory usage categories as well as for the screening devices. Each table includes the specific equipment item and the symbol that corresponds to its characterization based on each of the selection factor definitions. If a selection factor is not appropriate for a specific equipment item, not applicable (NA) is used to characterize that selection factor. Table 9–2 provides the table number and associated table pages for the handheld and mobile laboratory detection equipment usage categories.

Table 9–2. Evaluation results reference table

Table Name	Table Number	Page Number
Evaluation results of handheld biological detection equipment	9–3	9–4
Evaluation results of mobile laboratory biological detection equipment	9–4	9–5
Evaluation results of biological detection screening equipment	9–5	9–6

9.2.1 Handheld Portable Detection Equipment

Twenty-three handheld detection equipment items were identified in the development of this guide. Twelve handheld items had sufficient data to be evaluated using the selection factors. Two of the detection items use real-time PCR (a molecular technique), eight use immunochemical techniques, and two use ATP bioluminescence technology (an optical

technique). Table 9–3 details the evaluation results for these 12 evaluated handheld detection equipment items.

Table 9–3. Evaluation results of handheld biological detection equipment . March 2007

ID #	Detector Name	Start-Up Time	Response Time	Sensitivity	Specificity	Forms Detected	Type of Output	Data Interpretation	Ease of Use	Sample Preparation	Support Equipment Needed	Alarm Capability	Portability	Durability	Power Requirements	Environmental Requirements	Skill Level	Availability	Cost	Technical Support and Warranty
1	BADD™ BioWarfare Agent Detection Device	●	◔	◕	◑	●	◑	●	◕	◕	●	◑	●	●	●	●	◑	●	●	●
2	Rapid Response Hand Held Assay (RRHHA)	●	○	◕	◑	●	○	●	◕	◕	●	◑	●	●	●	●	◑	◕	●	⊗
3	Prime Alert™ Biodetection/Threat Verification System Model PAE002	◑	○	◕	◑	●	○	●	◑	●	●	◑	◔	●	●	●	◑	◕	◑	●
4	SMART II (Biothreat Detection Diagnostic Kits)	●	○	◕	◑	●	○	●	◑	●	●	◑	●	●	●	●	◑	●	●	●
5	BioSeeq™ Hand Held PCR	◕	○	●	●	●	○	●	◕	◑	◑	●	◕	●	●	●	◑	◑	○	●
34	PROFILE® 1 (Model 3560)	●	○	◕	◔	◔	◑	◑	◑	◑	●	◑	◕	●	●	●	◑	◕	◕	●
35	Defender TSR (Test Strip Reader) System (P–502)	◕	○	●	◑	●	○	●	◕	◑	●	●	◕	◕	●	◕	◑	◕	◑	●
36	MPD-based BW Detector (P-chip/ MPD/2004)	○	○	◑	◑	●	○	●	◑	○	◑	●	◕	●	●	●	◑	◕	◔	●
37	QTL Biosensor	◕	◑	◕	◑	●	○	●	●	◕	●	●	◕	●	◕	◕	●	◑	◑	●
38	Prime Alert® Biodetection System (096–3130)	◑	○	◕	◑	●	○	●	◑	●	●	◑	◔	●	●	●	◑	◕	◑	●
39	RAZOR® System (RAZR-ASY-0010)	◑	○	◕	●	◕	○	●	◑	◑	◕	◑	◑	●	●	◕	◔	◕	○	◑
40	Uni-Lite NG	●	◑	◕	◔	◔	○	●	◑	●	◕	●	●	●	●	◕	●	◕	◕	●

In addition to the 12 evaluated handheld items, data sheets with limited information for the remaining 11 handheld detection items are included in appendix G.

9.2.2 Mobile Laboratory Detection Equipment

Twenty-seven mobile laboratory detection equipment items were identified in the development of this guide. Sixteen mobile laboratory detection equipment items contained sufficient information to be evaluated using the selection factors. Three of the mobile laboratory detection equipment items use molecular techniques, six use immunochemical techniques, four use optical

techniques, two use physical techniques, and one is considered a hybrid technology. Table 9–4 details the evaluation results for these 15 equipment items.

Table* 9–4. *Evaluation results of mobile laboratory biological detection equipment March 2007

ID #	Detector Name	Start-Up Time	Response Time	Sensitivity	Specificity	Forms Detected	Type of Output	Data Interpretation	Ease of Use	Sample Preparation	Support Equipment Needed	Alarm Capability	Portability	Durability	Power Requirements	Environmental Requirements	Skill Level	Availability	Cost	Technical Support and Warranty
6	Idaho Technology R.A.P.I.D.® System	◑	○	●	●	◕	○	◑	◑	◑	◑	◑	○	●	◔	●	◑	●	○	●
7	RAMP® Biowarfare Detection System	●	○	◕	◑	●	○	●	●	◕	●	●	◕	◕	◕	◕	●	●	◔	●
8	The Guardian Reader System™ for Tetracore's BioThreat Alert™ Tests	●	◔	◕	◑	●	○	●	◕	◕	●	●	◕	●	●	◕	◑	◑	◑	●
9	BioThreat Alert™ Bio Threat Test Strips with Alexeter Reader	●	◔	◕	◑	●	◕	●	◕	◕	●	◑	●	●	●	●	◑	◕	●	●
10	MICROCYTE® Field and MICROCYTE® Aqua	◔	◔	◕	◔	◕	○	◑	○	◑	●	○	◑	◑	●	◔	◔	◑	○	●
11	Analyte 2000 Fiber Optic Fluorometer	○	○	●	◑	●	◑	◑	◕	◕	○	○	◑	●	●	●	◑	◑	○	◑
12	RAPTOR Plus	◔	○	●	◑	●	◑	●	◕	◑	◕	●	◔	●	●	●	◔	◑	○	◑
14	GeneXpert® System (GX1000N4–1)	◔	○	●	●	◕	●	●	◑	◕	○	◑	◔	◕	◑	◑	◑	◕	○	◑
15	LightCycler™ (Model 1.2)	●	○	●	●	◕	◑	◑	◑	○	○	◑	◔	◑	◔	◑	◑	●	○	●
18	M-SERIES® M1M Analyzer	◔	○	●	◑	●	◑	●	◑	◑	●	●	○	◕	●	◕	◑	◕	○	◑
41	Autotrack (Continuous Flow ATP Detector)	◔	◑	◑	◑	◔	◑	◑	◕	●	●	●	○	●	◑	◕	●	◕	○	●
42	VeroTect	◑	◕	NA	◔	◔	◕	●	●	●	●	●	○	●	●	●	●	◑	○	◑
43	4 WARN Sentry 3000 (Model 718866–901)	◕	◕	●	◔	◔	◕	●	●	●	●	●	◔	●	●	◕	●	◑	○	◑
44	KT1050 HazCat Tier 4 System	◔	○	◕	●	◕	○	◑	◑	◑	◑	○	○	◕	◕	◕	◑	◕	○	◑
45	Biological Alarm Monitor (MAB)	◑	●	◑	●	◔	◕	●	●	●	●	●	◔	◑	◕	●	●	◕	○	◕
47	BioThreat Alert™ ELISA Kits	NA	○	◕	●	●	◑	○	◑	◑	NA	◑	●	NA	●	◕	○	◕	●	NA

In addition to the 16 evaluated mobile items, data sheets with limited information for the remaining 11 mobile laboratory detection items are included in appendix G.

9.2.3 Screening Devices

Ten screening devices, two handheld, six mobile, one vehicle mounted/fixed-site, and one standoff/remote/monitoring system were identified in the development of this guide. Eight of these screening devices had sufficient data to be evaluated using the selection factors. Table 9–5 details the evaluation results for these eight screening devices.

Table 9–5. Evaluation results of biological detection screening equipment March 2007

ID #	Detector Name	Technology Area	Start-Up Time	Response Time	Sensitivity	Specificity	Forms Detected	Type of Output	Data Interpretation	Ease of Use	Sample Preparation	Support Equipment Needed	Alarm Capability	Portability	Durability	Power Requirements	Environmental Requirements	Skill Level	Availability	Cost	Technical Support and Warranty
27	**BioCheck™ Powder Screening Test Kit (GB 1001)**	Handheld Immuno chemical	●	◔	○	◔	◔	○	●	◕	●	●	◑	●	●	●	◕	●	◕	●	◕
28	**KT1030 HazCat Anthrax Screening Test Kit**	Mobile Immuno chemical	●	◔	○	◔	◑	○	◑	◕	◕	◑	◑	●	◕	●	◕	◑	◕	●	◑
30	**KT1035 HazCat® WMD Kit**	Mobile Immuno chemical	◔	○	○	◑	◑	○	◑	◕	◕	◑	◑	◔	◕	◕	◕	◑	◕	●	◑
31	**KT1040 HazCat® MicroCat/WMD**	Mobile Microscopy	◔	○	○	◑	●	○	◑	◑	◑	◑	○	◔	◕	●	◑	◑	◕	◔	◑
31	**HazMatID (023–1001)**	Mobile FTIR	◑	◕	○	◔	◔	○	◑	◕	●	●	◑	◔	●	●	●	◑	◕	○	●
32	**IlluminatIR ML Package (006–2019)**	Vehicle mounted or Fixed FTIR	◑	◔	○	◔	◔	○	●	◕	◕	◑	◑	◔	◑	◔	◕	◑	◕	○	◕
33	**HMB Portable Biohazard Detector (HMB V–PS)**	Handheld Biomass Readout	◑	○	○	◑	◔	○	●	◑	◑	●	●	●	●	◕	◕	◑	●	●	◕
46	**RespondeR RCI (024-1001)**	Mobile Raman	◑	◕	○	◑	◔	○	◑	◑	◑	◑	⊗	◑	◕	●	●	◑	◕	⊗	●

In addition to the eight evaluated screening devices, data sheets with limited information for the two remaining screening devices are included in appendix G.

9.2.4 Fixed-Site Detection Systems

Forty-three fixed-site detection systems were identified in the development of this guide. Data sheets for 9 of the fixed-site detection systems are included in appendix F. Limited information for the remaining 34 fixed-site systems is included in appendix G.

9.2.5 Standoff Detection Systems

Five standoff detection systems were identified in the development of this guide. None of the standoff detection systems had vendor-supplied data sheets. Data sheets with minimal information on these five items are included in appendix G.

9.2.6 Biological Samplers and Biological Reagent Kits

Biological samplers take the sample and biological reagent kits identify the sample as part of a detection system. Although these categories are not considered as biological detection equipment, they have an important role in biological operations. Also, several biological samplers were identified by the first responder community as devices they have in their inventory for biological situations.

Twenty-six biological samplers were identified in the development of this guide. There are 19 handheld biological samplers, five mobile laboratory biological samplers, and two fixed-site biological samplers. Information on the identified systems is included in appendix H.

Ten biological reagent kits were identified in the development of this guide. Five of the reagent kits had information supplied by vendors. Evaluation tables were not prepared for the biological reagent kits but information on the identified systems is included in appendix I.

10. REFERENCES AND ENDNOTES

Section 10 identifies the references and endnotes that were used in the compilation of this guide.

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APPENDIX B—POTENTIAL BIOLOGICAL AGENT DETECTION TECHNOLOGIES DEVELOPED BEFORE 2001

APPENDIX B
POTENTIAL BIOLOGICAL AGENT DETECTION TECHNOLOGIES DEVELOPED BEFORE 2001

For the purposes of this review: Extensive is classified as requiring more than 30 min and at least 3 or more steps; minimal requires less than two steps, ND = not done; and N/A = not applicable.

Analyte	Description	Transduction	Sensitivity/Selectivity	Sample prep.	Res. time	Refs.
S. aureus	A disposable amperometric enzyme-channeling immunosensor for quantitative, rapid, separation free enzyme immunoassay is described	Amperometry	1000 cells/mL	Minimal (real samples were not tested)	5min to 30 min	1
SEB	Immunosensor for detecting SEB is described. Detection is achieved by monitoring the impedance of a platinum film when the immobilized anti-SEB antibodies couple with SEB	Impedance	0.4 ng/mL	Minimal (real samples not tested)	20 min	2
Aflatoxins	A handheld, fully automated immunoaffinity biosensor for the detection of aflatoxins is described.	Optical—fluorescence	0.1 ppb	Minimal (prototype; real samples not analyzed)	2 min	3
SEB, Newcastle disease virus, B. melitensis, ricin	A biosensor assay that uses biotin-streptavidin mediated filtration capture onto nitrocellulose membrane in conjunction with silicon-based light-addressable potentiometric sensor	Light addressable-potentiometric sensor	SEB (5 pg/mL) New castle disease virus (2 ng/mL) *B. melitensis* (20 ng/mL) Ricin (100 pg/mL)	Minimal	2 h	4
B. globigii, SEB, MS2 bacteriophage	Array biosensor that with a single sensor substrate and a single detection step is described, for the detection of several analytes in a single test sample.	Optical—Planar waveguide	*B. globigii* (105 cfu/mL) SEB (10^7 cfu/mL) MS2 bacteriophage (10 ng/mL)	Minimal (real samples not tested)	14 min	5

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Analyte	Description	Transduction	Sensitivity/Selectivity	Sample prep.	Res. time	Refs.
B. anthracis	A minisoicator that facilitates spore lysis in less than 30 s is described. Coupled with PCR analysis, the minisonicator reduces assay time to less than 15 min	Fluorescence—PCR based	102 spores/mL	Minimal (automated)	15 min	6
B. Subtilus	A light addressable potentiometric sensor (LAPS) and a flow through immunofiltration-enzyme assay system for the detection of BWA. System is designed to assay up to 8 agents simultaneously. The detection system described here has been incorporated into the Biological Integrated Detection System (BIDS)	Potentiometric—enzymatic breakdown of urea causes a rapid change in pH producing a potential shift proportional to the amount of BWA	3×10^3 cfu/mL	Extensive reagent preparation is required such as dialysis and lyophilization of antibodies and buffers.	15 min (cumber some; multi-step assay)	7
Staphylococcal enterotoxin B; Bacteriophage M 13; *E. coli*	Automated optical flow cell multichannel immunosensor for the detection and identification of toxins, viruses and bacterial particles. The system consists of three channels allowing the detection of 3 agents simultaneously.	Light emitting diode and photodetector	10 ng/mL (SEB) 10^6 pfu/mL (M13) 10^7 cfumL (E.coli)	Minimal (but real samples were not used for this study.)	15 min (SEB) 16 min (M13) 20 min (E.coli)	8
B. anthracis *Y. pestis* *B. suis* *F. tularensis* *V. cholerae* *C. botulinum* *C. jejuni* *Vacinni virus*	Bead ARray Counter (BARC) biosensor is a multianalyte biosensor that uses DNA hybridization, magnetic microbeads and giant magnetoresistive (GMR) sensor to detect and identify biological warfare agents	Giant magneto resistive (GMR) sensors	100 fM using an optical detector Sensitivity expected to increase with detection of the GMR sensor signal.	Extensive since sample DNA extraction and biotinylation is required	5 min	9
B. anthracis *Brucella sp.* *F. tularensis* *Y. pestis* *C. botulinum* *S. aureus*	Colorimetric and fluorogenic DNA probe assays for the detection of BW agents. Fluorogenic assay does not require post PCR processing and allows for real-time detection within minutes to hours.	Optical detection	150 copies of B. anthracis 325 copies of Brucella sp. 25 copies of F. tularensis	Extensive; use of PCR amplification and the need for DNA extraction and purification	2 h to 6 h	10

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Analyte	Description	Transduction	Sensitivity/Selectivity	Sample prep.	Res. time	Refs.
Aerosolized biological agent, based on the fatty acid distribution observed upon pyrolysis of an organism *B. globigi*	Block I CBMS—based on an ion trap mass analyzer; it's a fieldable instrument, eliminated the need for a compressed helium buffer gas, since chemical ionization (CI) is used as opposed to electron ionization (EI)	Mass spectroscopy (of fatty acids of bacteria)	50 ACPLA (agent containing particle per liter of air) of *B. globigii*	Aerosolized samples are collected using an aerosizer LD biosampler. Liquid samples are injected directly into the pyrolysis tube	2 min	11
B. globigii *B. sabtilis E. herbicola*	Block II CBMS—an integrated instrument for detection of CW and BW agents on the battlefield, wheeled in a vehicle; includes sampler for aerosols from the air, interface for connecting to a ground sampling system, and a heated capillary for sampling agent vapors	Mass spectroscopy (of fatty acids of bacteria)	25 ACPLA Distinguishing proteins ch as ovalbumin is much more difficult than bacteria	Aerosolized samples are collected using an Aerosizer LD biosampler.	2 min	12
Myotoxins, Ricin, SE B VX Botulinum	Integrated system for the detection and subsequent removal of CW and BW agents, in water systems. System includes real time sensors, detection equipment, sampling system and manifold and treatment steps for both portable and non-portable devices	Optical—flow cytometer (antibody fluorescent tags)	ND	Minimal—water samples are directed to a mixing chamber	15 min	13
B. anthracis C. botulinum	Device for detecting B. anthracis and C. botulinum with high sensitivity and selectivity, using chelate-stabilized lanthanides. The chelate stabilized lanthanides react with the spore-specific target molecules to form a characteristic that is detected	Optical—spore-specific phosphorescence emission detection	500 spores (cfu)	Minimal	5 min to 15 min	14
Staphylococcus enterotoxin B (SEB) *Bacillus globigii*	The system uses rapid detection capability of mass spectroscopy and specific molecular markers of specific pathogens to detect and characterize the microbial threat within minutes	Mass spectroscopy (MALDI)	Sensitivity associated with mass spectroscopy (10 mole to 18 mole, i.e., attomole level)	Minimal—use of an aerosol sampler Minimal	2 min	15

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Analyte	Description	Transduction	Sensitivity/Selectivity	Sample prep.	Res. time	Refs.
Staphylococcus enterotoxin B (SEB)	Miniaturized (hand-held) flow cytometry; has not been used in the field due to the high power requirements for the laser. New developments of fieldable instrument are discussed	Optical detection—laser light scattering	Not discussed (however, flow cytometry has detection of about 100 fluorescent molecules/cell		2 min	16
Bacillus globigii	A two-dimensional array of complimentary nucleic acid probes immobilized within a 10 x 60 μm gel pad. The gel pads act as very small test tubes for carrying out annealing reactions between the complimentary probes and the rRNA oligonucleotides	Detection is achieved by breaking open the cells of interest cleaving rRNA, allowing the resulting oligonucleotides to flow over the chip and measure fluorescence using a fluorescence microscope.	ND	Extensive, since rRNA has to be extracted from the organisms	Hours	17
Yersina pestis	Fluorogenic assay coupled with PCR amplification of bDNA is used to detect Y. pestis	Optical-fluorometric	103 copies of target DNA	Extensive	ND	18
Cytomegalovirus (CMV)	Coupled Particle Light Scattering (Copalis™) is a homogeneous ligand binding detection technology. Copalis measures particle size using high resolution optical sizing to distinguish monomers from larger aggregates; this enables the simultaneous determination of multiple analytes in serum, plasma, or whole blood. It can be adopted to detect BWA.	Copalis™ measures changes in the light scattering properties of particles when they form couple (or aggregate) as a result of molecular recognition	0.07 μIU/mL of Thyroid stimulating hormone	Minimal	10 min	19, 20
Ovalbumin MS2 bacteriophage Bacillus subtilis var. globigii Erwinia herbicola	An evanescent planar waveguide system Mark 1.5 instrument has been used to detect simulants of BWA. Capture antibodies are immobilized onto an evanescent planar waveguide. Analytes are mixed with tracer antibodies covalently coupled to the fluorescent dye Cy5™. Fluorescence is monitored with laser excitation and a CCD camera.	ST-6 Charged Couple Device (CCD) camera	10 ng/mL (OV) 10^7 pfu/mL (MS2) 10^5 cfu/mL (BG) 5 x 10^5 cfu/mL (EH)	Total sample preparation time averaged < 2 min	6 min	21

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Analyte	Description	Transduction	Sensitivity/Selectivity	Sample prep.	Res. time	Refs.
B. anthracis	Anthrax spores were determined using selected PCR-amplified DNA aptamers in an aptamers-magnetic electrochemiluminescence (AM-ECL) assay. SELEX, a new technique by then, was used to generate very high affinity receptors that are composed of nucleic acids instead of proteins.	Electroluminescence (with PCR amplification)	Exact detection limit not discussed. However, a wide dynamic range is reported as 6 x 10^6 anthrax spores	Extensive—PCR , DNA extraction and purification procedures required.	ND	22

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APPENDIX C—POTENTIAL BIOLOGICAL AGENT DETECTION TECHNOLOGIES DEVELOPED POST 2001

APPENDIX C
POTENTIAL BIOLOGICAL AGENT DETECTION TECHNOLOGIES DEVELOPED POST 2001

For the purposes of this review: Extensive is classified as requiring more than 30 min and at least 3 or more steps; minimal requires less than two steps, ND = not done; and N/A = not applicable.

Analyte	Description	Transduction	Sensitivity/Selectivity	Sample prep.	Res. Time	Refs.
Ricin, SEB, cholera toxin, botulinum toxin	A microarray biosensor for the rapid and simultaneous detection of multiple analytes on the surface of a waveguide is described. Fluoroimmunoassays for the detection of both high and low molecular toxins is discussed.	Fluorescence – CCD camera	0.5 ng/mL	Minimal sample preparation	ND	1
Ricin, SEB, cholera toxin, botulinum toxin	Portable Array biosensor for the rapid and simultaneous multianalyte detection	Optical-fluorescence	1 ng/mL (toxins) 1000 cfu/mL (bacteria) 100000 pfu/mL (viruses)	Minimal.	15 min	2
Cholera toxin Diphtheria toxin Anthrax lethal factor and protective antigen SEB Tetanus toxin	Antibody based microarray for the multiplexed detection of cholera toxin, diphtheria toxin, anthrax lethal factor and protective antigen, SEB and tetanus toxin insignificant cross-reactivity	Optical-fluorescence	14 ng/mL (SEB)	Minimal (real samples not used)	ND	3
E. coli, *S. infantis*	A biosensor for the detection of pathogenic bacteria developed for biosecurity applications. The biosensor was developed by photolithography and employs immunological detection	Impedance	10^4-10^7 cfu/mL	Minimal	5 min	4
E. coli	An electrochemical screen printed biosensor array utilizing bioreceptor lectins immobilized onto ImmunoDyne ABC□ activated surfaces for the rapid detection of *E. coli*	Electrochemical (chronocoulometeric transduction)	1.8 x 10^7 cfu/mL of *E. coli*	Sample prep is extensive	40 min	5
B. globigii	A sensitive and selective chip-based immunoassay combined with a portable bioaerosol sampler that is readily adaptable for field use.	Optical - Compact biochip detection system that includes a miniature diode laser for excitation	100 *B. globigii* spores corresponding to 17 aerosolized spores/L of air	Minimal—Aerosolized spores were collected by a portable bioaerosal sampler	55 min incubation required	6
REVIEW	Review of electrochemical techniques	*REVIEW*	*REVIEW*	*REVIEW*		7

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Analyte	Description	Transduction	Sensitivity/Selectivity	Sample prep.	Res. Time	Refs.
Ovalbumin and horseradish peroxide (used as BWA protein simulants)	Portable SPR biosensor deployed on a surrogate unmanned aerial vehicle (UAV). A two-stage collector accumulates the sample prior to de-aeration and monitoring by SPR.	Optical—SPR	1 nM OVA 1nM HRP	SASS was used in the two-part sample collection stages Sensor surface fictionalization is a multi-step process that requires over 2 h	5 min for OVA5 min for HRP	8
Staphylococcus aureus enterotoxin B(SEB)	Battery powered (12V) fieldable SPR, with a miniature integrated two-channel SPR sensor with reference capability. It is similar to the single channel Spreeta™	Optical—SPR	With amplification, 100 fM SEB was detected. There is a trade of between response time and lower LOD	Extensive multi-step process for the preparation of the sensor slide surface Slide functionalization and amplification procedures are extensive	15 min	9
B. anthracis *Y. pestis* *B. globigii* Botulinum toxoid	Autonomous pathogen detection system (APDS) capable of continuously monitoring the environment for airborne BWA. It consists of preliminary immunoassays, which may be followed by PCR if a BWA is detected. Real sample analysis is reported.	Optical—PCR amplification and flow cytometry for preliminary immunoassays	3 x 10^5 cfu/mL for *B anthracis*. 6 x 10^5 for *Y. pestis*	Commercial wetted-wall cyclone sample collector (Smart Air Sampler System (SASS) 2000TM is used. An integrated module capable of automated PCR and immunoassays is used.	More than 30 min due to real- time PCR	10
Simulants used to mimic BWA MS2 for small pox; ovalbumin for protein toxins such as ricin, botulinum toxins and staphylococcal enterotoxins; *B. globigii* for anthrax and *E. herbicola* for plague	Liquid array based multiplex immunoassays have been used to demonstrate the simultaneous detection of four BWA simulants from a single sample. The liquid arrays (immunoassays) have been developed for use in the Autonomous Pathogen Detection System (APDS)	Optical—flow cytometry	6.0 x 10^4 cfu/mL (30 min incubation) 1.5 x 10^4 cfu/mL (65 min incubation)	Automated sample collector (see other references on APDS)	30 min	11

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Analyte	Description	Transduction	Sensitivity/Selectivity	Sample prep.	Res. Time	Refs.
B. anthracis Y. pestis	Autonomous detection of aerosolized *B. anthracis* and *Y. pestis* by Autonomous Pathogen Detection System (APDS) that is capable of continuously monitoring the environment for airborne biological threat agents	Multiplexed immunoassay with polystyrene beads embedded with fluorescent dyes. Laser excites the dye molecules inside the beads (optical)	3 x 10^5 cfu/mL for *B. anthracis* 6 x 10^5 for *Y. pestis* High selectivity	Aerosol sampler is used to collect samples followed by automated sample prep.	30 min to 60 min	12
B. globigii *Y. pestis* *B. globigii* Botulinum toxoid	(Previously sited under ref. # 8) APDS, podium sized that continuously monitors the air for BA. Performs continuous aerosol collection, sample preparation, and detection using a multiplexed immunoassay followed by a confirmatory PCR amplification (the new addition to this model)	Luminex 100 flow cytometer	3 x 10^5 cfu/mL for *B. anthracis* 6 x 10^5 for *Y. pestis*	Automated DNA extraction and PCR amplification Aerosol mixing chamber release time is 50 min Decontamination procedure is cumbersome	30 min	13
B. anthracis Y. pestis	Automated sample preparation module based on sequential injection analysis (SIA) for use with autonomous pathogen detection system. It interfaces aerosol sampling with multiplexed microsphere immunoassay. It has been used with the APDS	The sample preparation module was coupled to an APDS which uses both immunoassay (with optical detection) and flow cytometry for detection	Detection limits of 1 x 10^5 of *B. anthracis* and 1 x10^4 of *Y. pestis* were achieved for samples prepared using the SIA	A continuously stirred reservoir used to maintain microspheres in suspension and a reusable coaxial membrane-sequestering cell in which immunoassays are performed. The sequestering cell enabled capture, repeated washing and recovery of the microspheres to realize optimal immunoassay performance	30 min	14
Cholera toxin	Reagentless Optical Biosensor (ROB) based on protein specific assays and a waveguide-based evanescent fluorescent excitation; A laboratory based sensor and development of a hand-held prototype sensor are reported.	Optical (Fluorescence) waveguide	2.5 nM cholera toxin	Minimal—samples mixed with BSA and injected into the sample cartridge.	10 min	15

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Analyte	Description	Transduction	Sensitivity/Selectivity	Sample prep.	Res. Time	Refs.
Bacteriophage MS2	Bead-based electrochemical immunoassay. Biotinylated rabbit anti-MS2 IgG is attached to a streptavidin coated bead to capture MS2. In a sandwich format, rabbit anti-MS2 IgG-β-galactosidase is attached, which converts PAPG to PAP that's oxidized to PQI	Electrochemical—amperometry (RDE) and an interdigitated array electrode (IDA)	RDE—200 ng/mL (3.2 x 10^{10} viral particles/mL) IDA—90 ng/mL (1.5 x 10^{10} virus particles/mL)	Extensive immobilization steps Extensive sample preparation incubation)		16
S. aureus *F. tularensis* *C. botulinum*	Time-resolved fluorescence (TRF)	Optical—fluorescence	4 pg/mL—20 pg/mL Highly sensitive assay	Assay has several steps similar to ELISA making it cumbersome	2 h	17
SEB M13 *E. coli*	Chemiluminescence multichannel immunosensor (CL-MADAG) based on capillary ELISA in combination with a miniaturized fluidics system is described. The fluidics system allows for the three immunoassays to be performed simultaneously.	Optical - chemiluminescence	5 ng/mL SEB 10^5 cfu/mL *E.coli* 10^7 pfu/mL M13	Extensive capillary activation protocol. Takes at least 12 h Use of real samples not discussed	24 min	18
E. coli	Portable microfluidic biological device, with semi-automated immunoassay system that utilizes a dual enzyme amplification to improve sensitivity System can also be used to detect airborne pathogens by integrating it with an aerosol collector e.g., MesoSystems Biocapture aerosol collectors	Electrochemical amperometric	700 cells/mL for *E coli* 0.1 ng/mL for proteins	ND	60 min 40 min	19
E. herbicola B. subtilis var *niger*	Automated Biological Agent Testing System (ABATS) combines both PCR and electrochemiluminescent (ECL) immunoassay to analyze each sample. Results in a three-fold increase in sample throughput with a two-fold reduction in per sample cost.	Electrochemiluminescence	1 cfu/mL to10 cfu/mL (*E. herbicola)* 10^2 cfu/mL (*B. subtilis* var *niger* spores) LOD improved by bead beating	DNA extraction procedure is extensive (about 70 min) Sample prep to remove extraneous non-nucleic acid materials from environmental samples is discussed		20
SEB, ricin, chorera toxin	A Multi-Analyte Array Biosensor for simultaneously detecting and identifying multiple targets in complex samples with minimal user manipulation.	Optical waveguide	0.3 ng/mL (SEB)	Minimal	15 min	21

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Analyte	Description	Transduction	Sensitivity/Selectivity	Sample prep.	Res. Time	Refs.
E. coli	Flow through immunosensor with two stages of immunoreaction has been developed. *E. coli* antibodies were immobilized onto Toray paper to create a disposable immunofiltration membrane. Bacteria detection is achieved by use of HRP labeled antibodies which when coupled with a substrate of H_2O_2 and NaI yield an amperometrically measurable electro reduction in the order of microamps.	Electrochemical	50 cells/mL *E. coli* Use of the immunofiltration membranes increase the local concentration of agents in the immunoreaction, resulting in higher sensitivity	Minimal sample preparation	22 min	22
	Review on new probe-substitute antibodies refereed to as phage display.	N/A	N/A	N/A	N/A	23
B. subtilis var. niger	Optical metal clad leaky waveguide (MCLW) with an extended evanescent filed that provides significant light intensity over the entire volume of bound bacteria.	Optical metal clad leaky waveguide	Extended light propagation increased the LOD from 8 x 10^{-4} (refractive index detection) to 1 x 10^{-4} spores/mL	Extensive preparation of sensor surface Over 1 h bacterial binding times	Over 20 min	24
Influenza A virus (used as a surrogate for BWA)	Ion Channel Switch (ICSTM) biosensor that can rapidly detect pathogens, viruses or toxins with high sensitivity on small samples without the need for preliminary sample preparation.	Electrochemical— ICS bioelectronics	20 ng of total protein	Minimal sample preparation Sample prep not required for blood samples	15 min	25
A549 cancer cells	DOX 96-multiarray biosensor—multichannel system that is designed for simultaneous quantitative and Continuous measurement of dissolved oxygen	Electrochemical, at a fixed potential of 400 mV, the amount of O_2 is measured as cells or bacteria respirate. Electrical current produced is correlated to the cell content present in the well.	1 x 10^{-4} cells/well	An autonomous system that performs culture and detection simultaneously without added reagents	40 min	26

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Analyte	Description	Transduction	Sensitivity/Selectivity	Sample prep.	Res. Time	Refs.
B. globigii *C. glutamicum* *S. epidemidis* *Y. ruckeri* *E. adecarboxylata* *C. acidovorans* *A. odorans* *E. coli (3 strains)*	Fully autonomous electrochemical biosensor (DOX-PCA) with pattern recognition techniques for detection and classification of bacteria species and strain level. Classification scheme based on the different rates at which bacteria consume oxygen when affected by an antibiotic.	Electrochemical – oxygen reduction	Qualitative	Minimal sample preparation Autonomous device No added reagents Demonstrated for detection and classification of subspecies and strains	2 h	27
Staphylococcal enterotioxin B	Capillary Fluorescence Biosensor—for monitoring of DNA-analyte interaction in a microfluidic capillary acting as both sensor template and waveguide	Optical-Waveguide	30 pg/mL to 50 pg/mL SEB	Minimal; involves the preparation of samples in appropriate buffer	15 min to 30 min (after capillary preparation)	28
B. anthracis, *Y. Pestis* Botulinum toxin A	A proposed technique whereby expression patterns of selected protein markers in insects exposed to specific mixtures of biological agents to generate a library of biosignatures of exposure.	Fluorescence detection of protein biomarkers (e.g.,nitric oxide and glutathine Stransferase)	Will depend on the fluorescence detection of the proposed protein biomarkers	Minimal—airborne and water-borne sample will be collected by samplers already in the market	ND	29
E. coli DNA in water samples	QCM sensor labeled with DNA probe in conjugation with PCR amplification is used to detect *E. coli* DNA from water samples	Microgravimetric (with PCR amplification)	Less than 10 fg genomic *E. coli* DNA in water samples	Extensive; (DNA extraction and PCR amplification)	15 min	30
DNA sample prep from *B. anthracis, S. typhimurium*	A microchip solid phase extraction (μchip SPE) method for purification of DNA from complex biological samples such as whole blood is described. Comparison of the method to a commercial microcentrifuge method showed comparable amounts of PCR-amplifiable DNA from *S. typhimurium*.	PCR was used to evaluate the SPE method The integration of the SPE, PCR and separation on a single device has the potential to reduce detection time of BWA e.g., *B. anthracis* to about 30 min	Requires only 400 nL of bacterial culture per extraction	The only sample prep. required for DNA extraction from whole blood is mixing of blood with load buffer, prior to loading on the microchip	15 min	31

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Analyte	Description	Transduction	Sensitivity/Selectivity	Sample prep.	Res. Time	Refs.
E. coli, *B. anthracis* *E. herbicola*	Handheld advanced nucleic acid analyzer HANAA) offers real-time PCR, capable of running four simultaneous PCR experiments detecting bacterial pathogens in 30 min.	Optical detection—fluorescence	About femtogram level when purified DNA is used or 100 cells/mL for water samples	Extensive sample prep. (DNA extraction), before detection	30 min	32
B. anthracis	Handheld Advanced Nucleic Acid Analyzer (HANAA) is an instrument the size of a brick capable of rapid detection and identification of BWA using a TaqMan based PCR assay □	Optical—PCR based	10 individual bacteria	Minimal sample prep.; entails placing sample in a plastic tube and adding reagents. User must decide	30 min	33
B. anthracis F. tularensis Y. pestis	Bioseeq® is a an updated, redesigned version of the portable PCR instrument previously known as HANAA. Bioseeq® consists of six thermocycler units each independently programmable and operable. Reagents are contained in a small in a small disposable plastic device that serves as a swab for wiping a sampling, a chamber for mixing with buffer, the PCR reagents and a thin clear tube in which PCR is performed and thought which the fluorescence signal is detected.	Optical—fluorescence	Remarkable specificity to *B. anthracis B. anthracis* (10 spores to 100 spores) *Y. pestis* (125 copies or 100 cells) *F. tularensis* (some discrepancies)	Minimal sample prep. Swabs can be obtained from surfaces and used	ND	34
B. subtilis	BioDetect—Electronic biosensor capable of detecting the binding of a single DNA or RNA, therefore eliminates the need of PCR. It consists of oligonucleotides probes attached to multiple pairs of interdigitated electrodes on a microchip. Hybridization of target DNA to probes forms a DNA bridge connecting the two electrodes. The bridge is chemically coated with metal and the electrical resistance between the two electrodes measured.	Electrochemical—resistance	One DNA bridge results in 1000 fold reduction in resistance	DNA has to be extracted from the samples and has to be of appropriate length to span the inter-electrode gap Reduced assay time since amplification of DNA sequences (e.g., PCR) is eliminated	Shorter than PCR based methods	35

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Analyte	Description	Transduction	Sensitivity/Selectivity	Sample prep.	Res. Time	Refs.
B. cereus, E. coli, L. monocytogenes	Dielectrophoresis device (DEP) with the ability to separate BWA simulants from blood is described. PCR analysis that was inhibited by blood components in pre-analysis samples reveals bands in post separation samples containing a single or multiple BWA. The DEP can be use to reduce sample complexity in BWA detection	Potential Sample Prep. Technique for PCR based detection methods	N/A	Blood samples are suspended into buffer and loaded into the DES	5 min to 10 min	36
E. coli inoculated in whole rabbit blood	A fully integrated biochip device that consists of microfluidic mixers, valves, pumps, channels chambers, heaters and DNA microarrays sensors is described. The DNA microarray sensors that can perform DNA analysis on complex biological sample solutions. Sample preparation (including magnetic bead-based cell capture), cell preconcentration, purification, PCR, DNA hybridization, and electrochemical detection are all automated.	Electrochemical	Higher detection limits compare to Corresponding optical detection systems. LOD is not discussed	Sample prep: 50 min PCR: 90 min Pumping and valving: 10 min Hybridization: 60 min Sample prep. has been integrated with cell capture capabilities	3.5 h	37
B. cereus, E. coli, L. monocytogenes	Dielectrophoresis device (DEP) with the ability to separate BWA simulants from blood is described. PCR analysis that was inhibited by blood components in pre- analysis samples reveals bands in post separation samples containing a single or multiple BWA. The DEP can be use to reduce sample complexity in BWA detection	Potential Sample Prep. Technique for PCR based detection methods	N/A	Blood samples are suspended into buffer and loaded into the DES	5 min to 10 min	38
B. anthracis	A simple membrane-strip-based biosensor assay (universal biosensor) combined with a nucleic acid sequence based amplification (NASBA) for the detection of a small number of viable anthrax spores is described. The assay is based on oligonucleotides sandwich hybridization.	Optical—visual or handheld reflectometer	1 nM for specific mRNA	Whole assay takes about 4 h	15 min	39, 40

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Analyte	Description	Transduction	Sensitivity/Selectivity	Sample prep.	Res. Time	Refs.
Histamine	Whole-cell potentiometric biosensor for screening toxins is described; it consists of a confluent monolayer of human umbilical vein endothelial cells (HUVECs) attached to an Ion selective cellulose triacetate membrane modified with a covalently attached arginine-glycine-aspartic acid (RGD) peptide sequence.	Potentiometric—HUVEC from a confluent monolayer and ion transport is almost completely inhibited. Exposure to toxins increases permeability and a potential response from the ISE is achieved.	1 x 10^{-5} and 1 x 10^{-4} histamine Selectivity tested with L-histidine; with similar structure to histamine	Minimal—Histamine prepared in Tris buffer	25 min	41
E. coli	"Shotgun" proteomics is a methodology capable of distinguishing target species against a large database of background species from a single-component sample or dual-component mixtures with relatively the same concentration	Mass spectrometry Analysis of proteins in complex is a tremendous analytical challenge	Target species identified at 6 % but not 0.6 %	Extensive sample prep.; involves a lot of extraction and centrifugation steps	60 min to 240 min	42
E. coli *B. subtilis*	The analysis of bacteria and spores has been demonstrated using MALDI–ATOFMS to analyze individual aerosol particles sampled directly from the atmosphere	Mass spectroscopy—MALDI	50 particles of *B. subtilis*	MALDI spectra of single particles are obtained without pre-mixing the matrix	Few seconds	43
B. globigii	The potential of hyperspectral remote sensing as a standoff detection and monitoring technique for BWA is discussed. Use of terahertz (THz) sensing for through-container sensing of *B. globigii* is discussed	Development of a hyperspectral system by the Canadian army based on laser-induced fluorescence (LIF) is also mentioned.	The development of a handheld hyperspectral imager for standoff detection by Pacific Advanced Technology is mentioned.	N/A		44, 45

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EXISTING TECHNOLOGIES (COMMERCIALLY AVAILABLE)

Analyte	Description	Transduction	Sensitivity/ Selectivity	Sample prep.	Res. time	Ref
E. coli (BWA simulant)	Compact microfluidic system for the biological agent detection is described. Microfluidics provide the principle to accomplish biological agent collection, sample prep., rRNA extraction and electrochemical detection	Electrochemical—amperometry	1 x 10^{-5} cells	Sample preparation module is integrated into the microfluidic device; includes rRNA extraction	N/D	46
Anthrax, tularemia viruses and toxins	AirSentinel®1000B is a continuously – operating sensor that detects potentially harmful biological airborne BWA. It collects and detects elevated biological materials for subsequent laboratory confirmation analysis.	Optical detection Fluorescence	System in development	System is in development	30 s to 120 s	47
B. globigii	4WARN V2 is a fully automated third generation biological agent detection for real-time detection of biological system based on filed proven fluorescence particle detection for real-time detection of BA and antibody based assays for identification of specific agents.	Optical detection Fluorescence	10 ACPLA for *B. globigii* within 20 s	Liquid sample collection and detection takes about 22 min Total cycle time detection and identification ~20 min	20 s	48
B. anthracis Smallpox Botulinum Toxin Ricin	RAMP is a highly sensitive, portable detector for anthrax, smallpox, botulinum toxin and ricin. RAMP Anthrax is claimed to be the most reliable, rapid and sensitive on site anthrax test for environmental detection of potentially contaminated surfaces and fluids		Anthrax 4 ng (4000 spores) Bot Tox 5 ng Ricin 10 ng Pox 3.6 ng Cross reactivity tested for *B.subtilus, B. cereus, B. thuringiensis*	Minimal sample prep—Swabs or small samples added to single use disposable cartridge	15 min	49

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[47] MesoSystems, http://www.mesosystems.com/PDF/ASDatasheet_.pdf, Tel.:877–692–2120, email:jbazzell@MesoSystems.com
[48] General Dynamics, http://www.sil.sk.ca/4warnv2.pdf, Tel.: 403–295–5414 (Canada), email:busdev.Calgary@gdcanada.com
[49] LifeSafety Systems, http://www.lifesafetysys.com/osb/itemdetails.cfm/ID/599, Tel.: 831–728–9090, email: info@lifesafetysys.com

Analyte	Description	Transduction	Sensitivity/ Selectivity	Sample prep.	Res. time	Ref
Airborne aerosols	Microcyte® Field is a multipurpose easy-to-use flow cytometer for on-site analysis of microorganisms. Apparently it is the only mobile flow cytometer in the market for potentially contaminated sources or suspicious material. Can be used together with the BioSurveillance for rapid continuous air sampling.	Fluorescence–Flow cytometry	Algae (10 per mL) but depend on how well background level in the sample is controlled.	Microorganisms in the air are collected by an air sampling device such as the BioSurveillance and transferred to a liquid Powder samples need to be dissolved in water before analysis	~ 17 min	50
E. coli	The Threshold® system s used by the military as part of the BIDS. It was designed to measure contaminants in biopharmaceuticals including DNA and proteins. It currently used by the military to measure BWA.	Light addressable potentiometric sensor (LAPS) Urea is hydrolyzed by urease producing NH_3 and CO_2 which produces a pH change	Sensitivity depends on the analyte, e.g. DNA – 2 pg Immuno-ligand assay detection limits depend on the antibody used. BSA is 125 pg/mL, bovine IgG is 50 pg/mL, Protein A is 20 pg/mL E. coli plasmid pGEM3 is 400 attomoles or 760 pg	DNA assay excluding sample pretreatment takes ~2 h Immuno-ligand assays take between 1 h to 3.5 h depending on the antibody and the sensitivity required.	90 s	51
Anthrax toxin Botulinum toxin Ricin toxin	Biological Agent Detection Devices (BADD) are simple to use in-vitro immunochromatographic qualitative detection of toxins and spores	Lateral Flow Chromatography	Anthrax (1 μg/mL in solution and .25 μg on a smooth surface 100 ng ricin toxin 100 ng botulinum toxin	Minimum sample preparation required	15 to 30 min	52
Potential use for BWA detection	Aglient 2100 bioanalyzer is a microfluidics system for the analysis of DNA, RNA, proteins and cells. It is based on Lab-on-chip technology	Flow cytometry (electrophoresis)	ND	ND But probably extensive, since DNA extraction is required	ND	53

[50] LifeSafety Systems, http://www.lifesafetysys.com/osb/itemdetails.cfm/ID/360, http://www.biodetect.biz/products/MC.pdf, http://www.biodetect.biz/applications/app401.pdf, Tel.: 831–728–9090, email: info@lifesafetysys.com

[51] Molecular devices, http://www.moleculardevices.com/pages/reagents/threshold.html, Tel.: 800–635–5577, info@moldev.com

[52] Lab Safety Supply, http://www.labsafety.com/store/product_group.asp?dept_id=31172&parent_id=17411, Tel.: 800–356–0783, email: custsvc@labsafety.com

[53] Agilent Technologies, http://www.chem.agilent.com/Scripts/PDS.asp?lPage=51, Tel.: 800–227–9770, email: cag_sales-na@agilent. com

Analyte	Description	Transduction	Sensitivity/ Selectivity	Sample prep.	Res. time	Ref
Bioaerosol collector/ concenrator	XMX/2L-MIL Aerosol Collector is a liquid collector/ bio-aerosol concentrator. It is an aerosol separator, sample preparation and high-mass flow concentrator system designed for harsh field conditions. Has been sold to the US Air force.	Bioaerosol collector and sample prep.	Bioaerosols are usually in low conc. Therefore, concentration of sample may be necessary to get to detectable levels of concentration.	Can be used as sample prep. or concentration prior to PCR, culturing or immunoassay.	ND	54
B. globigi *B. sabtilis* *E. herbicola*	CBMS Block I is a mobile Ion-Trap Mass Spectrometer for the classification and monitoring airborne BWA. It forms a core component of the BIDS used by the U.S. Army	Mass spectrometry	ND	ND	3 min	55
Point detection of potential Biological threats	Fluorescence Aerosol particle Sensor III (FLAPS III) system provides three real-time measurements of individual airborne particles	Photomultiplier tubes Measures scattered-light intensity and fluorescence emissions in two wavelength regions	Rapid detection of BA aerosols under various backgrounds	ND	ND	56
Airborne biological agents	Short Range Biological Stand-off Detection System (SR-BSDS) is a multi wavelength LIDAR system with both UV and IR capability	PMT and APD detectors convert return signals for real time data processing	Can detect and track a biological aerosol cloud while discriminating between non-biological aerosols and hard targets	ND	ND	57
ND	RAZOR is a biological detector with a real time stand-alone battery operated thermocycler with built in analysis and detection software. It can perform thermocylcing analysis and detection without an external power source.	Fluorescence—PCR based	ND	Freeze dried sample is required (freeze drying takes a lot of time depending on sample size)	ND	58

[54] LifeSafety Systems, http://www.lifesafetysys.com/osb/itemdetails.cfm/ID/505, Tel: 831–728–9090, email: info@lifesafetysys.com
[55] Bruker Daltonics, http://www.bdal.com/modux3/modux3.php?pid=115,003,001,01,01,010,008,0&rid=115,003,000,01,01,010,004,0&width=1024&height=768#, Tel: 978–663–3660, email: prm@bdal.com
[56] TSI, Inc., http://www.tsi.com/Product.aspx?Cid=132&Cid2=135&Pid=100&count=1, Tel: 651–483–0900, email: info@tsi.com
[57] Fibertek, Inc., http://www.fibertek.com/bio.asp, Tel: 703-471-7671, email: info@fibertek.com
[58] Idaho Technology, Inc., http://www.idahotech.com/rapid/index.html, Tel: 801–736–6354, email: it@idahotech.com

Analyte	Description	Transduction	Sensitivity/ Selectivity	Sample prep.	Res. time	Ref
Screening against biomolecules	BioCheck powder is used in colorimetric test that changes color when the presence of a biomolecule found in all living organisms and many toxins is present. It provides a rapid screen for possible presence of anthrax or ricin toxin while ruling out most other substances. Currently used by first responders in DC.	Colorimetric	ND	Samples are collected as swabs that are immersed in a solution that provides color for a positive. Kits also contains negative controls	5 min	59
B. anthracis Brucella Species *F. Tularensis Y. pestis C. botulinum* Type A	R.A.P.I.D. is based on the LightCycler®32 high-speed thermocycler technology. It has an in-built fluorescence monitoring and is capable of automatically analyzing samples for the presence of DNA sequences. RAPID was the instrument referred to by the military in their Joint Biological Agent Identification and Diagnostic systems (JBAID) program.	Optical waveguide Fluorescence	ND	ND Probably extensive, since DNA has to be extracted Brochure says place "prepared sample" into the well	30 min	60
Monitor air for BWA's	CBMS Block III is a mobile Ion-Trap Mass Spectrometer for the classification and monitoring airborne BWA. It is an improvement of the CBMS Block I that has been discussed earlier. It's been field tested by the U.S. Army.	ND	ND	Due to the concept of Pyrolysis Mass Spectrometry, no liquid consumables are required	ND	61
B. anthracis *Y. pestis* *B. abortus* *F. tularensis* SEB *E. coli*	RAPTOR is an automatic, portable four-channel fluorometric system. It performs user-defined multi-step assay protocols for monitoring fluorescent labeled reactions occurring on each of the four disposable optical waveguide sensors.	Optical waveguide Fluorescence	ND	ND	ND	62

[59] LifeSafety Systems, http://www.lifesafetysys.com/osb/itemdetails.cfm/ID/598, Tel.: 831–728–9090, email: info@lifesafetysys.com
[60] Idaho Technology Inc., http://www.idahotech.com/rapid/index.html, Tel. 801–736–6354, email: it@idahotech.com
[61] LifeSafety Systems, http://www.lifesafetysys.com/osb/itemdetails.cfm/ID/120, Tel.: 831–728–9090, email: info@lifesafetysys.com
[62] LifeSafety Systems, http://www.lifesafetysys.com/osb/itemdetails.cfm/ID/121, Tel.: 831–728–9090, email: info@lifesafetysys.com

Analyte	Description	Transduction	Sensitivity/ Selectivity	Sample prep.	Res. time	Ref
ND Not specific organisms mentioned	The Analyte 2000 is a 4-channel, single wavelength fluorometer optimized for performing evanescent-wave fluoro-immunoassays that was developed in conjunction with the Naval Research Laboratory for biowarfare detection. This low-power, microprocessor-controlled instrument provides parts-per-billion sensitivities to biochemical species by monitoring antibody/antigen reactions on tapered glass waveguides, or injection molded polystyrene waveguides.	Optical waveguide Fluorescence	Provides parts-per-billion sensitivities to biochemical species by monitoring antibody/antigen reactions	ND	N	63
	Biological Integrated Detection System (BIDS) consists of a detector suite of complimentary biological detection technologies mounted in the S-788 lightweight shelter on a HYV-HMMWV vehicle that also tows the power generator set	The BIDS consist of a High volume Aerodynamic particle Sizer (HVAPS), Liquid Sampler (LS), Biological sampler, Flow Cytometer (FCM), Threshold Workstation (THS)	N/A	N/A	N/A	64
Not specified	WMDetect ™ BioChecker 2 is a screening test for any biological compound	Colorimetric	ND	Minimal sample prep	3 min for protein	65
E. coli and other organisms	BAX® is a detection system is for screening food and environmental samples for pathogens or other organisms. It uses DNA based detection.	Optical detection – Fluorescence with PCR amplification	ND	Extensive sample pretreatment to rapture cell walls to release the DNA	4 h to 24 h	66

[63] LifeSafety Systems, http://www.lifesafetysys.com/osb/itemdetails.cfm/ID/Tel.: 831–728–9090, email: info@lifesafetysys.com
[64] http://www.globalsecurity.org/military/systems/ground/bids.htm, last updated 4–27–05, email: info@globalsecurity.org
[65] ChemSecurity, http://www.chemsecurity.com/PDF/BioScreen%20flier%20050701.pdf, Tel.: 989–224–2819, email: techsupport@chemsecurity.com
[66] DuPont Qualicon, http://www.qualicon.com/bax.html, Tel.: 800–441–7515, E-mail: Corporate Information Center

Analyte	Description	Transduction	Sensitivity/ Selectivity	Sample prep.	Res. time	Ref
Anthrax Botulinum toxin Brucella Plague SEB Tularemia	BioThreat™ Alert Kit are test strips that show two red lines for a positive detection and a single line for negative detection	Lateral flow chromatography	ND	Minimal	ND	67
Anthrax, Orthopox, Botulinum (A&B) toxin, Brucella, Plague, SEB, Ricin, Tularemia	Defender Reader TM is a hand-held field ready offering 8 biological tests. It is compatible with the BioThreat™ Alert test kits. It will be commercially available in the fall 2005.	Lateral flow chromatography	ND	Minimal	18 min or 8 test in 39 min	68
Botulinum neurotoxins A, B, E and F SEB, SEA, Ricin, Anthrax, E. coli, Salmonella, Listeria, Campylobacter and Cryptosporidium parvum oocysts	BioVerifyTM Tests use a sandwhich immunoassay format. An antibody specific to the pathogen is immobilized onto the microbeads while another antibody is labeled with BioVeris BV-TAGTM label. When target analyte is present, both antibodies bind to it linking together the microparticles, analytes and label. The bound BV-TAGTM is stimulated with an electrode and emits light	Electrochemiluminescence (ECL)	1300 spores/mL; ricin, depending upon matrix, 0.5 pg/mL (baby powder) to 7 pg/mL (Enfamil); botulinum neurotoxins 3 pg/mL to 8 pg/mL; Staphylococcal enterotoxins 2.1 pg/mL to 2.8 pg/mL	Minimal	20 min	69
Bioaerosol	Biological Aerosol Warning System (BAWS) is a UV-fluorescence-based bioaerosol detection system. It is an array of point biological aerosol detectors networked to detect BA's. The system is designed for early detection capability for biological attack and for perimeter monitoring of key areas and high-value assets.	Optical detection Aerosol particles are drawn into the optical interaction chamber where they are illuminated by a pulsed UV laser. If the particle is biological, it will elastically scatter light and also fluoresce at longer wavelength	ND	ND	8 min from start-up	70

[67] Tetracore, Inc., http://www.tetracore.com/products/domestic.html, Tel.: 301–258–7553, Email: jcallahan@tetracore.com
[68] Alexeter Technologies, http://www.alexeter.com/downloads/Defender%20Reader%20Sell%20Sheet.pdf, Tel.: 877–591–5571, Email: service@alexeter.com
[69] Bioveris Corporation, http://www.bioveris.com/products_services/bioverify.htm, Tel.: 301–230–0158, Email: bvcorp@bioveris.com
[70] Lockheed Martin Naval Electronics & Surveillance Systems-Undersea Systems, http://www.navalsupport.com/pdfs/NBC_BAWS.pdf, Tel.: 800–325–4019 (x1546), Email: richard.read@lmco. com

Analyte	Description	Transduction	Sensitivity/ Selectivity	Sample prep.	Res. time	Ref
Non-specific detection of bacteria	Continuous Flow ATP Detector (CFAD) detects microbial contamination in a liquid sample using ATP bioluminescence technology.	Bioluminescence	ND Bioluminescence techniques can detect presence of bacteria but cannot identify specific bacteria	Automated sampling	2 min depending on flow rate	71
Potential use for BWA detection	Biacore®T100 is an improvement of the Biacore® 2000. These instruments use the surface plasmon resonance technology Biacore 2000 is a fully automated system for biomolecular interaction analysis, ideally suited for larger institution research facilities with multi-user and routine applications requiring speed and accuracy in analyzing large numbers of samples.	Surface plasmon resonance	ND	ND Instrument is bulky not suited for first responders	ND	72
Airborne organisms that contain sulfur and phosphorous	Biological Alarm Monitor (MAB) for airborne organisms. Sulfur and phosphorous emit light of specific wavelength at high temperatures. Optical filters harness the transmitted light and give out a signal proportional to the conc. S or P. Since living organisms contain S and P they can be detected by the technology.	Flame spectrophotometry	ND Detects S and P in regards to the atmospheric background	NA	1 min	73

[71] Biotrace International, Inc., http://www.biotrace.co.uk/content.php?hID=2&nhID=48&pID=16&offset=0, Tel.: 425–398–7993, Email: sales@biotrace.com
[72] Biacore Life Sciences, http://www.biacore.com/lifesciences/products/systems_overview/t100/system_information/index.html, Tel.: 800–242–2599, Email:rgargano@biacoreinc.com
[73] Proengin, Inc., http://www.proengin.com/pdf/mab.pdf, Tel.: 954–760–9990, Email:contact@proengin.com

APPENDIX D—QUESTIONS TO BE POSED TO MANUFACTURERS OF BA DETECTION TECHNOLOGIES

APPENDIX D—QUESTIONS TO BE POSED TO MANUFACTURERS OF BA DETECTION TECHNOLOGIES[1]

1. What biological agents have been examined with this equipment/technology?
2. Who conducted the tests? Have the tests been verified by an independent laboratory?
3. What were the results?
4. What is the selectivity, sensitivity, limit of detection and detection range? Can the equipment detect both high and low concentrations?
5. What is the response time? How quickly does the equipment respond to a spike in the agent concentration? Has the device been tested on real samples? If yes, which agents have been tested?
6. How extensive is the sample preparation for real samples?
7. What common substances cause a "false positive" reading or interference with the proper operation?
8. Does the equipment run on batteries and for how long? How long does it take before the batteries need to be replaced or recharged?
9. What additional items are required to operate/maintain the equipment?
10. What is the shelf life of the equipment? (open exposed, closed exposed, closed unexposed)
11. What are the environmental limitations?
12. What training is required to use the equipment and interpret the results?

[1] Information provided by the National Domestic Preparedness Office (NDPO) in coordination with the National Institute of Justice and the Technical Support Working Group.

APPENDIX E—BIOLOGICAL DETECTOR DATA FIELDS

APPENDIX E—BIOLOGICAL DETECTOR DATA FIELDS

Fifty-five data fields were used to provide information relating to biological detection equipment. The 55 data fields are comprised of data fields from the market survey vendor questionnaire requesting specifics about their products. Because of the database limitations, several data fields on the vendor questionnaire were combined, but all the vendor-supplied information was entered into the database. All data fields were developed using input from the emergency responder community.

The data fields are organized into five categories:

- General (10 data fields).
- Operational (17 data fields).
- Physical (5 data fields).
- Logistical (13 data fields).
- Special Requirements (10 data fields).

The remainder of this section defines each of the 53 data fields by category.

1.0 General

1.1 Detector Name

The Detector Name data field identifies the full commercial name of the equipment plus appropriate acronyms and pseudonyms (military/commercial versions of identical equipment).

1.2 Date Information was Last Updated

The Date Information was Last Updated is a placeholder for future updates.

1.3 Picture

The Picture data field includes a picture or image of the equipment.

1.4 Detector ID

Detector ID # is for identification purposes only.

1.5 Detection System Used

Detection System Used identifies the type of technology employed by the equipment and if the detection is based on molecular, immunochemical, optical, physical, ligand-based, biosensor-based, standard culture, or other technologies. Specific examples of technologies include real-time polymerase chain reaction (PCR), enzyme-linked immunosorbent assay (ELISA), fluorescence, and mass spectrometry.

1.6 Manufacturer

The Manufacturer is the company that developed the equipment. This data field includes the manufacturer's name, address, telephone and fax numbers, point of contact, and e-mail addresses.

1.7 Source/Manufacturer Website

The Source/Manufacturer Website indicates the original source of the equipment being discussed. Potential sources can include other market surveys, websites, industry journals, and other scientific publications.

1.8 Availability

Availability refers to how readily available a piece of equipment is (e.g., how long it takes to receive equipment upon ordering).

1.9 Application (formally Detector Type)

Application identifies the intended use of the detector.

1.10 Current User/Period of Use

The Current User/Period of Use identifies organizations (i.e., military use, commercial applications, civil-service instrument, etc.) that are currently using the piece of equipment. This information may include the average number of units each client has in operation and the average number of years these units have been in use.

2.0 Operational

2.1 Specific Biological Agents Detected

Specific Biological Agents Detected identifies BAs that can be detected by the equipment, using available reagents. Special note should be made where special or restricted reagents are required for the assay to detect an agent.

2.2 Sample Preparation

Sample Preparation indicates whether a sample requires preparation or treatment prior to detection. Examples of sample preparation include purification, tagging, dilution, and concentration. Also included here is the amount of time required to prepare the sample for analysis.

2.3 Standard Operating Procedure for Sample Preparation

Standard Operating Procedure for Sample Preparation references standard operating procedures (SOPs) for sample preparation that are provided by the manufacturer.

2.4 Type of Sample

The Type of Sample data field indicates the physical state of the sample that can be applied in an assay using the equipment, to include types such as aerosol, liquid, solids, or sludge.

2.5 Calibration Requirements

Calibrations Requirements are adjustments necessary to bring operating characteristics into substantial agreement with recognized standards. This field should include specific information about frequency (how often calibration is required) and support (end user or manufacturer) for calibration. This field should also include if calibration is manual or automatic.

2.6 Start-up Time

Start-up Time is the amount of time required to set up the instrument and begin sampling. This category also includes the required warm-up time and calibration time for the detector.

2.7 Response Time

Response Time is defined as the time it takes for an instrument to take a sample, analyze the sample, determine if an agent is present, and provide results.

2.8 Time for Data Analysis

Time for Data Analysis is the time it takes to complete the assay and report the final result. It should indicate whether the results are a direct readout from the equipment or if they require additional interpretation by the operator.

2.9 Alarm Capability

Alarm Capability is the ability of the detector to auto alarm either through visible or audible means, or both.

2.10 Sensitivity for Each Biological Agent

Sensitivity is the lowest level of detection for each BA. Sensitivity for Each Biological Agent should be given as colony forming units (CFUs) for bacteria, plaque forming units (PFUs) for viruses, nanograms (ng) for target DNA, or micrograms (μg) of protein. If ng of DNA is given, there should be an indication of the equivalent number of CFUs or PFUs.

2.11 Confidence Interval for Sensitivity (at the limit of detection)

The Confidence Interval for Sensitivity at the limit of detection (LOD) is the statistical range within which the data is expected to fall. This field should include the manufacturer's confidence interval for sensitivity for each BA.

2.12 Specificity for Each Biological Agent

Specificity for Each Biological Agent indicates the ability of the assay to specifically identify a BA. This data field should include a list of any cross reactivities to other material and any interferents (including any other BAs) that may negatively impact the accuracy of the test.

2.13 Confidence Interval for Specificity

The Confidence Interval for Specificity is the statistical range within which the data is expected to fall. This field should include the manufacturer's confidence interval for the specificity for each biological agent.

2.14 Resistance to Interferents

Resistance to Interferents, or detector specificity) is a measure of the ability of the equipment to distinguish between various compounds in the sample. An interferent is a compound that causes a detector to false alarm or fail to alarm. The two types of false alarms are false positives and false negatives.

2.15 Number of False Positives

The Number of False Positives includes the number of false positives read by the equipment for each agent detected.

2.16 Number of False Negatives

The Number of False Negatives includes the number of false negatives read by the equipment for each agent detected.

2.17 Testing Information

Testing Information includes any data regarding testing, such as validation testing. Testing should be done by an external organization; however, manufacturer testing data is acceptable.

3.0 Physical

3.1 Size

Size indicates the external dimensions of the equipment, including height, width, and depth.

3.2 Working Space

Working Space provides an estimate of the area needed for support equipment, consumables, and for sample preparation.

3.3 Weight (including batteries)

Weight (including batteries) provides the total weight of the equipment in operational status.

3.4 Weight of Support Equipment and Consumables

Weight of Support Equipment and Consumables includes the total weight of the support equipment and consumables.

3.5 Power Requirements and Capabilities

Power Requirements and Capabilities indicates the type of power required to operate the equipment and any ancillary components (battery and/or ac electrical power). If battery power is necessary, it includes the type of battery (i.e., standard size, manufacturer specific, rechargeable, etc.) that is required.

4.0 Logistical

4.1 Mobility

Mobility is the ability of the equipment to be readily packed, shipped, or transported under typical and atypical conditions. Important information includes whether the equipment requires lockdown and expert personnel to package, move, and set up the equipment after it is moved. The equipment dimensions and weight are two important factors to consider, because they determine if a single person can transport the equipment or if the equipment requires vehicular transport.

Level of mobility can be described as handheld, mobile laboratory, fixed-site, or standoff (monitoring) systems.

4.2 Durability

The Durability of a piece of equipment describes the ruggedness of the equipment under environmental and transportation extremes.

4.3 Ease of Use

Ease of Use provides information on whether the equipment can be accurately used by an operator under challenging circumstances, such as wearing personal protective equipment (PPE). This data field also provides the number of steps and level of accuracy needed to obtain a result.

4.4 Environmental Conditions

Environmental Conditions identify the conditions under which a piece of equipment may be used and still be accurate. For example, some equipment is designed to operate in the field under extreme outdoor weather conditions and climates, while other equipment requires climate-controlled environments.

4.5 Support Equipment

Support Equipment lists the number and types of additional equipment needed for either sample preparation or data interpretation and analysis. This also includes any parts and special tools that are needed during preventative maintenance.

4.6 Consumables Required

Consumables Required lists the consumables needed to perform one assay.

4.7 Cost of Consumables

Cost of Consumables provides the cost of the consumables needed to perform one assay.

4.8 Preventative Maintenance Required

Preventative Maintenance Required includes services and parts necessary to keep the equipment at its peak operational readiness. This includes the level of support provided by the manufacturer, as well as any parts and special tools that are needed during preventative maintenance.

4.9 Ability to be Stored

This data field refers to the length of time the equipment can be stored without being serviced or replaced prior to being used. This includes if consumables require special handling after being stored (i.e., thaw time).

4.10 Shelf Life

Shelf Life, or the ability of consumables to be stored, refers to the length of time and conditions that consumables unique for the equipment can be stored. Some materials are more susceptible to long-term storage than others (soft plastics, rubber gaskets, light sources, etc.).

4.11 Unit Cost

The Unit Cost is the cost of the piece of equipment for immediate use upon receipt. The cost includes the set-up cost and initial consumables.

4.12 Maintenance Cost

Maintenance Cost is the average cost to maintain and operate the equipment, normally based on equipment usage rates. Any preventative maintenance contract costs are included in the cost.

4.13 Decontamination Method

Decontamination Method identifies the method of decontamination needed after the equipment is used. Specifics may include, but are not limited to, the ability to completely immerse the unit, recommended cleaning solutions, and resistance to decontamination methods.

5.0 Special

5.1 Operator Skills Required

Operator Skills Required refers to the level of education or specific training required to operate the equipment and interpret data for a final analysis.

5.2 Training Required

Training Required is the amount of instruction time the operator needs to become proficient in operating the instrument. For example, higher-end equipment may require in-depth training, such as specialized classes for operation, maintenance, and calibration of the equipment.

5.3 Training Available

Training Available may range from reading a manual or viewing a video to participating in formal courses offered through the manufacturer or an outside training contractor. The courses may or may not result in certification.

5.4 Manuals Available

Manuals Available indicate which manuals are supplied as standard equipment or if they need to be ordered separately. Manuals may include user manuals, repair manual with illustrated components and parts, or training documentation.

5.5 Data Storage

Data Storage indicates if the data obtained in the field can be stored in the system to be printed out at a later time or if a connected computer is required to save the data.

5.6 Communications Interface Capability

Communications Interface Capability refers to the ability of the equipment to interface with a communications system. This section also includes any optional interface components that are

available as an upgrade to the specific equipment (including command control communication, computers, intelligence standardization, interoperability, or commonality).

5.7 Security

Security includes all mechanisms that are standard and optional with the equipment to prevent potential vandalism or mechanism alteration. Examples of tamper resistance include password protection, encryption, or lock-out.

5.8 Warranty

Warranty information describes the specific terms and conditions as set by the manufacturer, including any restrictions by the manufacturer.

5.9 Applicable Regulations

Applicable Regulations includes any government and/or safety regulations that may apply to the possession, use, or storage of a piece of equipment (for example, some detectors may require the use of a radioactive source material, which requires licensure by the Nuclear Regulatory Commission). In addition, PCR is proprietary technology protected by U.S. patents, therefore, licensing is required for processing (practice of PCR), as well as for instruments used in the PCR process.

5.10 Safety Requirements

Safety Requirements include any applicable government and/or safety regulations that may apply to the possession, use, or storage of a piece of equipment.

APPENDIX F—BIOLOGICAL DETECTOR INDICES AND DATA SHEETS

APPENDIX F—BIOLOGICAL DETECTOR INDICES AND DATA SHEETS

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Index by Biological Detector ID#

ID #	Name	Manufacturer	Rated	Mobility	Page F–#
1	BADD™ BioWarfare Agent Detection Devices	ADVNT Biotechnologies	Yes	Handheld	F–1
2	Rapid Response Hand Held Assay (RRHHA)	ANP Technologies, Inc.	Yes	Handheld	F–3
3	Prime Alert™ Biodetection/Threat Verification System (Model PAE002)	GenPrime, Inc.	Yes	Handheld	F–5
4	SMART II (Biothreat Detection Diagnostic Kits)	New Horizons Diagnostics Corporation	Yes	Handheld	F–8
5	Bio-seeq™ Handheld PCR Detector (Model 2430999)	Smiths Detection	Yes	Handheld	F–10
6	R.A.P.I.D.® System (9200)	Idaho Technology, Inc.	Yes	Mobile Laboratory	F–13
7	RAMP	Response Biomedical Corp.	Yes	Mobile Laboratory	F–16
8	Guardian Reader System (P–102)	Alexeter Technologies	Yes	Mobile Laboratory	F–18
9	BioThreat Alert Bio Threat Test Strips	Tetracore, Inc.	Yes	Mobile Laboratory	F–21
10	MICROCYTE® Field Family MICROCYTE® Field and MICROCYTE® Aqua	BioDETECT AS	Yes	Mobile Laboratory	F–24
11	Analyte 2000 Biowarfare Detection (Analyte 2000 Fiber Optic Fluorometer)	Research International	Yes	Mobile Laboratory	F–27
12	RAPTOR Plus	Research International	Yes	Mobile Laboratory	F–29
14	GeneXpert® System (GX1000N4–1)	Cepheid	Yes	Mobile Laboratory	F–32
15	LightCycler™ (Model 1.2)	Roche Applied Science	Yes	Mobile Laboratory	F–35
17	Gen-Probe Leader 450i	Gen-Probe	No	Fixed-Site	F–37
18	M-SERIES® M1M Analyzer	BioVeris Corporation	Yes	Mobile Laboratory	F–39

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19	M-SERIES® 384 Analyzer	BioVeris Corporation	No	Fixed-Site	F–43
20	FACSCaliber	BD Biosciences Immunocytometry Systems	No	Fixed-Site	F–47
21	BD FACSCount (337858)	BD Biosciences Immunocytometry Systems	No	Fixed-Site	F–50
22	Agilent 2100 Bioanalyzer	Agilent Technologies	No	Fixed-Site	F–53
23	HPLC Diode Array Detector 20/20	GROTON Biosystems	No	Fixed-Site	F–55
24	Agilent 6850; Agilent 6850 Series II Network GC	Agilent Technologies	No	Fixed-Site	F–57
25	Capillary Electrophoresis System (GPA100)	GROTON Biosystems	No	Fixed-Site	F–59
26	HPLC Fluorescence Detector (FD500)	GROTON Biosystems	No	Fixed-Site	F–61
27	BioCheck™ Powder Screening Test Kit (GB 1001)	20/20 GeneSystems Inc.	Yes	Handheld	F–63
28	KT1030 HazCat Anthrax Screening Test Kit	Haztech Systems, Inc.	Yes	Mobile Laboratory	F–66
29	KT1235 HazCat® WMD Kit	Haztech Systems, Inc.	Yes	Mobile Laboratory	F–68
30	KT1040 HazCat® MicroCat/WMD	Haztech Systems, Inc.	Yes	Mobile Laboratory	F–70
31	HazMatID (023–1001)	Smiths Detection Danbury	Yes	Mobile Laboratory	F–72
32	IlluminatIR ML Package (006–2019)	Smiths Detection Danbury	Yes	Fixed-Site; Vehicle Mounted	F–75
33	HMB Portable Biohazard Detector (HMB V–PS)	BioTech International, Inc.	Yes	Handheld	F–77
34	PROFILE® 1 (Model 3560)	New Horizons Diagnostics Corporation	Yes	Handheld	F–80
35	Defender TSR (Test Strip Reader) System (P–502)	Alexeter Technologies	Yes	Handheld	F–82
36	MPD-based BW Detector (P-chip/MPD/2004)	BioTraces, Inc.	Yes	Handheld	F–85
37	QTL Biosensor (Model 2000 and 2200)	QTL Biodefense	Yes	Handheld	F–87
38	Prime Alert® Biodetection System (096–3130)	GenPrime, Inc.	Yes	Handheld	F–89

ID #	Name	Manufacturer	Rated	Mobility	Page F–#
39	RAZOR® System (RAZR-ASY-0010)	Idaho Technology, Inc.	Yes	Handheld	F–92
40	Uni-Lite NG	Biotrace International, Ltd.	Yes	Handheld	F–95
41	Autotrack (Continuous Flow ATP Detector)	Biotrace International, Ltd.	Yes	Mobile Laboratory	F–97
42	VeroTect	Biral	Yes	Mobile Laboratory	F–99
43	4 WARN Sentry 3000 (Model 718866–901)	General Dynamics Canada	Yes	Mobile Laboratory	F–101
44	KT1050 HazCat Tier 4 System	Haztech Systems, Inc.	Yes	Mobile Laboratory	F–105
45	Biological Alarm Monitor (MAB)	Proengin USA	Yes	Mobile Laboratory	F–107
46	RespondeR RCI (024-1001)	Smiths Detection Danbury	Yes	Mobile Laboratory	F–109
47	BioThreat Alert™ ELISA Kits	Tetracore, Inc.	Yes	Mobile Laboratory	F–111

Note: Detector (ID #16) removed by manufacturer.

Index by Biological Detector Name

ID #	Name	Manufacturer	Rated	Mobility	Page F–#
43	4 WARN Sentry 3000 (Model 718866–901)	General Dynamics Canada	Yes	Mobile Laboratory	F–101
24	Agilent 6850; Agilent 6850 Series II Network GC	Agilent Technologies	No	Fixed-Site	F–57
22	Agilent 2100 Bioanalyzer	Agilent Technologies	No	Fixed-Site	F–53
11	Analyte 2000 Biowarfare Detection (Analyte 2000 Fiber Optic Fluorometer)	Research International	Yes	Mobile Laboratory	F–27
41	Autotrack (Continuous Flow ATP Detector)	Biotrace International, Ltd.	Yes	Mobile Laboratory	F–97
1	BADD™ BioWarfare Agent Detection Devices	ADVNT Biotechnologies	Yes	Handheld	F–1
21	BD FACSCount (337858)	BD Biosciences Immunocytometry Systems	No	Fixed-Site	F–50
27	BioCheck™ Powder Screening Test Kit (GB 1001)	20/20 GeneSystems Inc.	Yes	Handheld	F–63
45	Biological Alarm Monitor (MAB)	Proengin USA	Yes	Mobile Laboratory	F–107
5	Bio-seeq™ Handheld PCR Detector (Model 2430999)	Smiths Detection	Yes	Handheld	F–10
9	BioThreat Alert Bio Threat Test Strips	Tetracore, Inc.	Yes	Mobile Laboratory	F–21
47	BioThreat Alert™ ELISA Kits	Tetracore, Inc.	Yes	Mobile Laboratory	F–111
25	Capillary Electrophoresis System (GPA100)	GROTON Biosystems	No	Fixed-Site	F–59
35	Defender TSR (Test Strip Reader) System (P–502)	Alexeter Technologies	Yes	Handheld	F–82
20	FACSCaliber	BD Biosciences Immunocytometry Systems	No	Fixed-Site	F–47
14	GeneXpert® System (GX1000N4–1)	Cepheid	Yes	Mobile Laboratory	F–32
17	Gen-Probe Leader 450i	Gen-Probe	No	Fixed-Site	F–37
8	Guardian Reader System (P–102)	Alexeter Technologies	Yes	Mobile Laboratory	F–18
31	HazMatID (023–1001)	Smiths Detection Danbury	Yes	Mobile Laboratory	F–72
33	HMB Portable Biohazard Detector (HMB V–PS)	BioTech International, Inc.	Yes	Handheld	F–77

ID #	Name	Manufacturer	Rated	Mobility	Page F–#
23	HPLC Diode Array Detector 20/20	GROTON Biosystems	No	Fixed-Site	F–55
26	HPLC Fluorescence Detector (FD500)	GROTON Biosystems	No	Fixed-Site	F–61
32	IlluminatIR ML Package (006–2019)	Smiths Detection Danbury	Yes	Fixed-Site; Vehicle Mounted	F–75
28	KT1030 HazCat Anthrax Screening Test Kit	Haztech Systems, Inc.	Yes	Mobile Laboratory	F–66
30	KT1040 HazCat® MicroCat/WMD	Haztech Systems, Inc.	Yes	Mobile Laboratory	F–70
44	KT1050 HazCat Tier 4 System	Haztech Systems, Inc.	Yes	Mobile Laboratory	F–105
29	KT1235 HazCat® WMD Kit	Haztech Systems, Inc.	Yes	Mobile Laboratory	F–68
15	LightCycler™ (Model 1.2)	Roche Applied Science	Yes	Mobile Laboratory	F–35
10	MICROCYTE® Field Family MICROCYTE® Field and MICROCYTE® Aqua	BioDETECT AS	Yes	Mobile Laboratory	F–24
36	MPD-based BW Detector (P-chip/MPD/2004)	BioTraces, Inc.	Yes	Handheld	F–85
19	M-SERIES® 384 Analyzer	BioVeris Corporation	No	Fixed-Site	F–43
18	M-SERIES® M1M Analyzer	BioVeris Corporation	Yes	Mobile Laboratory	F–39
38	Prime Alert® Biodetection System (096–3130)	GenPrime, Inc.	Yes	Handheld	F–89
3	Prime Alert™ Biodetection/Threat Verification System (Model PAE002)	GenPrime, Inc.	Yes	Handheld	F–5
34	PROFILE® 1 (Model 3560)	New Horizons Diagnostics Corporation	Yes	Handheld	F–80
37	QTL Biosensor (Model 2000 and 2200)	QTL Biodefense	Yes	Handheld	F–87
6	R.A.P.I.D.® System (9200)	Idaho Technology, Inc.	Yes	Mobile Laboratory	F–13
7	RAMP	Response Biomedical Corp.	Yes	Mobile Laboratory	F–16
2	Rapid Response Hand Held Assay (RRHHA)	ANP Technologies, Inc.	Yes	Handheld	F–3
12	RAPTOR Plus	Research International	Yes	Mobile Laboratory	F–29

ID #	Name	Manufacturer	Rated	Mobility	Page F–#
39	RAZOR® System (RAZR-ASY-0010)	Idaho Technology, Inc.	Yes	Handheld	F–92
46	RespondeR RCI (024-1001)	Smiths Detection Danbury	Yes	Mobile Laboratory	F–109
4	SMART II (Biothreat Detection Diagnostic Kits)	New Horizons Diagnostics Corporation	Yes	Handheld	F–8
40	Uni-Lite NG	Biotrace International, Ltd.	Yes	Handheld	F–95
42	VeroTect	Biral	Yes	Mobile Laboratory	F–99

Index by Biological Detector Manufacturer

ID #	Manufacturer	Name	Rated	Mobility	Page F–#
27	20/20 GeneSystems Inc.	BioCheck™ Powder Screening Test Kit (GB 1001)	Yes	Handheld	F–63
1	ADVNT Biotechnologies	BADD™ BioWarfare Agent Detection Devices	Yes	Handheld	F–1
22	Agilent Technologies	Agilent 2100 Bioanalyzer	No	Fixed-Site	F–53
24	Agilent Technologies	Agilent 6850; Agilent 6850 Series II Network GC	No	Fixed-Site	F–57
8	Alexeter Technologies	Guardian Reader System (P–102)	Yes	Mobile Laboratory	F–18
35	Alexeter Technologies	Defender TSR (Test Strip Reader) System (P–502)	Yes	Handheld	F–82
2	ANP Technologies, Inc.	Rapid Response Hand Held Assay (RRHHA)	Yes	Handheld	F–3
20	BD Biosciences Immunocytometry Systems	FACSCaliber	No	Fixed-Site	F–47
21	BD Biosciences Immunocytometry Systems	BD FACSCount (337858)	No	Fixed-Site	F–50
10	BioDETECT AS	MICROCYTE® Field Family MICROCYTE® Field and MICROCYTE® Aqua	Yes	Mobile Laboratory	F–24
33	BioTech International, Inc.	HMB Portable Biohazard Detector (HMB V–PS)	Yes	Handheld	F–77
40	Biotrace International, Ltd.	Uni-Lite NG	Yes	Handheld	F–95
41	Biotrace International, Ltd.	Autotrack (Continuous Flow ATP Detector)	Yes	Mobile Laboratory	F–97
36	BioTraces, Inc.	MPD-based BW Detector (P-chip/MPD/2004)	Yes	Handheld	F–85
18	BioVeris Corporation	M-SERIES® M1M Analyzer	Yes	Mobile Laboratory	F–39
19	BioVeris Corporation	M-SERIES® 384 Analyzer	No	Fixed-Site	F–43
42	Biral	VeroTect	Yes	Mobile Laboratory	F–99
14	Cepheid	GeneXpert® System (GX1000N4–1)	Yes	Mobile Laboratory	F–32
43	General Dynamics Canada	4 WARN Sentry 3000 (Model 718866–901)	Yes	Mobile Laboratory	F–101
3	GenPrime, Inc.	Prime Alert™ Biodetection/Threat Verification System (Model PAE002)	Yes	Handheld	F–5

ID #	Manufacturer	Name	Rated	Mobility	Page F–#
38	GenPrime, Inc.	Prime Alert® Biodetection System (096–3130)	Yes	Handheld	F–89
17	Gen-Probe	Gen-Probe Leader 450i	No	Fixed-Site	F–37
23	GROTON Biosystems	HPLC Diode Array Detector 20/20	No	Fixed-Site	F–55
25	GROTON Biosystems	Capillary Electrophoresis System (GPA100)	No	Fixed-Site	F–59
26	GROTON Biosystems	HPLC Fluorescence Detector (FD500)	No	Fixed-Site	F–61
28	Haztech Systems, Inc.	KT1030 HazCat Anthrax Screening Test Kit	Yes	Mobile Laboratory	F–66
29	Haztech Systems, Inc.	KT1235 HazCat® WMD Kit	Yes	Mobile Laboratory	F–68
30	Haztech Systems, Inc.	KT1040 HazCat® MicroCat/WMD	Yes	Mobile Laboratory	F–70
44	Haztech Systems, Inc.	KT1050 HazCat Tier 4 System	Yes	Mobile Laboratory	F–105
6	Idaho Technology, Inc.	R.A.P.I.D.® System (9200)	Yes	Mobile Laboratory	F–13
39	Idaho Technology, Inc.	RAZOR® System (RAZR-ASY-0010)	Yes	Handheld	F–92
4	New Horizons Diagnostics Corporation	SMART II (Biothreat Detection Diagnostic Kits)	Yes	Handheld	F–8
34	New Horizons Diagnostics Corporation	PROFILE® 1 (Model 3560)	Yes	Handheld	F–80
45	Proengin USA	Biological Alarm Monitor (MAB)	Yes	Mobile Laboratory	F–107
37	QTL Biodefense	QTL Biosensor (Model 2000 and 2200)	Yes	Handheld	F–87
11	Research International	Analyte 2000 Biowarfare Detection (Analyte 2000 Fiber Optic Fluorometer)	Yes	Mobile Laboratory	F–27
12	Research International	RAPTOR Plus	Yes	Mobile Laboratory	F–29
7	Response Biomedical Corp.	RAMP	Yes	Mobile Laboratory	F–16
15	Roche Applied Science	LightCycler™ (Model 1.2)	Yes	Mobile Laboratory	F–35
5	Smiths Detection	Bio-seeq™ Handheld PCR Detector (Model 2430999)	Yes	Handheld	F–10

ID #	Manufacturer	Name	Rated	Mobility	Page F–#
31	Smiths Detection Danbury	HazMatID (023–1001)	Yes	Mobile Laboratory	F–72
32	Smiths Detection Danbury	IlluminatIR ML Package (006–2019)	Yes	Fixed-Site; Vehicle Mounted	F–75
46	Smiths Detection Danbury	RespondeR RCI (024-1001)	Yes	Mobile Laboratory	F–109
9	Tetracore, Inc.	BioThreat Alert Bio Threat Test Strips	Yes	Mobile Laboratory	F–21
47	Tetracore, Inc.	BioThreat Alert™ ELISA Kits	Yes	Mobile Laboratory	F–111

GENERAL

BADD™ BioWarfare Agent Detection Devices

ADVNT Biotechnologies
2102 W. Quail Avenue
Suite 3
Phoenix, Arizona 85027
888–223–3269 (Tel)
623–879–9697 (Fax)
sales@advnt.org
Information Source: http://www.advnt.org
Status: The vendor has responded—11/17/2006
Evaluated: Yes


Technology: Immunochemical
Portability: Handheld Detection Equipment

Unit Cost: Less than $25
Availability: Depending on quantities required, most orders will ship next day. No additional consumables are required with the BADD product line. The test is completely self-contained.
Description: Lateral Flow Immunochromatography—Rapid handheld assay for the detection of anthrax, ricin, and botulinum toxins
Application: Designed for the rapid detection of biowarfare agents (anthrax, ricin, botulism, Y. pestis, and SEB) on surfaces and in liquids. Additionally, the tests are designed to be very specific and very sensitive to the agents they are designed to detect with little or no cross-reactivity. Available kits include:

Anthrax—Anth-kit-10	Sim-box-30
Simulation device—Sim-kit-10	Botulinum toxin—Bot-kit-10
Mix-box-30-ARB (10 Anthrax, 10 Ricin, 10 Botulinum)	Anth-box-30
Ricin toxin—Ric-kit-10	Y. pestis—PLA-10
SEB—SEB-10	

Current Users: Military (DoD,), first responders (hazmat, first responder community), corporate security, mailrooms, police and fire departments, security personnel, diagnostic labs (reference laboratories, state health labs, CDC), scientific research labs (university/schools), hospitals (VA, Baptist, Johns Hopkins), wildlife preservation, public places, transportation organizations, commercial carriers, etc.

OPERATIONAL PARAMETERS

BAs Detected: Bacilus anthracis, Y. pestis, botulinum toxins, ricin, and SEB
Type of Sample: Liquid, solid, surface wipes, and air sampler liquid (Sceptor)
Sample Preparation: None required
SOP Sample Preparation: None required
Start-up Time: Not applicable (startup time not required)
Calibration Requirements: None required
Response Time: Immediate response time results in as little as 1 min
Data Analysis Time: Immediate
Alarms: None
Sensitivity: Bacilus anthracis (50 ng/mL), Y. pestis (1.0 µg/mL), botulinum toxins (33 ng/mL), ricin (5 ng/mL); and SEB (10 ng/mL)
Confidence Interval/Sensitivity: Greater than 95 % for anthrax
Specificity: >99 %—There is no cross reaction to other organisms or proteins. No cross reaction was found with either Bacillus globigii or Bacillus thuringiensis.
Confidence Interval/Specificity: 100 % for anthrax (provided by DOD and EPA)

- **False Positives**: Zero false positives
- **False Negatives**: Zero false positives

Resistance to Interferents: There are no known environmental interferents
Testing Information: Test—OSG BADD Anthrax Test; Date—April 11, 2002 to April 24, 2002; Lot# 0912EXP1202
Tester—Department of Defense, Dugway Proving Ground (Dr. Cox and Dr. Harper)
Materials tested—Live Ames, Sterne, and New Hampshire spores. Also live BG spores (close anthrax relative used for cross-reactivity). Notice: This information provided by the Department of Defense, U.S. Army Dugway Proving Ground does not represent an endorsement of the BADD™ anthrax test device, nor does it serve as a merchantability statement. The

information is provided by the Department of Defense, Dugway Proving Ground as a courtesy in its evaluation of the sensitivity and specificity of the BADD™ anthrax test device.

PHYSICAL PARAMETERS

Size: Each test kit is 1.9 cm x 7 cm x 0.6 cm (0.75 in x 2.75 in x 0.25 in)
Working Space: Minimal space required—30 cm x 30 cm (12 in x 12 in)
Weight: 28 g (1 oz)—no additional equipment is required
Total Weight: No additional support equipment required. Each test is completely self-contained.
Power Requirements: Power not required. Can be used easily in any environment or setting. Similar to a home pregnancy test.

LOGISTIC PARAMETERS

Durability: Double sealed for stability
Ease of Use: Completely self-contained and extremely easy to use with easy to follow instructions. As simple to use as a home pregnancy test. No special skills required and no sophisticated/expensive readers needed.

1. Open package and put contents on flat surface.	4. Elute sample into diluent vial.
2. Moisten swab, using diluent provided.	5. Using transfer pipette, place 5 drops of collected sample into device.
3. Collect sample with moistened swab.	6. Read results at designated time interval.

Environmental Conditions: Highly robust device with wide range of function and temperature ranges. Can be kept at room temperature functional in a wide range of temperatures 0 ºC to 49 ºC (32 ºF to 120 ºF). Above 49 ºC (120 ºF) lowers shelf life and below -16 ºC (4 ºF) is not recommended. Device must be run immediately after opening in humidity <80 %. Device may fail in rain.
Support Equipment: No additional support equipment required
Consumables: Test is self contained, includes all consumables:

1—BADD detection device (for desired toxin)/sealed pouch	1—disposable dropper
1—sample collection swab	1—resealable biohazard bag
1—microtube with sample diluent	1—chain of custody label

1—instructions for use
The BADD boxes can contain up to 30 tests, ranging from 30 of 1 product to 10 packs of 3 different products of your choice, including anthrax, ricin toxin, and simulation devices.
Consumable Costs: No additional consumables required
Maintenance: Each test is completely self-contained. Once a Reader device indicates a positive result, a reader unit is then contaminated and must be sent off for decontamination. Readers allow only one test at a time to be analyzed.
Shelf Life (Equipment): The BADD detection kits can be stored at room temperature, in the original sealed pouch. No refrigeration required. Expiration date 2 yr from manufacture date.
Shelf Life (Consumables): Temperature above 49 ºC (120 ºF) can lower shelf live. Storage not recommended below -16 ºC (4 ºF).
Maintenance Costs: Not applicable
Decontamination: No decontamination required as with other reader type devices. BADD devices are completely self-contained and can be sent out for verification in its own resealable pouch.

SPECIAL PARAMETERS

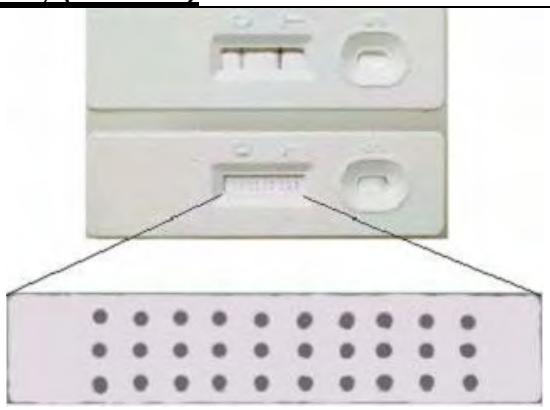
Skills Required: No special skills are required. High school education. Operator does not have to analyze raw data to determine results.
Training Required: Training is not required
Training Available: Offsite training (at manufacturer site) or onsite training (where equipment will be used or stored) is available but not required to operate test. BADD certification couse is available.
Manuals Available: Complete instructional use is included with every test device and available on our web site. Training manual for BADD certification course.
Data Storage: Complete information of the results of individual tests can be stored on the “chain of custody” form included with every device
Warranty: Replacement for defective tests, guaranteed for 2 yr from manufactured date

Communications: Not applicable	**Security**: Not applicable
Safety Requirements: None	**Applicable Regulations**: Not specified

GENERAL

Rapid Response Hand Held Assay (RRHHA)

ANP Technologies, Inc.
824 Interchange Boulevard
Newark, Deleware 19711
Robert G. Daniel
302–283–1730 (Tel)
302–283–1733 (Fax)
robert@anptinc.com
Information Source: http://www.anptin.com



Status: The vendor has responded—10/28/2005
Evaluated: Yes

Technology: Immunochemical
Portability: Handheld Detection Equipment

Unit Cost: Not specified
Availability: Lead time can vary anywhere from 1 wk to 3 mo depending on availability of materials and the specific target for which the device is designed.
Description: Lateral Flow Immunochromatography/Antibody Based
Application: The RRHHA is designed to quickly and accurately provide presumptive identification of biological warfare agents in source and treated water. The assay is also useful for first responders when assessing evacuation decisions. The RRHHA can be used with an automated reader system that is interfaced to a laptop computer. A stand alone reader device will be available soon.
Current Users: The RRHHA is used by several DoD activities. Currently diagnostic labs, the military, first responders, scientific rescarch labs, and hospitals all use similar technology. A major metropolitan fire department is field testing the RRHHA for a government agency. Negotiations are under way with a major metropolitan water department for the fielding of this product.

OPERATIONAL PARAMETERS

BAs Detected: B. anthracis: <1000 cfu/mL
Brucella melitensis: <500 000 cfu/mL
Francisella tularenius: <5 000 000 cfu/mL
Salmonella enteritidis: unkown
Y. pestis: <10 000 cfu/mL
E. coli O157:H7: unkown
Coxiella burnetii: <15 000 000 cfu/mL
Orthopoxvirus: <5 000 000 pfu/mL
Alphavirus (Venezuelan Equine Encephalitis virus): unknown at this time
Botulinum toxins: <25 ng/mL
Ricin: <1 ng/mL
Staphylococcal aureus enterotoxin: <1 ng/mL
Type of Sample: Liquid, solid (if suspended in aqueous solution), sludge (possibly), and surface wipes (if the wipes are wet enough for a sample to be removed)
Sample Preparation: Sample preparation is not required
SOP Sample Preparation: The sample must be a liquid or suspended in a liquid in order for the device to perform properly. Approximately 100 µL of solution (3 to 4 drops) is added to the assay sample well, and the assay is allowed to develop for 15 min. Either a visual examination of the assay is made, or the assay is inserted into the reader for automatic result interpretation.
Start-up Time: Unpack and plug the instrument in. If assay is refrigerated, it must be at room temperature before use.
Calibration Requirements: Calibration not required
Response Time: Immediate
Data Analysis Time: 15 min or less
Alarms: No alarm, but result is visually displayed
Sensitivity: Bacteria <10 000 CFU/mL

Virus <5 000 000 PFU/mL
Toxins <0.001 µg/mL

Confidence Interval/Sensitivity: Not specified
Specificity: Environmental interferents include soil, air pollunants, and sometimes the presence of environmental bacteria. The assay does not differentiate between viable and nonviable organisms, but the assay detects spores.
Confidence Interval/Specificity: Not specified

- **False Positives**: Not specified
- **False Negatives**: Not specified

Resistance to Interferents: Not specified
Testing Information: Not specified

PHYSICAL PARAMETERS

Size: 7 cm x 2 cm x 0.5 cm (2.76 in x 0.79 in x 0.2 in)
Working Space: 0.6 m x 0.9 m (2 ft x 3 ft), enough for one person
Weight: Less than 28 g (1 oz)
Total Weight: Less than 113 g (4 oz)
Power Requirements: Not applicable

LOGISTIC PARAMETERS

Durability: Unopened assay can be used. It can be dropped from counter height without effect. If left in hot environment, factory calibration is required.
Ease of Use: The components of a test kit can be customized to anticipated operating conditions in order to ensure ease of use when wearing most types of PPE, including MOPP-4
Environmental Conditions: Assay may not function properly at temperatures above 45 ºC (113 ºF). Possible decrease in sensitivity at temperature below -80 ºC (-112 ºF).
Support Equipment: None required
Consumables: Disposable transfer pipettes, pipette tips, and solutoions
Consumable Costs: <$1
Maintenance: None required. The assay is a single use item.
Shelf Life (Equipment): 1 yr
Shelf Life (Consumables): After more than 1 yr, sensitivity can be expected to decrease and false positive rates can be expected to increase
Maintenance Costs: Not specified
Decontamination: Not specified

SPECIAL PARAMETERS

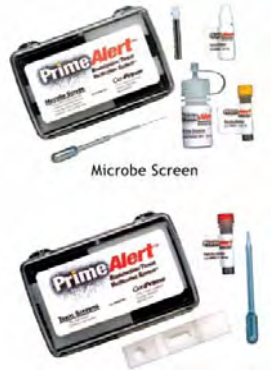
Skills Required: No special skills but training required, high school diploma. Operator does not need to anaolyze raw data to reach a final result.
Training Required: Less than 4 h training required
Training Available: Manual training
Manuals Available: User manual is available
Data Storage: Not specified
Communications: Not specified
Security: Not specified
Safety Requirements: Not specified
Applicable Regulations: Not specified
Warranty: Not specified

GENERAL

Prime Alert™ Biodetection System (Model PAE002)

GenPrime, Inc.
157 S. Howard , Suite 605
Spokane, Washington 99201
Buck Somes
509–624–9855 (Tel)
866–624–9855 (Tel, toll free)
509–462–2847 (Fax)
bsomes@genprime.com
Information Source: www.genprime.com

Status: The vendor has responded—11/27/2006
Evaluated: Yes



Technology: Immunochemical
Portability: Handheld Detection Equipment

Unit Cost: $10.5K—complete Prime Alert® Biodetection, which includes all the equipment and five Complete Microbe and Toxin Screens
Availability: The Prime Alert Biodetection System is available for shipment within 2 wk to 4 wk. All consumables and components necessary to run Microbe Screens and Toxin Screens are included in the Prime Alert System. Consumables can be ordered separately as needed. No support equipment is required.
Description: Lateral Flow Immunochromatography/Optical
• Lateral flow immunochromatography—Toxin screens for ricin and Botulinum are lateral flow antibody tests.
Fluorescent-based Technology
• Optical/Fluorescence/Emission—Prime Alert microbe screen is a fluorescent-based assay using binding dyes and a hand held fluorometer.
Application: The Prime Alert Biodetection/Threat Verification System allows first responders to perform a rapid, on-site test to determine if a substance is a potential biohazard or merely a hoax. The simple and reliable technology alerts the responder to the presence of suspicious levels of any microbe in one five-minute test. A negative result is quickly followed by tests for ricin and botulinum toxins. In less than 10 min reliable information is obtained, allowing the first response team to make an informed decision regarding incident closure. The Microbe Screen® is performed using a proven fluorescent-based technology in a hand-held reader and the Toxin Screens™ are carried out using lateral flow antibody tests.
Current Users: Diagnostic Labs—Environmental Hydrogeological Consultants
Military—Navy Regional Fire Rescue, Fairchild Air Force Base, Defense Forces of Ireland, U.S. Army Aberdeen Proving Ground, and Singapore Civil Defense Forces
First Responders—Chicago Fire Department, Seattle Fire Department, Washington DC Special Operations, Atlanta Fire Department, Dekalb County Fire Department, Spokane City Fire Department, Glendale Fire Department, Bellevue Fire Department, Brunswick Fire Department, Columbus Fire Department, Denver Fire Department, Massachusetts Department of Fire Services, Prince William County Fire Department, Rochester Fire Department, Rapid City Fire Department, Athens-Clarke Co. Fire Department, Augusta Richmond County Fire Department, Berks County Emergency Management Agency, Beverly Hills Fire Department, Brunswick Fire Department, Cecil County Emergency Management, Cherokee County Fire Department, Dublin Fire Department, County of Los Angeles Fire Department, Forest Park Fire Department, Greenwood Fire Department, Mankato Fire Department, Robeson Co. Emergency Management, Savannah Fire Department, Vancouver Fire Department, and Virginia Fire Marshalls Office
Scientific Research Labs—U.S. Army Dugway Proving Ground and Krel Laboratories
Hospitals—Baylor Medical Center and Williamsport Hospital
United States Postal Inspection Service, U.S. Coast Guard, LSU Academy of Counter Terrorism, Houston Chronicle, Northern Trust Company, U.S. Steel Corporation, Chicago Fire Training Academy, KAPL Lockheed, and Progressive Insurance Company
U.S. Coast Guard, LSU Academy of Counter Terrorism, Houston Chronicle, Northern Trust Company, U.S. Steel Corporation, Chicago Fire Training Academy, KAPL Lockheed, and Progressive Insurance Co.

OPERATIONAL PARAMETERS

BAs Detected: Bacilus anthracis, Brucella abortus, Brucella melitensis, Brucella suis, Brucella canis, Corynebacterium diptheria, Francisella tularenius, Burkholderia mallei, Burkholderia pseudomallei, Shigella spp., Salmonella typhimurium,

Salmonella enteritidis, Salmonella typhi, Vibrio cholerae, Yersinia pestis, E. coli O157:H7, Coxiella burnetii, Rickettsia prowazekii, Rickettsia tsutsugamushi, Rickettsia rickettsii, Chlamydia psittaci, Clostridium botulinum, Botulinum toxins, Clostridium perfringens, Clostridium tetani, and Staphylococcal aureus enterotoxin B

Type of Sample: Powder

Sample Preparation: No sample preparation is required. Sample powder is collected with tools provided and suspended in buffer provided. No additional support equipment is required for the Prime Alert.

SOP Sample Preparation: No sample preparation is required. A specific volume of sample is required and collection tools are provided.

Start-up Time: 2 min equipment set-up time (unpack and calibrate); 2 min start up for microbe screen; no start up time necessary for toxin screen. Instrument requires one quantitative calibration at startup.

Calibration Requirements: Average calibration time is <2 min. Manual calibration is required for each microbe screen. No calibration is required for toxin screen. Equipment includes internal standards for calibration with sample run. Calibration is a simple 3 step process and takes less than 2 min: 1) blank the instrument, 2) calibrate the instrument, and 3) verify calibration.

Response Time: <15 min

Data Analysis Time: <1 min

Alarms: No alarm, but result is visually displayed

Sensitivity: The sensitivity for bacterial spores ranges from 1.1×10^5 cfu/mL to 2.2×10^6 cfu/mL depending on the species. The sensitivity for ricin is 0.05 µg/test or 0.4 µg/mL. The sensitivity for botulinum is 0.05 µg/test or 0.4 µg/mL.

Confidence Interval/Sensitivity: Confidence interval for sensitivity (at the limit of detection) is 98 % for microbe screen, 100 % for toxin screen. The determination of the reproducibility and sensitivity of the assay was carried out by the Battelle Memorial Institute, Columbus, Ohio. The Prime Alert fluorescent results were compared with colony forming units as determined by standard plate counts using Bacillus subtilis spores, Bacillus thuringiensis spores, and Bacillus subtilis var. niger spores. Standard statistical tests were carried out and the correlation coefficient for these studies was R2 = 0.9853 with a C.V. of 1.3 %.

Specificity: Microbe screen—all bacteria and bacterial spores; toxin screen—ricin and botulinum toxin

Confidence Interval/Specificity: Confidence interval for sensitivity (at the limit of detection) is 98 % for microbe screen and 100 % for toxin screen. The confidence interval for specificity of the microbe screen is 96 %. The determination of the reproducibility and specificity of the assay was carried out by the Battelle Memorial Institute, Columbus, Ohio. The Prime Alert fluorescent results were compared to nonbiological powders, those not containing bacteria or bacterial spores.

- **False Positives**: <4 % for microbe screen; 0 % for toxin screen
- **False Negatives**: 0 % at sensitivity threshold for microbe screen; 0 % at sensitivity threshold for toxin screen

Resistance to Interferents: Known environmental interferents include excess environmental DNA. The assay can detect spores. The assay does not cross-react with proteins or other organisms.

For the toxin screen, the following substances were tested for cross-reactivity—sodium chloride, bovine serum albumin, nondairy creamer, sugar, household dust, talcum powder, nonfat dry milk, flour, baking soda, baking powder, laundry detergent, and purified water.

For the microbe screen, the following substances were tested for cross-reactivity—cultured buttermilk, buttermilk pancake mix , unbleached flour, bleached flour , whole grain brown rice flour, nonfat dry milk, vanilla ensure, coffee mate coffee creamer, Western Family Coffee Creamer, All Kitchens nonDairy Creamer, Vanilla Pudding mix, chicken gravy, chicken bouillon, beef bouillon, instant dry mashed potatoes, corn starch, corn meal, gelatin, pure cane sugar, powdered sugar, equal sweetener (aspartame), Sweet 'N Low (saccharin), sugar in the raw, brown sugar, corn sugar (dextrose), iodized table salt, meat tenderizer, Ever Fresh, baking soda, baking powder, soy protein powder, garlic salt, paprika, white pepper, black pepper, ground mustard, taco seasoning, Good Host iced tea mix, ground cinnamon, ground ginger, Cascade dishwashing detergent, Tide with bleach, Western Family laundry detergent, Comet, Johnson & Johnson Baby Powder, Western Family talcum powder, Desenex, Gold Bond, General Foods International French Vanilla Instant coffee mix, General Food International Hazelnut instant coffee mix, General Foods International Mocha instant coffee mix, hot cocoa mix, sawdust, bentanite, crushed asprin, powdered make-up, crushed yeast, malt extract, tryptic soy broth, granulated solidifying agar, Lactobacillus growth medium (Americana medium), B. thuringeinsis bacteria, B. thuringeinsis spores, B. subtilis bacteria, B. subtilis spores, Lactobacillus, Lactococcus, E. coli, L. rhamnosus R-011, L. casei R-256, L. plantarum R-202, L. acidophilus, B. longum BB536, and B. breve R-070.

Testing Information: The Prime Alert Microbe Screen was validated by the Battelle Memorial Institute, Columbus, Ohio

PHYSICAL PARAMETERS

Size: 41 cm x 33 cm x 18 cm (16 in x 13 in x 7 in) for total system; 8 cm x 13 cm (3 in x 5 in) for individual microbe or toxin screen

Working Space: Test can be performed in a 61 cm x 61 cm (2 ft x 2 ft) workspace

Weight: Total weight of equipment kit, including carrying case, sampling tools, hand-held reader, consumable test kits, and batteries is 0.345 kg (12 lb 2 oz)
Total Weight: Consumable test weighs 170 g (6 oz)
Power Requirements: <12 h of continual use with 4 AAA batteries (6V, 0.3W)

LOGISTIC PARAMETERS

Durability: Contained in a hard shell pelican case that can be packed and moved by a single person with little training.. The handheld reader is fully sealed, and is resistant to vibration, shock, and temperature extremes. The Prime Alert reader can be transported quickly and does not require recalibration. In addition, the Prime Alert may be dropped from counter height or left in hot or cold temperatures without effect, but recalibration is recommended.
Ease of Use: The Prime Alert is easy to operate and can be carried out by a single individual in a Level A suit

Prime Alert Microbe Screen is carried out in 4 basic steps:	Prime Alert Toxin Screen is carried out in 3 basic steps:
1. Mix solutions.	1. Collect sample and place in solution.
2. Collect sample and place in solution.	2. Transfer solution to test strip.
3. Insert sample into reader and obtain result.	3. Obtain result.
4. Verify result.	

Environmental Conditions: Can be used under any environment conditions; humidity does not affect operation
Support Equipment: No support equipment is required
Consumables: One Complete Screen, which includes a microbe screen and ricin and Botulinum toxin screens
Consumable Costs: $135—total cost of consumables for one assay
Maintenance: No maintenance is required. Batteries should be changed yearly. There is 24 h technical support provided by the manufacturer or authorized agency. There is a loaner option during maintenance or malfunctioning. Upgrades including new testing capabilities may be added.
Shelf Life (Equipment): The equipment kit including the reader should not suffer for at least 5 yr
Shelf Life (Consumables): There is a 1 yr shelf life for all consumables
Maintenance Costs: $5 per yr—routine maintenance cost (estimated yearly battery replacement). Extended warranty available: 1 yr—$1.5K; 2 yr—$2K; 3 yr—$2.5K.
Decontamination: All components of the Prime Alert can be decontaminated or disposed of after use. O-ring seals in the reader make the unit completely submersible in alcohols, 10 % bleach, liquid detergents, and other appropriate decontamination solutions.

SPECIAL PARAMETERS

Skills Required: No specific skill level and no specialized training beyond hazmat training are required to learn how to use the Prime Alert. A person with a high school education can learn to use the equipment. The operator does not need to analyze raw data before a final result can be determined.
Training Required: Informal training—each Prime Alert Equipment kit comes with a comprehensive training video and CD, a written user guide, and quick reference cards. Training can be accomplished in less than 30 min. Formal training is available from the manufacturer.
Training Available: Training from the manufacturer can be accomplished with the training video and CD included with the equipment. In addition, GenPrime offers group “train the trainer” sessions at customer’s facility. Training results in certification.
Manuals Available: Comprehensive instruction manual, quick reference cards, training video, and CD are included with each equipment kit at no charge
Data Storage: The Prime Alert reader for microbe screens can store up to 1000 data points
Communications: The data points stored in the Prime Alert reader for Microbe Screens can be transferred to an Excel spreadsheet on any PC via an RS-232 serial port
Security: No special security mechanisms are required with the Prime Alert. The reader maintains internal parameters set by the manufacturer, which can be checked by the operator. All consumables are packaged in tamper proof pouches in order to maintain integrity of all components.
Safety Requirements: No safety requirements apply to the possession of the Prime Alert Biodetection System
Applicable Regulations: No regulations apply to the possession of the Prime Alert Biodetection System
Warranty: The Prime Alert® Biodetection System comes with a 1 yr warranty.
Loaner replacement units are included as part of the warranty. Extended warranties are available. The expected useful lifetime of the equipment is in excess of 5 yr.

GENERAL

SMART II (Biothreat Detection Diagnostic Kits)

New Horizons Diagnostics Corporation
9110 Red Branch Road
Columbia, Maryland 21045
David Trudil
410–992–9357 Ext. 235 or 222 (Tel)
410–992–0328 (Fax)
nhdiag@aol.com
nhdetect@aol.com
Information Source: http://www.nhdiag.co

Status: The vendor has responded—11/29/2006
Evaluated: Yes

Technology: Immunochemical
Portability: Handheld Detection Equipment

Unit Cost: $25 to $36 per test
Availability: Readily available
Description: Lateral Flow Immunochromatography/Screening—SMART®, in this case, is an acronym for the commercially available Sensitive Membrane Antigen Rapid Test. SMART® is a registered trademark of New Horizons Diagnostics Corporation. The Colloidal Gold Immunoassay test method was was first invented by NHD 20 yr ago. The SMART® identification tickets are self-contained, colorimetric, solid-phase immuno-filtration assays designed to be used in conjunction with a liquid interface. Two types of SMART® devices have been developed: One kit is capable of detecting endospore-forming bacteria. The other kit is capable of detecting proteinaceous toxins or soluble antigens, including bacteria. The SMART® devices utilize a colloidal gold particle concentration immunoassay to effect sensitive and selective detection of biological materials.
Application: Detection of specific targets from environmental, human, or culture samples
Current Users: Used by diagnostic labs, military, first responders, scientific research labs, hospitals, public health labs, and food testing labs

OPERATIONAL PARAMETERS

BAs Detected: Lateral flow test devices for the following: Bacilus anthracis (spore and PA), Francisella tularenius, Vibrio cholerae, Yersinia pestis, E. coli O157:H7, Botulinum toxins, Ricin, Salmonella, Brucella and Staphylococcal aureus enterotoxin B. Other tests are in development and available for investigation or special needs basis
Type of Sample: Liquid, solid, and surface wipes (all suspended in liquid); and culture, stool, and blood
Sample Preparation: Sample preparation is not required
SOP Sample Preparation: Not applicable
Start-up Time: <20 s technician time
Calibration Requirements: None
Response Time: 15 min (no longer than 30 min)
Data Analysis Time: See table to interpret test
Alarms: No alarm, but distinct color reaction on capture membrane
Sensitivity: Generally 10^5 cfu/mL for bacteria:
Bacilus anthracis—10^5 cfu/mL
Francisella tularenius—10^5 cfu/mL
Vibrio cholerae—10^5 cfu/mL
Yersinia pestis—10^4 cfu/mL
E. coli O157:H7—10^5 cfu/mL
Generally 50 ng/mL for toxins:
Botulinum toxins—50 ng/mL
Ricin—50 ng/mL
Staphylococcal aureus enterotoxin B—<50 ng/mL
Confidence Interval/Sensitivity: Between 93 % to 98 %
Specificity: Environmental interferents include pH and very high lab grade salt concentrations that exceed 30 %. This test is a rapid, screening assay.

Confidence Interval/Specificity: >95 % (antibody specific)

- **False Positives**: <2 %
- **False Negatives**: Depends on level of target

Resistance to Interferents: Not specified
Testing Information: MIHE Pulawy, Poland data
NDMC/IPM, Taiwan data
IPP, Obolensk data
ECBC, TR 171
CDC, CO data
Acta Microbiological Polona, 2002, Vol 51, No.2 12–129

PHYSICAL PARAMETERS

Size: 0.51 cm x 2.54 cm x 5.08 cm (0.2 in x 1 in x 2 in)
Working Space: <0.05 m^2 (0.5 ft^2)
Weight: 56.7 g (2 oz)
Total Weight: Not applicable
Power Requirements: Not applicable

LOGISTIC PARAMETERS

Durability: Able to be transported quickly without protective packaging; no calibration
Ease of Use: Easy to use wearing PPE; 3 steps to transfer drops; simple low level of accuracy
Environmental Conditions: Outside of temperature range of 0 ºC to 45 ºC (32 ºF to 113 ºF), flow is altered, and reactivity is effected
Support Equipment: None
Consumables: SMART reagent pouch and transfer pipette
Consumable Costs: $25 to $36 per test
Maintenance: None
Shelf Life (Equipment): Can be stored for several years, however, consumables may be affected after 1 y
Shelf Life (Consumables): Room temperature storage
Maintenance Costs: Not applicable
Decontamination: Not specified

SPECIAL PARAMETERS

Skills Required: No special skills but training required; high school diploma
Training Required: <4 h training required
Training Available: Classroom training available at manufacturer site. Training simulants available. Charges relating to training are not included in prices unless noted in writing.
Manuals Available: Manual available
Data Storage: Not applicable
Communications: Not applicable
Security: Not applicable
Safety Requirements: None
Applicable Regulations: Not specified
Warranty: New Horizons Diagnostics Corporation guarantees the quality of its reagents if used and stored as recommended. Any reagents found to be defective will be replaced free of charge upon return of product. New Horizons Diagnostics Corporation disclaims any implied warranty of merchantability or fitness for a particular purpose, and in no event shall New Horizons Diagnostics Corporation be liable for consequent damages.

GENERAL

Bio-Seeq™ Handheld PCR Detector (Model 2430999)

Smiths Detection
2202 Lakeside Boulevard
Edgewood, Maryland 21040
410–510–9100 (Tel)
410–510–9496 (Fax)
Nonmilitary, U.S. Customers:
Susan Cooper
Pine Brook, New Jersey
973–830–2131 (Tel)
U.S.A. Military Personnel:
Sales Department
Edgewood, Maryland
410–510–9385 (Tel)
Info@smithsdetection.com

Information Source: http://www.smithsdetection.com
Status: The vendor has responded—11/17/2006
Availability: Call manufacturer for availability
Evaluated: Yes

Technology: Molecular

Portability: Handheld Detection Equipment

Unit Cost: Bio-SeeqTM: $35K
Description: Real Time PCR and Fluorescence/Emission—PCR is a new molecular technique that replicates the DNA structure of a bacterial or viral pathogen. With as little a molecule, PCR can replicate the molecule up to a billion-fold, providing enough genetic material for specific detection and positive identification of biological and viral agents of mass destruction. At the heart of the Bio-Seeq unit are six detection modules called Thermocycler/Optics modules. These modules perform the thermal cycling, optical reading, and alarm detection for each test. Each module has two independent optical channels that can be used during a single test. With suitable reagents, these channels can allow the user to run a target sample with a positive control in the same tube, eliminating the need to prepare a separate positive control. Each module is individually controlled by a microprocessor allowing each test to be performed completely independently of other tests. Unlike other instruments available, it is not necessary to run in a "Batch" mode. Bio-Seeq allows the user to run any test, in any module, at any time. The modules are designed for reliability and redundancy, and are user replaceable without the need to recalibrate the instrument; all calibration information is contained in nonvolatile memory in the unit's processor.
Application: Homeland security and military applications. Bio-terrorism and biological warfare pose physical threats to military and civilian forces, as well as to the civilian populations they protect. Detection systems used to identify these dangerous bacterial and viral pathogens must do so accurately and quickly in order to contain the threat and save lives. Portable, handheld thermocycler capable of detecting both bacterial and viral pathogens quickly and accurately, using PCR technology. PCR is a new molecular technique that replicates the DNA structure of a bacterial or viral pathogen. With as little a molecule, PCR can replicate the molecule up to a billion-fold, providing enough genetic material for specific detection and positive identification of biological and viral agents of mass destruction. Possesses the ability to run tests in the field, with accurate results in a critical situation where a biological or viral pathogen is suspected. Through smart design, simplified sample preparation and PCR technology, the Bio-Seeq provides a way for military personnel and first responders to identify, contain, and save lives.
Current Users: Military—U.S. ARMY
First Responders—U.S. Customs; Baltimore City Police Department
Scientific Research Labs—LLNL and MIT-LL

OPERATIONAL PARAMETERS

BAs Detected: Call manufacturer for specific detection limits for nonspecific anthrax, tularemia, plague, orthopox, and ricin
Type of Sample: Liquid, solid, surface wipes, and other
Sample Preparation: Sample prepartion takes less than 5 min
Sample preparation (adding reagents and, usually removing inhibitors) must be performed prior to inserting the sample into the Bio-Seeq®. See your supervisor for instructions if you do not use the Bio-Seeq® sample preparation cartridges.

The Bio-Seeq® sample cartridge is a self-contained, single-use device that includes all of the components needed to collect sample, reconstitute reagents and remove inhibitors, and deliver the sample and reagent to the Bio-Seeq®. This device is intended to meet the needs of first responders in the field.
NOTE: Dispose of sample cartridges that displayed positive as hazardous waste.
SOP Sample Preparation: 1. Remove one (1) foil bag labeled "Reagent Base" with desired test (i.e., Anthrax, Training, etc.) and one (1) paper bag labeled "Plunger" from box
2. Tear open foil bag and remove the "Reagent Base"
NOTE: Once "Reagent Base" is removed from foil bag, it MUST be prepared within 5 min. Wear protective gloves until sample is confirmed as a negative result
3. Swab sample. Do not overload.
4.Tear open paper bag and remove the "Plunger"
Screw "Plunger" into "Reagent Base"
NOTE: You will hear two (2) pops. The first pop will be the buffer seal breaking and the second pop indicates that the consumable is screwed all the way down.
6. Let the cartridge sit for 90 s
7. Shake the cartridge horizontally for 20 s
8. Whip the cartridge 5 times as shown
The sample cartridge is now ready for use in the Bio-Seeq®. Go to paragraph Error! Reference source not found for instructions on running an assay
Start-up Time: Assembly requires 1 step, the installation of battery for field use. Detector start-up time, including calibration is less than 1 min.
Calibration Requirements: Calibration not required at start-up. Instrument requires vendor support for quantitative calibration.
Response Time: 40 min (dependant upon protocol)
Up to 6 tests simultaneously
Data Analysis Time: 0 min
Alarms: Auto, visible, and audible alarm alerts of any positive outcomes
Sensitivity: Call manufacturer for specific detection limits for nonspecific anthrax, tularemia, plague, and ricin
Confidence Interval/Sensitivity: Not specified
Specificity: Not specified
Confidence Interval/Specificity: Not specified

- **False Positives**: Not specified
- **False Negatives**: Not specified

Resistance to Interferents: Environmental interferents include soil, pH, and animal waste. It does not detect spores. Each assay in external validation did not cross-react with nearest neighbors. Validation reports are available.
Testing Information: Validation reports are available

PHYSICAL PARAMETERS

Size: 28 cm x 9 cm x 18 cm (11 in x 3.5 in x 7 in)
Working Space: Not specified
Weight: 2.9 kg (6.5 lb)
Total Weight: 2.9 kg (6.5 lb)—including commercial batteries
Power Requirements: External 12 V dc, internal batteries, or vehicle power; lithium ion rechargeable battery (2.5 h continuous operation)

LOGISTIC PARAMETERS

Durability: Rugged
Ease of Use: Ease of use by first responders and other personnel is a priority for the Bio-Seeq. The Bio-Seeq is designed for ease of use with protective clothing. Large keyboard and simplet menu driven display simplifies unit operation. Visual and audible alarms are provided.
Environmental Conditions: Not in temperatures above +40 ºC (104 ºF); not in temperatures below -20 ºC (-4 ºF)
Support Equipment: Sample preparation cartridge contains all the necessary reagents, filters, and mixing chemicals required to process a biological or viral sample, eliminating the need for pipettors, tips, and sample vials; and battery charger
Consumables: Various consumable reagents are available to detect various pathogens. They are color coded as well as labeled. Reagent base and plunger.
Consumable Costs: $30 per test; $300 for box of 10

Maintenance: The modules are designed for reliability and redundancy. If any module fails, it does not affect the operation of the instrument. The Thermocycler/Optics modules are also user replaceable.
There is a 24 h technical support provided by the manufacturer or authorized agency. There is a loaner option during maintenance or malfunctioniom. The equipment upgradeable.
Shelf Life (Equipment): Thermal Cycler calibration would suffer if stored >1 yr
Shelf Life (Consumables): Consumable shelf life is 1 yr
Maintenance Costs: $3K per year for all parts and labor
Decontamination: Not specified

SPECIAL PARAMETERS

Skills Required: No special skills but training required. High school diploma. Equipment does not require the operator to analyze raw data before a final result can be determined. Raw data is available for trained operators to analyze in the event of a positive indication.
Training Required: 4 h training required
Training Available: Hands on training is available at time of sale. Training materials (manuals and CDs) are available and packaged with the delivered unit.
Manuals Available: Users manual is provided on CD with the delivered equipment
Data Storage: Simple, easy to use data interface
Communications: RS-232E compatible with ACMS RF systems
Security: Not specified
Safety Requirements: Not specified
Applicable Regulations: Practice of the patented PCR process requires a license. The Bio-Seeq Thermal Cycler is an Authorized Thermal Cycler and may be used with PCR licenses available from Applied BioSystems. Its use with Authorized Reagents also provides a limited PCR license in accordance with the label rights accompanying such reagents.
Warranty: Equipment comes with a 1 yr warranty on parts and labor

GENERAL

R.A.P.I.D.® System (Model 9200)

Idaho Technology, Inc.
390 Wakara Way
Salt Lake City, Utah 84108
Michael T. Hurley, Bio-Defense Programs
801–556-3234 (Tel)
801–588–0507 (Fax)
mike_hurley@idahotech.com
Information Source: http://www.Idahotech.com

Status: The vendor has responded—11/28/2006
Evaluated: Yes

Technology: Molecular
Portability: Mobile Laboratory Detection Equipment

Unit Cost: $55K—commercial unit pricing/unit. R.A.P.I.D. 9200 system includes laptop computer, backpack, micro-centrifuge, basic use toolkit, 1 pack of 96 reaction cuvettes, cords/cables, and user manuals
Other consumables—$8.44/assay; freeze-dried reagents ($180/50 extractions); 1-2-3 DNA Purification Kit
Availability: Immediate availability. Commercially available off the shelf (COTS) since 1999.
Description: Real Time PCR
Application: Detection and identification of biological organisms by real-time PCR
Current Users: Diagnostic labs—state public health labs (Louisiana and Illinois)
Military—U.S. Department of Defense (USA, USAF, USN, USMC), U.S. National Guard CSTs, and U.S. Army Technical Escort Units, international customers (UK, Italy, Spain, Czech Republic, Slovakia, Singapore, Canada, and Australia)
First responders—Miami-Dade Hazmat, Chicago Fire Department, and West Palm Beach Fire
Research labs—Signature Science, Battelle, and MRI
Hospitals—Some military hospitals in U.S., and DOD
Other—United Nations (UNMOVIC) and several private companies

OPERATIONAL PARAMETERS

BAs Detected: Commercially available freeze-dried assays manufactured by Idaho Technology Inc. Freeze dried assays are available for the following: All ITI's assays have a DNA detection limit of 100 fg.
Bacilus anthracis, Brucella spp., Francisella tularenius, Salmonella spp, Yersinia pestis, E. coli 0157, Cryptosporidium spp., Clostridium botulinum Type A, Rcininus communis, Variola, Avian Influenza H5 subtype, Influenza Type A, and Listeria monocytogenes.
Type of Sample: Air, liquid, solid, sludge, surface wipes, and swabs
Sample Preparation: Idaho Technology Inc highly recommends DNA sample preparation to remove potential PCR inhibitors (inhibitors may cause false negative results). Idaho Technology Inc., manufactures and produces the 1-2-3 DNA Purification Kit for Environmental Samples. Sample preparation is achieved using a manual kit (e.g., Idaho Technology Inc., 1-2-3 DNA Purification kit) and a bead-beating device. Sample preparation is <15 min.
SOP Sample Preparation: Sample preparation is recommended to remove inhibitors that may otherwise disrupt the PCR reaction. Sample prep is achieved using a manual kit (e.g., Idaho Technology Inc., 1-2-3 kit) and a bead-beating device. The procedure is two-fold, sample is bead-beaten to break open cellular material and then DNA is concentrated and purified using buffers and spin columns.
Start-up Time: 2 min—unpack and plug the instrument in
Calibration Requirements: Calibration is not required
Response Time: Under 30 min
Data Analysis Time: Less than 1 min—no operator analysis required
Alarms: Visual alarm (detector) appears at the conclusion of the run
Sensitivity: The R.A.P.I.D. ® Detection Kit is able to reliably detect up to 100 fg of amplifiable DNA material in a single reaction, this is approximately 20 copies of bacterial DNA
Bacteria—1 DNA copy or 1 organism
Virus—1 DNA copy or 1 organism
Toxins—not applicable

Target DNA—100 fg (femtograms = 10e-12)
Confidence Interval/Sensitivity: >95 % at 100 fg
Specificity: No known interferents if correct sample preparation procedures are followed. The R.A.P.I.D. detection kit has demonstrated specific detection of versus a panel of 80 agents, both related and unrelated. Does not differentiate between viable and non-viable organisms. Specificity is a 100 %.
Confidence Interval/Specificity: 100 fg of DNA for 80 different organisms. Every assay is tested over a dynamic range for sensitivity and specificity. LOD is determined at greater than 95 % confidence interval over greater than 100 samples for the determined limit of detection. Specificity studies are done at an independent DoD laboratory against over 80 different organisms that are both closely related to the target organism and/or commonly occurring.

- **False Positives**: None reported
- **False Negatives**: None reported

Resistance to Interferents: No know interferents. The R.A.P.I.D.® Detection Kit has demonstrated specific detection versus a panel of 80 agents, both related and unrelated. Specificity is a 100 %.
Testing Information: 1. From March 1999 through June 1999, the R.A.P.I.D.® System participated in the BAWS test.
JPO-BD NATO 50
U.S. Army, Dugway Proving Ground
Dugway, Utah
2. In February 1999 an OUT&E was performed on the R.A.P.I.D.® System
AFOTEC DET2/FR–99–095
HQ AFOTEC/CC
8500 Gibson Boulevard SE
Kirkland AFB, New Mexico 87117–5558
3. 1998 to present:
AFIP Assay Validation for R.A.P.I.D.® System freeze-dried BioReagents
Armed Forces Institute of Pathology (AFIP)
14th St. and Alaska Ave., NW 4109
4. U.S. Air Force
Molecular Epidemiology Lab
Brooks AFB, Texas 78235
5. February 2002 to present:
Joint Biological Agent Identification and Diagnostic Systems (JBAIDS)
U.S. Army Space and Missile Defense Command

PHYSICAL PARAMETERS

Size: 49 cm x 36 cm x 27 cm (19.4 in x 14.3 in x 10.5 in)
Working Space: Card table size—0.9 m x 0.9 m (3 ft x 3 ft)
Weight: 22.7 kg (50 lb)
Total Weight: 11 kg (25 lb)
Power Requirements: CONUS—100 V to 130 V 50/60 Hz, 4.5 A 600 W
OCONUS—200 V to 240 V 50/60 Hz, 2.5 A 600 W

LOGISTIC PARAMETERS

Durability: R.A.P.I.D.® System was designed for field/portable use. It is a man-portable ruggedized unit that exceeds 810E Transport MIL standard for shock and vibration. This unit also withstands 1 m drop test, resists vibration, and can operate on the move.
Ease of Use: Moderate complexity. The R.A.P.I.D.® System requires minimal lab technique and computer skill. The complexity is similar to other types of instruments, but faster and more sensitive.
Environmental Conditions: The R.A.P.I.D.® System can be operated between -20 ºC to 40 ºC (-4 °F and 103 °F). Slow cooling of air shuts the machine off. The recommended relative humidity instrument operation is below 95 %.
Support Equipment: Laptop computer
5212 Start up kit
5214 Bubble centrifuge and adapters
5216 Camouflage backpack
5208 Basic use tool kits
Composite reaction cuvettes, cords, cables, and user guide
Other support items may include pipetters and Turbo-Mixer with bead-beater attachment

Consumables: The following consumables are required for each run (varies according to test volume): freeze-dried PCR master mix (specific test assay), sterile PCR grade water, DNA sample prep kit, capillary tubes, gloves, and disposable pipette tips.
Consumable Costs: Capillary tubes (cuvettes)—$0.58/tube
Lyophilized PCR Master Mix—$6 each
Sterile PCR grade water (Sigma)—$20/L
Other consumables include:
Idaho Technology freeze-dried reagents—$8.98 per reaction (small scale production)
Idaho Technology sample preparation kit—$180 per 50 extractions
Maintenance: The R.A.P.I.D.® System unit does not require regular service/maintenance, however periodic user maintenance is recommended. Loaner option during maintenance or malfunctioning is available, and 24 h technical support is provided by the manufacturer. Several upgrades are available, including software, new assay, and parts (i.e., filters).
Shelf Life (Equipment): Instrument can be stored for up to 10 yr without being serviced before it is used
Shelf Life (Consumables): Shelf life for 1-2-3 DNA Purification kit is 1 yr. Shelf life for consumables and freeze-dried master mixes (test assays) is 6 mo (if stored properly).
Maintenance Costs: $2K—set-up cost
Decontamination: 10 % bleach is recommended to surface decontaminate the R.A.P.I.D.® System. Gas hydrogen peroxide is possible if exposed to hot zone.

SPECIAL PARAMETERS

Skills Required: High school level education or higher, enlisted military personnel. Operator requirements include familiarity and general knowledge of R.A.P.I.D.® System user manual (instrument operation, sample preparation, reagent set-up, and decontamination procedures). Scientific and technical background is also helpful. Operator does not need to analyze raw data before a final result can be determined.
Training Required: 24 h instruction and practice time is sufficient to learn equipment operation. Frequent practice will reinforce learning and maintain proficiency and readiness.
Training Available: Idaho Technology offers a 3 d training on the R.A.P.I.D.® System included with purchase. Training program includes instrument set-up, sample preparation and reagent set-up, concepts of operations, and troubleshooting. The USAF also provides an additional 2 wk comprehensive training course to USAF and DOD personnel.
Both onsite and offsite training available. Training conducted at the customers site is an additional charge.
Manuals Available: Operator and technical manuals (text and CD-ROM) are included with R.A.P.I.D.® System. Operator manual includes instructions to set-up, run, and report results (common user). Technical manual also includes instructions to use Advanced Software Options (run programming, data analysis, and detector module).
Data Storage: Data can be stored as text files and printed out at a later date and time. A computer is necessary to operate the machine, so storage of data on computer is not a problem.
Communications: Windows NT program with dual interface.
The R.A.P.I.D.® System is a field-hardened instrument used for pathogen identification. The portable instrument allows a Minimally Trained Care Provider (MTCP) to operate in remote and non-lab environments. While the MTCP is crucial to operating, the Subject Matter Expert (SME) will need to monitor, and ultimately verify the test results.
Security: Not applicable
Safety Requirements: This instrument generates minimal heat and noise. It is CE approved.
Applicable Regulations: Not specified
Warranty: Idaho Technology provides a 1 yr warranty on parts, and labor and continuous customer and technical support. Additional long-term warranties are also available.

GENERAL

RAMP

Response Biomedical Corp.
100–8900 Glenlyon Parkway
Burnaby, B.C. V5J 5J8
M. T. Bayliss
Business Development
604–456–6010 (Tel)
604–456–6083 (Fax)
mbayliss@responsebio.com
biodefense@responsebio.com
info@responsebio.com

Information Source:
http://www.responsebio.com/intro.htm

Status: The vendor has responded—11/17/2006

Evaluated: Yes

Technology: Immunoassay

Portability: Mobile Detection Equipment

Unit Cost: Please contact manufacturer

Availability: 24 h availability

Description: Lateral Flow Immunochromatography/Fluorescence

Application: The RAMP System consists of a portable scanning fluorescence Reader and single-use, disposable test cartridges. To use, a small sample is added to the test cartridge and then inserted into the Reader. RAMP provides a positive or negative result in minutes.

Current Users: Diagnostic labs, military, first responders, scientific research labs, hospitals, and industry

OPERATIONAL PARAMETERS

BAs Detected: B. anthracis, orthopox, botulinum toxin, and ricin

Type of Sample: Liquid, solid, surface wipes, or airborne particulates suspended in a liquid. These samples are processed in an inexpensive immunochromatographic test cartridge, with results provided in minutes by a low-cost, portable reader.

Sample Preparation: To perform a test, a suspect surface is swabbed and the sample is recovered into the sample buffer. This takes less than 1 min.

SOP Sample Preparation: The RAMP System consists of a portable scanning fluorescence reader and single-use, disposable test cartridges. To use, a small sample is added to the test cartridge and then inserted into the Reader. RAMP provides a positive or negative result in minutes, with no additional user intervention.

Start-up Time: Upack and plug in

Calibration Requirements: Calibration not required at start-up. Instrument is qualitatively calibrated automatically with every run.

Response Time: Within minutes

Data Analysis Time: Anthrax—15 min

Alarms: Visible and audible

Sensitivity: Anthrax—4000 spores
Orthopoxvirus—3.6 ng
Botulinum toxins—5.0 ng
Ricin—10 ng

Confidence Interval/Sensitivity: Greater than 95 %

Specificity: RAMP's performance has been separately validated by some of the leading research facilities in North America, including the U.S. Army Edgewood Chemical Biological Center, the State of Maryland Department of Health, and DRDC Suffield. The system has consistently demonstrated to be 100 % reliable in detecting anthrax at or above 4000 spores and does not cross-react with interfering substances, such as baking powder, or with nonpathogenic strains of anthrax.

Confidence Interval/Specificity: See testing information

- **False Positives**: None, see testing information
- **False Negatives**: None, see testing information

Resistance to Interferents: Does not cross-react with interfering substances, such as baking powder, or with nonpathogenic strains of anthrax

Testing Information: Recently, the Department of Homeland Security funded AOAC collaborative study declared the RAMP System was the ONLY commercially available rapid anthrax detection system to meet the performance standard, following a comprehensive evaluation of five commercially available field tests at 12 separate laboratories led by U.S. Army Dugway Proving Grounds. The RAMP System received AOAC Official MethodsSM Certificate 070403. All other commercially available rapid anthrax detection systems failed to meet this performance standard. The task force responsible for this evaluation was comprised of 50 experts on anthrax, assay development, validation study design, and statistics from 36 federal and 9 military agencies, including:

- Department of Homeland Security
- Department of Defense
- Food and Drug Administration
- Health and Human Services/Centers for Disease Control
- U.S. Postal Service
- Federal Bureau of Investigation, and representatives of state and municipal agencies, academia, and first responders

Following the AOAC evaluation, RAMP was listed as the only Hand Held Biological Detection Assay on the Department of Homeland Security's I.A.B. Standardized Equipment List and ODP's Authorized Equipment List.

PHYSICAL PARAMETERS

Size: 27 cm x 25 cm x 15 cm (10.5 in x 10 in x 6 in)
Weight: 2.1 kg (4.6 lb)
Working Space: 60 cm x 60 cm (24 in x 24 in)
Total Weight: 0.45 kg (1 lb)
Power Requirements: NiCad battery (up to 12 h continual use)

LOGISTIC PARAMETERS

Durability: Not specified
Ease of Use: RAMP is regularly used by first responders wearing appropriate protective gear
Environmental Conditions: Temperature ranging from -10 ºC to 50 ºC (14 ºF to 122 ºF); 5 % to 50 % rh
Support Equipment: None necessary
Consumables: The RAMP System consists of a portable scanning fluorescence reader and single-use, disposable test cartridges. To use, a small sample is added to the test cartridge and then inserted into the Reader.
Consumable Costs: Approximately $25
Maintenance: 24 h technical support is provided by the manufacturer, a loaner option is available during maintenance or malfunctioning, and the instrument is upgradeable
Shelf Life (Equipment): Not specified
Shelf Life (Consumables): 1 yr minimum shelf life for test cartridges
Maintenance Costs: None necessary
Decontamination: Not specified

SPECIAL PARAMETERS

Skills Required: Special skills not required. Equipment does not require the operator to analyze raw data before a final result can be determined. High school diploma is sufficient.
Training Required: Less than 4 h formal training
Training Available: FREE on-site training with purchase of RAMP Starter Kit. Training results in certification. CD training also available.
Manuals Available: Operator's manual included
Data Storage: The Reader's self-contained memory can store results for up to 500 tests. Data may be printed on the included printer or uploaded to a computer using a standard RS–232 interface cable.
Communications: Computer interface, data transfer capability (interface), and networking capability
Security: The reader can function in an enhanced control manner by enabling the "User Lock-out" function. This requires the supervisor to set a Master P.I.N., which provides controlled access to the SYSTEM SETTINGS Menu. Functions available through the SYSTEM SETTINGS Menu include changing the instrument clock, setting and enabling User Ids and associated P.I.N.s, transferring operator data, erasing data, and setting QC timers. The User Lock-out mode ensures that only operators with a valid supervisor-controlled P.I.N. are allowed to run tests on the Reader.
To operate the Reader with User Lock-out, a user may ensure the SYSTEM SETTINGS Menu has limited access by setting a Master P.I.N. and that a User ID and P.I.N. are defined for each operator.
Safety Requirements: Not specified
Applicable Regulations: Not specified
Warranty: 1 yr parts and labor warranty

GENERAL

Guardian Reader System (P–102)

Alexeter Technologies
830 Seton Court
Suite #6
Wheeling, Illinois 60090
847– 419–1507 (Tel)
847–419–1648 (Fax)
Tom Fryzel
tfryzel@alexeter.com
service@alexter.com
Information Source: http://www.alexeter.com
Status: The vendor has responded—11/21/2006
Evaluated: Yes

Technology: Immunochemical (Imunoassay)
Portability: Mobile Laboratory Detection Equipment

Unit Cost: ~$10K, including 200 test strips, training strips, collection materials and on-site training anywhere in the U.S. Cost per assay of total consumable is $24.
Availability: Lead time is generally 2 wk
Description: Lateral Flow Immunochromatography—Advanced mono- and polyclonal sandwich assays
Reflectance Meter with Linear array optics—The Guardian Reader™ from Alexeter Technologies is designed to accept and analyze BioThreat Alert and BioDetect test strips. The Reader offers greater accuracy, as its optical technology can recognize positive results that might be missed by the human eye, due to faint positives or poor ambient lighting. Sensitivity is generally one order of magnitude higher when using the Reader. Guiding the operator through the evaluation procedure, the Reader provides a printout of the test results and date, while minimizing both type I and type II errors. Embedded radio frequency identification (RFID) technology ensures that the chain of custody is documented for each individual test strip.
Application: Field detection of biological agents from environmental samples
Current Users: State and federal health diagnostic laboratories; U.S. Military; over 1200 hazmat teams; multiple scientific research laboratories; several hospitals; and most "three letter" security agencies in Washington, including the FDA

OPERATIONAL PARAMETERS

BAs Detected: B. anthracis, Brucella abortus, Brucella melitensis, Brucella suis, Brucella canis, Francisella tularenius, Yersinia pestis, orthopoxvirus, botulinum toxins (A and B), ricin, abrin, and S. aureus enterotoxin B
Type of Sample: The Guardian Reader System™ and tests are capable of testing for all types of samples including liquid, solids, surface wipes, and airborne particulates suspended in a liquid
Sample Preparation: The sample preparation requires mixing the substance to be tested with a proprietary buffer solution. A dilution may need to be performed depending on the viscosity of the solution, or type of screening test being used. Sample preparation time is <1 min
SOP Sample Preparation: Powders and granular solids—Wet a swab with buffer solution and take a swipe sample. Mix with 1 mL of buffer solution. Add 5 drops of this mixture to a test strip.
Liquids—Sample the liquid with a dry swab. Mix with 1 mL of buffer solution. Add 5 drops of this mixture to a test strip.
Aerosol samples—Concentrate the aerosol using a particle concentrator such as the BioCapture 650. Add 5 drops of the concentrated sample to a test strip. Note: Depending on the concentration of particles in the air, this method may not yield a sample sufficiently concentrated for evaluation with an immunoassay. Follow up negative results with microbiological evaluation at a qualified laboratory. Detailed SOPs are provided by Alexeter Technologies.
Start-up Time: There are no start-up requirements, just unpack and plug in. The Guardian auto-calibrates using an internal standard. Upon power-up, the Guardian Reader™ takes approximately 30 s to perform a series of self-tests to ensure a successful automatic calibration has taken place.
Calibration Requirements: The Guardian Reader performs a quantitative calibration every time a test in run using internal tiles (NIST traceable standards). No user interaction is required.
Response Time: <5 min
Data Analysis Time: <15 min
Alarms: Visible and audible
Sensitivity: Bacterial tests are generally sensitive at 10^5 CFU/mL
Our only virus test (orthopox) is sensitive to 500 ng/mL
Toxin tests are sensitive from 5 ng/mL to 20 ng/mL

B. anthracis—10^5 CFUs/mL
Brucella abortus—10^5 CFU/mL
Brucella melitensis—10^5 CFU/mL
Brucella suis—10^5 CFU/mL
Brucella canis—10^5 CFU/mL
Francisella tularenius—10^5 CFU/mL
Yersinia pestis—10^5 CFU/mL
Orthopoxvirus—250 ng to 500 ng
Botulinum toxins—20 ng/mL
Ricin—5 ng/mL
S. aureus enterotoxin B—12 ng/mL
Abrin—to be determined

Confidence Interval/Sensitivity: Greater than 95 %

Specificity: Alexeter's test for anthrax does not cross-react with near neighbors BT (Bacillus thuringiensis) or BG (Bacillus globigii). All other tests shall demonstrate at least 95 % specificity across a standard battery of at least 20 other potential interfering substances.

Confidence Interval/Specificity: Greater than 95 %

- **False Positives**: Alexeter's Guardian Reader System™ is currently running at a <0.02 % false positive rate
- **False Negatives**: None to date

Resistance to Interferents: Environmental interferents include soil and pH variations. Spores can be detected. Organisms or proteins the assay cross-react to—the tests are very specific, call Alexeter for details. Organisms or proteins that have been tested in cross-reactivity studies—multiple studies are available, call Alexeter for details.

Testing Information: Independent test results are available from Alexeter by request to http://www.alexeter.com/feedback.htm or by calling Alexeter's customer service department at 847–419–1507

PHYSICAL PARAMETERS

Size: 9 cm x 24 cm x 9 cm (11.5 in x 9.5 in x 3.5 in)

Working Space: Can be operated in both field and lab settings where minimal space is required, i.e., 0.2 m^2 (2 ft^2) would suffice

Weight: 1.6 kg (3.5 lb); weight in carrying case—7 kg (16 lb)

Total Weight: Total system weight, carried into the field is ~7.7 kg (17 lb). Tetracore's BioThreat Alert™ test kit [1 box of 25 tests is 283 g (10 oz)].

Power Requirements: 120 V ac to 240 V ac, an international power adaptor is supplied (line power is not required); 4 AA alkaline batteries (<4 h of continual use)

LOGISTIC PARAMETERS

Durability: Easily hand carried to any location in the field. It is supplied in a watertight case. The Guardian Reader autocalibrates if it is moved or dropped. It may be left in hot or cold environments without effect.

Ease of Use: Can be used up to Level A protective gear. The Guardian Reader's large button format was designed with hazmat operations in mind, while eliminating subjective judgment calls in low-light or highly stressful situations.

Environmental Conditions: Operating temperature range: 4 ºC to 41 ºC (40 ºF to 105 ºF)
Storage temperature range: -29 ºC to 60 ºC (-20 ºF to 140 ºF)
Not above 80 % humidity for temperatures up to 31 ºC (87.8 ºF), decreasing linearly to 50 % above 40 ºC (104 ºF)
Keep out of direct sunlight, rain, and snow

Support Equipment: None required

Consumables: Sample swab, vials and buffer solution, all provided with the test kits

Consumable Costs: Each test strip costs approximately $24, including all consumables required. Quantity discounts are available.

Maintenance: Preventative maintenance is not required. Alexeter provides worldwide technical support 24/7. Any malfunctioning unit will be replaced while under warranty. Extended warranties are available. Because the Guardian Reader is software-driven, upgrades are simply flashed to nonvolatile memory inside the unit. For example, new biological agents and changing test parameters can be easily accommodated.

Shelf Life (Equipment): Battery in the reader can be stored up to 5 yr. Equipment's estimated life span is 10 yr.

Shelf Life (Consumables): >1 yr

Maintenance Costs: Recertification is required after 5 yr of deployment

Decontamination: Wipe down outer surfaces. Paraformaldehyde gas decontamination has also been employed. For Hazmat teams, Alexeter will replace, free of charge, any unit contaminated with one of the biological agents listed. Call for details.

SPECIAL PARAMETERS

Skills Required: Hazmat technician level training, or high school diploma, is adequate. The operator is not required to analyze raw data to determine a final result. The Reader delivers objective "Positive" or "Negative" results.
Training Required: No special skills but <8 h formal training is required
Training Available: Alexeter System Training is offered onsite (where equipment will be used or stored). Manual training is also available. Training does not result in certification.
Manuals Available: Full manual shipped with each unit. Updates area always available on Alexeter's website.
Data Storage: Internal data storage and printout provided for last 200 tests. All test results are written directly to an RFID contained in each test strip. All test results can be exported to a PC via serial cable.
Communications: Serial communication interface provided for data transfer capability (interface)
Security: RFID secures test data
Safety Requirements: Consult OSHA regulations
Applicable Regulations: No regulations currently apply to environmental testing
Warranty: 1 yr warranty standard, extended warranties available. Equipment's estimated life span is 10 yr.

GENERAL

BioThreat Alert™ Bio Threat Test Strips

Tetracore, Inc.
9901 Belward Campus Drive
Suite 300
Rockville, Maryland 20850
240–268–5400 (Tel)
240–268–1107 (Fax)
Customer support: service@alexeter.com
General Information: Info@alexeter.com
Sales@alexeter.com
Information Source: http://www.tetracore.com
http://www.alexeter.com
Status: The vendor has responded—11/22/2006
Evaluated: Yes

Technology: Immunochemical
Portability: Mobile Laboratory Detection Equipment

Unit Cost: Anthrax—(box of 25) $605 (unit cost $24)
Ricin—(box of 25) $605 (unit cost $24)
Bot Tox—(box of 25) $605 (unit cost$24)
SEB—(box of 25) $605 (unit cost $24)
Plague—(box of 25) $605 (unit cost $24)
Tularemia—(box of 25) $605 (unit cost $24)
Brucella—(box of 25) $605 (unit cost $24)
Orthopox—(box of 25) $605 (unit cost $24)
Abrin—(box of 25) $605 (unit cost $24)
* Call Tetracore for most current pricing (240–268–5400)
*Tetracore products are considered authorized equipment purchases for OJP Domestic Preparedness Equipment Program Funds. See www.ojp.usdoj.gov.
Availability: Tetracore's BioThreat Alert™ test strips are available through Tetracore and are in stock, guaranteed to ship within 15 business days
Description: Lateral Flow Immunochromatography—The BioThreat Alert™ test strips from Tetracore utilize lateral flow devices in which reagents are separated across the test strip, allowing for fewer false positives in environmental samples. The technology employs two antibodies in combination to specifically detect a target substance in solution. When the level of the target substance is present in the sample above a certain concentration, the antibodies and target substance combine in the test strip to form a reddish band that appears in a window. The test is positive if two colored lines appear. If only one colored line appears in the "C" window, the test is negative.
Application: The BioThreat Alert™ test strip system is designed for the rapid collection, detection, and identification of threatening BAs in the field. The system can be used in both field and laboratory applications but is not intended for use on clinical samples. The test strips for anthrax have no cross reaction with common bacteria such as commercial form of B. thuringiensis.
Current Users: Tetracore began shipping the BioThreat Alert™ test strips in August 2000. They are currently being used by first responders, law enforcement, military, federal, state, and local governments, and corporate security professionals, both domestic and international.

OPERATIONAL PARAMETERS

BAs Detected: The system tests for multiple biowarfare agents including, but not limited to, anthrax, SEB, plague, tularemia, ricin, botulism toxin, brucella, abrin, and pox
Type of Sample: The BioThreat Alert™ tests are capable of testing for all types of samples including powders, liquids, and solids. Aerosols can be tested using additional equipment.
Sample Preparation: The sample preparation requires mixing the substance to be tested with a proprietary buffer solution. A dilution may need to be performed depending on the viscosity of the solution, or type of screening test being used.
SOP Sample Preparation: Detailed SOPs are provided by Tetracore
Start-up Time: The BioThreat Alert™ test strips may be used as a stand-alone, providing a visual indication in the 1 min to 15 min range
Calibration Requirements: The BioThreat Alert™ test strips are factory-calibrated to ensure accuracy

Response Time: The BioThreat Alert™ test strips may be used as a stand-alone, providing a visual indication in the 1 min to 15 min range
Data Analysis Time: Results can be read in 1 min to 15 min
Alarms: When the target substance is present at or above the detectable amount in the test sample (the TV-threshold value), a reddish "band" or "stripe" will appear in the sample "S" window of the BioThreat Alert™ test strip. Two red lines indicate a positive assay, (one under the sample line "S" and one under the control line "C"). No control line indicates an incomplete assay.
Sensitivity: Anthrax (Bacillus anthracis)—10^5 CFUs/mL
Plague (Yersinia pestis)—10^5 CFUs/mL
Tularemia (F. tularensis)—7×10^4 CFUs/mL
Ricin (Communis Agglutinin II)—50 ng/mL
Bot tox (Botulimun Toxin)—10 ng/mL
SEB (Staphylococcal Enterotoxin B)—2.5 ng/mL
Brucella—1 µg/mL to 2 µg/mL
Orthopox—250 ng/mL to 500 ng/mL
Abrin—10 ng/mL to 20 ng/mL
Confidence Interval/Sensitivity: Not applicable
Specificity: The BioThreat Alert™ test for anthrax does not cross-react with near neighbors BT (Bacillus thuringiensis) or BG (Bacillus globigii). All other tests shall demonstrate at least 95 % specificity across a standard battery of at least 20 other potential interfering substances.
Confidence Interval/Specificity: Not applicable

- **False Positives**: Alexeter's Guardian Reader System™ is currently running at a <0.2 % false positive rate in "actual" field use, according to a survey of top hazardous material teams using the Guardian System™ in the U.S. since the "Anthrax Scares" of 2001
- **False Negatives**: To date, Alexeter has had "0" false negatives reported with Tetracore's BioThreat Alert™ tests in field use

Resistance to Interferents: All BioThreat Alert Tests show minimal interference against a standard battery of substances that include—Bacillus thuringiensis (spore and vegetative cells), Bacillus globigii (spore and vegetative cells), bovine serum albumin, ovalbumin, Naproxin sodium, acetaminophen, talc, red clay, gravel, and mulch
Testing Information: Independent test results are available from the company by request to http://www.alexeter.com/feedback.htm or by calling The Alexeter Customer Service Department at 847–419–1507. The CDC/FBI test results are available on Alexeter's website at www.alexeter.com.

PHYSICAL PARAMETERS

Size: Each test ~2.5 cm x 7.6 cm (1 in x 3 in)
Working Space: The BioThreat Alert ™ tests can be operated in both field and lab settings where minimal space is required
Weight: Tetracore's BioThreat Alert™ test kit [1 box of 25 tests is 283 g (10 oz)]
Total Weight: Tetracore's BioThreat Alert™ collection kit weighs approximately 283 g (10 oz)
Power Requirements: No power requirements

LOGISTIC PARAMETERS

Durability: Not applicable
Ease of Use: The BioThreat Alert™ tests can be operated in both Level A and Level B protective gear
Environmental Conditions: Operating temperature range: 4 ºC to 41 ºC (40 ºF to 105 ºF) fermented
Support Equipment: Proficiency Test Strips (used for training on the proper use of the Guardian Reader system without consuming the Biothreat Alert™ Test strips). Contains 10 positive control and 10 negative control tests strips. Highly recommended on any initial customer purchase.
Standard collection kit—Contains 3 bottles of Biothreat Alert Sample buffer, 25 sample collection vials, 25 alcohol pads, 3 pairs of tweezers, 3 pairs of scissors, 5 spatulas, 25 cotton-tipped swabs, and 1 permanent marker.
Consumables: The BioThreat Alert™ buffer solution
Consumable Costs: The BioThreat Alert™ buffer solution can be provided by Alexter Technologies at no charge upon the customer's request
Maintenance: No maintenance is required other than replacing the BioThreat Alert™ test strips upon expiration
Shelf Life (Equipment): The BioThreat Alert™ test strips and Guardian Reader™ do not require refrigeration and should be stored above freezing (15 ºF to 130 ºF). The test strips must be protected from repeated freeze-thaw cycles and should not be

stored in direct sunlight or above 90 ºF for prolonged periods of time. Bring the Guardian Reader™ and BioThreat Alert™ test strips to room temperature before use.
Shelf Life (Consumables): Stored at room temperature 15 ºC to 30 ºC (59 ºF to 86 ºF). Unopened BioThreat Alert Test Strips have a shelf life of 12 mo from manufacture.
Maintenance Costs: Upon expiration, tests can be purchased through Alexeter Technologies at $605 per box
Decontamination: Not applicable

SPECIAL PARAMETERS

Skills Required: The BioThreat Alert™ tests should only be operated by trained professionals with a working knowledge of hazardous materials
Training Required: 4 h in service training performed by one of Alexeter's certified hazardous material trainers
Training Available: A complete training program is offered that includes a 4 h lecture/laboratory class on site at the customer's location. Currently, Alexeter has approximately 70 trainers nationwide. Also an Anthrax Response Training Video is available.
Manuals Available: The Guardian Reader System™ comes with operating manuals and reference guides for both the Guardian Reader™ and BioThreat Alert™ test strips
Data Storage: The BioThreat Alert™ tests contain an RFID microchip embedded in the test strip. This enables it to be read elsewhere so it can be tracked through a laboratory analysis and also serve as a basis for evidentiary purposes.
Communications: Not applicable
Security: Embedded RFID microchips in each strip ensure chain-of-custody
Safety Requirements: As with all screening tests, result from any of the BioThreat Alert Test Strips should be confirmed by a qualified reference laboratory
Applicable Regulations: Product covered by ITAR regulations and require State Department Export license for exportation
Warranty: Not applicable

GENERAL

MICROCYTE® Field Family
MICROCYTE® Field and MICROCYTE® Aqua

BioDETECT AS,
Olav Helsetsv 5, inng. K
POB 56 Bogerud, N–0621
Oslo, Norway
+47 91354691 (Tel)
+47 22628152 (Tel)
+47 22628153 (Tel)
+47 22628151 (Fax)
POC: Per Brandshoi (U.S. Sales Manager)
Email: brandshoi@biodetect.biz
+47 22628152 (Tel)
+47 22628153 (Tel)
+47 91354691 (Tel-Mobile)
+47 22628151 (Fax)
Information Source: http://www.biodetect.biz
Status: The vendor has responded—11/17/2006
Evaluated: Yes

Technology: Physical
Portability: Mobile Laboratory Detection Equipment

Unit Cost: Not specified
Availability: Not specified
Description: Flow Cytometry—Rapid counting and analysis of biological cells and other microscopic particles in a liquid by the use of a laser. The patented optical design, where all lenses, filters, light source, detectors, and flow cell are mounted in one, solid aluminum block, facilitates enhanced sensitivity and stability. For detection of scattered and fluorescent light solid-state photo detectors are used.

Light source: 5 mW diodelaser, avalanche photo diode (wavelength 650 nm to 900 nm)
Fluorescence detector: Avalanche photo diode, wavelength 650 nm to 900 nm
Flow cell: Closed flow channel, 0.25 mm x 0.25 mm
Sample: 100 µl to 1 ml in micro centrifuge tubes
Concentration range: 1×10^2 to 1×10^7 particles per mL
Detection limit: 10 particles per mL
Analyzing volume: 1 µL 10 µL, or 100 µL (corresponding to analyzing time of 2 s, 20 s, or 200 s, respectively)
Settings: Light scatter/fluorescence, log/linear amplifications, and threshold gating

Application: Truly portable flow cytometer products are used both as an on-site test instrument in the pharmaceutical industry and in and beverage production. BioDETECT provides a complete detection system, consisting of the MICROCYTE® instrument and complementary nucleic acid stains, that within minutes reveals whether an air, water, or powder sample is potential dangerous. Rugged, portable flow cytometer for on-site verification of potentially contaminated sources or suspicious material and bio-surveillance.
Current Users: Military, civil defense, large multinational pharmaceutical companies, water works, and several NATO military organizations. The MICROCYTE® may be used in force protection and to secure employee, customer, and public safety, as well as accommodate smooth operations of governmental services, airports, railway stations, or other places where the public gather.

OPERATIONAL PARAMETERS

BAs Detected: It detects fluorescence and light scatter for counting cells or particles in the 0.4 µ to 15 µ size range
Type of Sample: Air, water, or powder sample
Sample Preparation: Common for all applications are simple sample preparations and rapidly obtained results
SOP Sample Preparation: Not specified
Start-up Time: Not specified
Calibration Requirements: Calibrate the instrument by the 17 min test and with the manufacturer calibration kit (PDF, 500 KB). Particles with defined size and fluorescence are used to test and calibrate the instrument to ensure stable operating conditions.

Response Time: Within minutes. At BioDETECT we aim at offering reliable results within 1/3 of the equivalent time used by traditional cultivation methods.
Data Analysis Time: Not specified
Alarms: Not specified
Sensitivity: Light scatter sensitivity—0.4 µm to 15 µm measured with mono disperse polymer particles (C.V. = 5 %)
Fluorescence sensitivity—1000 to 100 000 molecules equivalents of Cy-5 (C.V. = 5 %)
The detection limit is determined by how carefully the background level in the sample is controlled. Fluorescent particles (i.e., algae) may be detected at levels <10 per mL.
Confidence Interval/Sensitivity: Light scatter sensitivity—0.4 µm to 15 µm measured with mono disperse polymer particles (C.V. = 5 %)
Fluorescence sensitivity—1000 to 100 000 molecules equivalents of Cy-5 (C.V. = 5 %)
Specificity: Not specified
Confidence Interval/Specificity: Counting may be performed in two independent regions of interest. The wavelength of the laser reduces the problem with auto-fluorescence from most bacteria. Auto-fluorescence from algae may be used to analyze these microorganisms without the use of dyes.

- **False Positives**: Not specified
- **False Negatives**: Not specified

Resistance to Interferents: Advantageous of applying linear amplification rather than logarithmic:
• When two peaks overlap in the "large region" of the display (i.e., over 1 mm), switching to linear mode can help in separating these peaks. Useful feature for DNA-analysis in FL mode and analysis of blood cells of similar sizes.
Special features of the optics that allow simultaneous detection of light scatter and fluorescende:
• Two detectors, dichroic filters, long pass filter, quarter wave plate allow simultaneous detection of light scatter and fluorescence.
A red diode laser is used because it is small, uses little power, has long lifetime (20 000 h), has low noise, and has a wavelength that eliminates undesired autofluorescence from bacteria.
Testing Information: FFI/Rapport—2002/00772 (Norwegian Defense Research Establishment)

PHYSICAL PARAMETERS

Size: 43 cm x 16 cm x 33 cm (16.9 in x 6.3 in x 13 in)
Working Space: Not specified
Weight: 12 kg (26.4 lb)—Microcyte Field; 11.8 kg (26 lb)—Microcyte Aqua
Total Weight: Not specified
Power Requirements: 12 V dc to 18 V dc, 2 A, from battery pack; mains adapter (100 V ac to 240 V ac 50/60 Hz) or car battery (12 V); internal 2 V, 2.5 Ah, rechargeable NiCad battery—2 h to 3 h use. The internal battery is 2.2 Ah, which at 0.7 A gives a theoretical "life span" of 3.1 h.

LOGISTIC PARAMETERS

Durability: Cabinet is aluminum
Ease of Use: The MICROCYTE® can be operated from the instrument itself. No instrument adjustments are required prior to analysis. Results are presented directly as counts per mL. Files can be saved in several formats for subsequent analysis (e.g., Excel). The software provides four modes of data registration and controls the automatic washing functions. Results are presented as dot plot or as color histograms.
Environmental Conditions: Flow rate is influenced by temperature, viscosity, and the liquid level of the sheath fluid tank and the sample tube
Support Equipment: Not specified
Consumables: Suitable dyes—TOTO-3, TO-PRO-2, APC, Cy-5, CNFDA, NFDA, and SYTO 60-63
Stain yeast, bacteria, and microorganisms with staining kits (PDF, 300 KB)
Consumable Costs: Not specified
Maintenance: Keep your Microcyte uncontaminated with: Maintenance kits (PDF, 300 KB)
Shelf Life (Equipment): Not specified
Shelf Life (Consumables): Not specified
Maintenance Costs: Not specified
Decontamination: Autowash routines in software. External tanks for sheath fluid and waste reduce the contamination risk of the instrument.

SPECIAL PARAMETERS

Skills Required: Not specified
Training Required: Not specified
Training Available: Not specified
Manuals Available: PDF files
Data Storage: Optional software for instrument control and data registrations.
Minimum requirements:

- Microsoft Windows NT
- Windows 95 or later
- Minimum 500 MHz
- Serial port for connection to MICROCYTE®
- Color monitor, minimum 256 colors
- 800 x 600 resolution
- Minimum 256 MB RAM

Communications: One 2.5 mm jack for dc supply
Light scatter signal outlet, BNC plug (female)
Fluorescence signal outlet, BNC plug (female)
RS-232C, 9 pin D-type (male)
Two tube connections for external containers for sheath fluid and waste (standard feature on Microcyte Lab and BPC)
Security: Not specified
Safety Requirements: Not specified
Applicable Regulations: Not specified
Warranty: 2 yr on workmanship and materials. Customers can enter into an extended global warranty by signing a service contract. With a service contract, BioDETECT will immediately provide a replacement unit during repair of any nonfunctioning MICROCYTE®.

GENERAL

Analyte 2000 Biowarfare Detection (Analyte 2000 Fiber Optic Fluorometer)

Research International, Inc.
17161 Beaton Road SE
Monroe, Washington 98272
East Coast Office:
Jonathan Tobelmann, Director of Marketing
703–803–8380 (Tel)
jtobelmann@cs.com
info@resrchintl.com
Information Source: http://www.resrchintl.com

Status: The vendor has responded—10/31/2005
Evaluated: Yes

Technology: Physical
Portability: Mobile Laboratory Detection Equipment

Unit Cost: $15K—single channel configuration; $32K—4 channel configuration
Availability: 90 d
Description: Optical Wave Technology/Laboratory evanescent wave fiber optic fluorometer—The Analyte 2000™ is a patented 4-channel, solid-state fluorometer system based on careful integration of optics, electronics, and software. It can monitor the progress of immunological reactions on exposed optical waveguide surfaces using fluorescent-tagged reagents. Up to four sensor waveguides can be simultaneously interrogated with 635 nm light and monitored for fluorescence levels. This system, about the size of a large brick, has been optimized for use in the development of fiber optic immunoassays in which sample and reagent introduction are separately controlled.
Application: May be used for any sensing application that can generate a fluorescent signal. Used primarily for fluoroimmunoassay development for bioweapons and diagnostics. With the addition of fluidic handling systems, it has been flown in UAVs. It has seen considerable used as a remotely RF-controlled biodetector in UAVs and has gained a reputation for ruggedness, and an ability to survive airframe crashes.
Current Users: Naval Research Laboratory since 1995—UAV applications, assay development
University of South Florida, Daniel Lim, since 1999—assays for food pathogens and bioweapons
USDA since 1999—bacterial contamination of sprouts
University of Maryland, M Eldefrawi, since 1998—drugs of abuse assays
U.S. Army, Natick

OPERATIONAL PARAMETERS

BAs Detected: Any for which antibodies are available in either sandwich or competitive formats.
Assays have been developed for: Cocaine, TNT, RDX, ovalbumin, ricin, Staphylococcal enterotoxin B, Cholera toxin, D-dimer, Protein C, Bacillus globigii, Bacillus anthracis, Erwinia herbicola, Yersinia pestis F1 antigen, Brucella abortus, Francisella tularensis, Escherichia coli O157:H7, Salmonella typhimurium, Giardia lamblia, and MS2, RSV.
Type of Sample: Liquids and suspensions
Sample Preparation: The sample must be in solution with a particulate size that will not plug the cuvette (<0.5 mm)
SOP Sample Preparation: Not applicable
Start-up Time: 15 min for instrument warm-up and 15 min for baseline assay
Calibration Requirements: Hardware calibration is performed automatically. Assay calibration is performed during preparation of waveguides.
Response Time: 15 min
Data Analysis Time: Performed on off-board computer in spreadsheet program. Time required is 1 min to 15 min, depending on sophistication of user.
Alarms: Not applicable
Sensitivity: Ovalbumin—0.005 µg/mL
Ricin—0.001 µg/mL
Staphylococcal enterotoxin B—0.1 to 0.5 ng/mL
Cholera toxin—0.1 ng/mL to 1 ng/mL
D-dimer—0.2 µg/mL
Protein C—0.16 µg/mL

Bacillus globigii—2.5 x 10^4 CFU/mL
Sterne strain—100 CFU/ml
Ames strain, irradiated—5 x 10^4 CFU/mL
Erwinia herbicola—10^7 CFU/mL
Yersinia pestis F1 antigen—0.001 µg/mL
Brucella abortus—7 x 10^4 CFU/mL
Francisella tularensis—5 x 10^4 CFU/mL
Escherichia coli O157:H7—100 CFU/g to 1000 CFU/g (direct)
0.08 CFU/g to 0.4 CFU/g (6 h enrichment)
Salmonella typhimurium—2 x 10^4 CFU/mL
Giardia lamblia—5 x 10^4 CFU/mL
MS2—10^9 pfu/mL

Confidence Interval/Sensitivity: Not determined
Specificity: Dependent on antibody
Confidence Interval/Specificity: Not determined

- **False Positives**: Not determined
- **False Negatives**: Not determined

Resistance to Interferents: Not determined
Testing Information: Not available

PHYSICAL PARAMETERS

Size: 20 cm x 11 cm x 9 cm (7.9 in x 4.4 in x 3.4 in)
Working Space: From 12 cm^2 to 131 cm^2 (0.4 ft^2 to 4.3 ft^2) depending on operating scenario
Weight: 1.6 kg (3.53 lb) for instrument; 0.5 kg to 2 kg (1.1 lb to 4.4 lb) for batteries, depending on operating scenario
Total Weight: 1 kg (2.2 lb)
Power Requirements: 12 V wall plug transformer or rechargeable battery pack; 2 W nominal power consumption

LOGISTIC PARAMETERS

Durability: Rugged—has survived UAV crashes
Ease of Use: Can be easy to use but not designed for MOPP suit operation
Environmental Conditions: Not applicable
Support Equipment: Windows based software provided
Host hardware requirements include IBM 486, 100 MHz or compatible, 8 MB RAM running Windows 95
Consumables: Antibody-coated optical waveguide; buffer—5 mls; secondary antibody solution (reusable)—100 µL
Consumable Costs: $1 to $10 depending on antibody costs
Maintenance: Cleaning of optical surfaces and cuvettes, which is easily performed by operator
Shelf Life (Equipment): Hardware has indefinite storage period
Shelf Life (Consumables): Antibody-coated waveguides and lyophilized secondary antibody mixture can be stored for 3 mo to 6 mo. Requires 5 min hydration period.
Maintenance Costs: $500 per yr
Decontamination: Clean with 5 % bleach (sodium hypochlorite) solution

SPECIAL PARAMETERS

Skills Required: B.S. level education
Training Required: Less than 1 wk
Training Available: Manual training is sufficient. On-site training offered.
Manuals Available: Yes
Data Storage: Requires off-board computer for operation and data storage.
Data logging also incorporates an event feature that allows the user to insert markers into the data file at random points.
Communications: Communication and manipulation of incoming data is performed on a host PC that is connected to the fluorometer via an RS-232 link. The system also features RS-232 output, allowing the transmission of data from a remote location via telephone lines or an RF communications link. This connection may be hardwired or wireless.
Security: None
Safety Requirements: Not applicable
Applicable Regulations: Not specified
Warranty: There is no formal warranty because this is a prototype instrument. Generally 1 yr service is provided.

GENERAL

RAPTOR Plus

Research International, Inc.
17161 Beaton Road SE
Monroe, Washington 98272
East Coast Office:
Jonathan Tobelmann, Director of Marketing
703–803–8380 (Tel)
jtobelmann@cs.com
Information Source: http://www.resrchintl.com

Status: The vendor has responded—10/28/2005
Evaluated: Yes

Technology: Immunochemical
Portability: Mobile Laboratory Detection Equipment

Unit Cost: Hardware—$50K; consumables—$100; coupon and reagents—$~200 depending on agents
Availability: Lead-time is 30 d to 90 d depending on build schedule. Assay coupons for anthrax and ricin require 30 d.
Description: Immunochemistry—"sandwich format" fluoroimmunoassay—The RAPTOR is an automated fluoroimmunoassay system for the rapid detection of protein toxin, viruses, and bacteria.
Optical Waveguide—Waveguide (excitation and detection of fluorescence)
Application: The RAPTOR (Rapid Automatic Portable Fluorometric Assay System) may be used for environmental, water safety, food safety, and biowarfare applications. It may be used in both portable and fixed-site scenarios. It represents a careful integration of optics, fluidics, electronics, and software into one compact system for use in laboratory settings and field assays. This unit can automatically perform a user-defined, multistep assay protocol while simultaneously tracking fluorescently-tagged chemical reactions occurring on the surface of each of the system's four disposable optical waveguide sensors. Each waveguide may be functionalized for a different assay, allowing simultaneous monitoring of up to four different pathogens. Up to 63 different assay recipes can be stored in the RAPTOR at one time. To run an assay after coupon insertion, the user simply presses the "Run Assay" key.
Current Users: Military—13 units in use for up to 6 yr
University research—11 units in use for 3 yr
Mailrooms—4 units in commercial mail sorting facilities for 2 yr

OPERATIONAL PARAMETERS

BAs Detected: Any for which antibodies are available in either sandwich or competitive formats. Assays have been developed for Bacilus anthracis, Brucella abortus, Francisella tularenius, Salmonella typhimurium, Vibrio cholerae, Yersinia pestis, E. coli O157:H7, Orthopoxvirus
Botulinum toxins, Ricin, and Staphylococcal aureus enterotoxin B.
Type of Sample: Air—particulates must be collected
Solid, sludge, and surface wipes must all be extracted into liquid. Airborne particulates must be suspended in a liquid.
Sample Preparation: Minimal sample preparation is required. Filtration to remove large particles and buffering to avoid denaturation of the antibodies. Even crude food and sewage preps may be analyzed.
Less than 1 min for most liquids and swabs
Less than 15 min for solid samples
SOP Sample Preparation: Airborne particulates—filter through a 250 µ filter
Swabs, etc.—extract into buffer for 1 min to 2 min, filter if necessary
Liquids—filter through 250 micron filter, adjust pH if very high or low
Solids—extract into buffer, filter through 250 µ filter
Start-up Time: Detector start-up is less than 30 min. Assembly set-up requires 5 steps: Unpack, plug in if using mains power, hydrate reagents, insert coupon, and prepare filler buffer container.
Calibration Requirements: Equipment auto-calibrates at start-up. Calibration curves for assay coupons are generated during assay development by manufacturer or third party. Quality control verifies that new batches match cal curve.
Response Time: Response time is less than 15 min, depending on assay
Data Analysis Time: Analysis and interpretation time is less than 1 min

Alarms: Auto, visible, and audible alarms are optional
Sensitivity: Bacteria—10^4 CFU/mL to 10^5 CFU/mL
Virus—10^5 PFU/mL to10^7 PFU/mL
Toxins—0.1 ng/mL to 1.0 ng/mL
Bacilus anthracis—50 CFU/mL
Brucella abortus—7 x 10^4 CFU/mL
Francisella tularenius—5 x 10^4 CFU mL
Salmonella typhimurium—5 x 10^5 CFU/mL
Vibrio cholerae—Toxin @ 1 ng/mL
Yersinia pestis—1F1 antigen @ 1 ng/mL
E. coli O157:H7—1 x 10^3 CFU/mL
Orthopoxvirus—Vaccinia 2.5x10^5 pfu/mL
Botulinum Toxins—1 ng/mL
Ricin—1 ng/mL
Staphylococcal aureus enterotoxin B—0.5 ng/mL
Confidence Interval/Sensitivity: Assay development and third party testing. LoD is set at 95 % confidence level
Bacteria, viruses, toxins—CFU/mL, PFU/mL, ng/mL
Specificity: Related to antibody. E.coli O157:H7 specificities are >10 000.
Confidence Interval/Specificity: Not determined

- **False Positives**: <0.1 % when tested in an environment with few true positives
- 1 % to 2 % when tested in an environment with frequent true positives
- **False Negatives**: 1 % when agent is 10 times LOD

Resistance to Interferents: Environmental interferents include temperatures below freezing, temperatures above 50 °C (122 °F), pH outside 4 to 9 range. Instrument detects spores and antibodies determine cross reactivity.
Testing Information: Validated tests have been performed at Dugway Proving Ground, Naval Medical Research Center, and Naval Research Laboratory

PHYSICAL PARAMETERS

Size: 28 cm x 19 cm x 20 cm (11 in x 7.3 in x 8 in)
Working Space: 0.8 m sq (2.7 ft sq)
Weight: 5.6 kg (12.3 lb) without battery; 6.4 kg (14.2 lb) with battery
Total Weight: Carrying case 0.9 kg (2 lb)
Buffer 0.09 kg (0.2 lb)
Syringes and filters 0.09 kg (0.2 lb)
Total weight including carrying case with shoulder strap is 7.53 kg (16.6 lb)
Power Requirements: BA5590/U primary battery; BA5590/U extended life battery provides for 24 h operation

LOGISTIC PARAMETERS

Durability: May be used in both portable and fixed-site scenarios. Equipment is able to be transported quickly without protective packaging, to be dropped from counter height without effect, left in hot environment and cold environment (above freezing) without effect. Passed MIL–SPEC 810–E tests.
Ease of Use: Operable by unskilled personnel in files (designed for Marines and special forces). Ability to add about 1 mL of sample to instrument and push button.
Environmental Conditions: Operates in field above freezing and below 45 ºC (113 ºF); 5 % and 90 %
Support Equipment: Computer required to download assay files. Not required for field operation.
Consumables: Test tube for extraction, syringe and 250 µ filter, and water or buffer (~ 7 mls); coupon with 4 different primary capture antibodies
Secondary antibody reagents, antibodies will last 12 h to 24 h and up to 50 assays depending on conditions
Consumable Costs: Cost per assay is ~$1 when 50 tests for 4 different agents are performed with one set of reagents and coupon
Maintenance: Daily clean with water (no positives)—15 min
Monthly clean with bleach (no positives)—30 min
Yearly calibrate pumps and optics
There is no 24 h technical support nor loaner option available. However, software upgrades are provided free of charge and hardware upgrades are provided if feasible.
Shelf Life (Equipment): Hardware can be stored indefinitely

1 y shelf life for tubing (may be distorted if stored for more than 1 yr)
Shelf Life (Consumables): 6 mo cold storage lifetime of antibody components
Maintenance Costs: Estimated costs for end user <$500
Daily clean with water (no positives)—15 min <$5
Monthly clean with bleach (no positives)—30 min <$10
Yearly calibrate pumps and optics—$2K (service contract)
Decontamination: Unit may be immersed in 5 % sodium hypochlorite for decontamination. Alternatively unit may be treated with ethylene oxide.

SPECIAL PARAMETERS

Skills Required: ield operation may be performed by unskilled personnel. Operator does not have to analyze raw data. Lab operation and assay development performed by biochemists with advanced degrees.
Training Required: Formal training (less than 8 h) is required
Training Available: Classroom (offsite or onsite) or manual training. Training does not result in certification.
Manuals Available: User manual and training presentation
Data Storage: All assay data is stored on the system during field use. Currently, memory can hold about 200 assays. Data must be downloaded to a computer after field use.
Communications: Computer (control)—can be operated as stand alone or from computer
Computer interface—custom windows program
Data transfer Capability (Interface)—RS–232
Radio frequency (RF) communication—low power RF link available as option
Hardwire capability—RS–232 connection standard
Security: None
Safety Requirements: None
Applicable Regulations: None
Warranty: 1 yr parts and labor warranty on hardware. No warranty on assays at this time.

GENERAL

GeneXpert® System (GX1000N4–1)

Cepheid
904 Caribbean Drive
Sunnyvale, California 94089
408–541–4191 (Tel)
408–541–4192 (Fax)
Technical Support:
888–838–3222 (Tel)
408–734–1346 (Fax)
Customer Service
888–838–3222 (Tel)
408–734–1260 (Fax)
Information Source:
http://www.cepheid.com/pages/home.html
Status: The vendor has responded—11/17/2006
Evaluated: Yes

Technology: Molecular
Portability: Mobile Laboratory Detection Equipment

Unit Cost: GeneXpert, 1 Site First Response System, Laptop and TD case $22K; GeneXpert, 2 Site First Response System, Laptop and TD case $37K; GeneXpert, 3 Site First Response System, Laptop and TD case $51K
Availability: The 2005 introduction of the GeneXpert® System into the market, with its "sample in, answer out" ease-of-use, moves genetic assessment into the realm of routine clinical care. By automating the entire testing process in a self-contained closed cartridge, GeneXpert System expands genetic testing beyond hospital and laboratory settings and into physician's offices, clinics, and other point-of-care settings. The GeneXpert was certified and designated as a Qualified Anti-Terrorism Technology (QATT) under the DHS SAFETY Act in March 2006.
Description: Real Time PCR—Integrated sample preparation for automated and self-contained testing. The GeneXpert® System is the world's first and only real-time PCR instrument which combines fully integrated sample preparation with the amplification and detection process. The cornerstone of the GeneXpert testing process are Cepheid's patented, self-contained, single use cartridges. This ground-breaking technology allows laboratory and nonlaboratory personnel to conduct sophisticated molecular-based testing in a wide range of environments—including hospitals, research laboratories, physician offices, public health clinics or factories. Most DNA analysis and detection procedures start with DNA that has been extracted or removed from the sample. In many cases, samples are complex in composition (whole blood, human cells or tissue, swabs) and the associated sample preparation protocols are complex and time-consuming. In addition, many real world applications involve detection of a very small number of pathogens or target genes in a large volume of sample.
Application: The GeneXpert System is a 1 to 4-site, random access instrument integrating real time amplification and detection features seen in the SmartCycler System, but delivering results from unprocessed samples in less than 30 min. The internal module is the common technology link between the SmartCycler and GeneXpert, performing real time amplification and detection. The GeneXpert automates sample preparation, integrating the complex steps of DNA extraction in the microfluidic cartridges. Each GeneXpert cartridge also incorporates a syringe drive, rotary drive and a sonic horn. The sonic horn delivers ultrasonic energy necessary to lyse the raw specimen and release nucleic acids contained within, while the combination of the syringe drive and rotary drive moves liquid between cartridge chambers in order to wash, purify, and concentrate these nucleic acids. After the automated extraction is complete, the nucleic acid concentrate is moved into the cartridge reaction chamber where amplification and detection takes place. The GeneXpert software and barcode scanner easily manage data and display results. The GeneXpert has a small footprint and low power requirement making it suitable for applications requiring portability.
Current Users: The GeneXpert module forms the core of the Biohazard Detection System deployed nationwide by the U.S. Postal Service for anthrax testing in mail sorting facilities. In use for 2 yr at the Department of State for mail and package screening.

OPERATIONAL PARAMETERS

BAs Detected: Bacillus anthracis, Francisella tularensis, and Yersinia pestis
Type of Sample: Liquid, solid, sludge (in most cases), surface wipes and swabs, airborne particulates suspended in a liquid, e.g., water as an output resulting from a cyclone separator device such as a SpinCon
Sample Preparation: All sample preparation is achieved automatically within the assay cartridge after a 1mL to 3 mL raw sample is introduced into the cartridge

SOP Sample Preparation: 1. Using the pipette tip provided puncture the cartridge seal in the three areas marked "1","2", and "S"

2. Pipette 1.5 mL of raw sample into the cartridge chamber thru the hole on the seal marked "S"
3. Squeeze entire contents of buffer 1 bottle into cartridge chamber thru the hole on the seal marked "1"
4. Squeeze entire contents of buffer 2 bottle into cartridge chamber thru the hole on the seal marked "2"
5. Click on "Create Test"
6. Barcode cartridge ID
7. Select available site and insert cartridge
8. Close door and wait ~40 min

Delivers results from unprocessed samples in approximately 40 min
Start-up Time: Approximately 5 min
Calibration Requirements: A total internal control method was developed that is comprised of a conventional PCR internal control, a separate sample preparation control, and a method for evaluating the integrity of the hybridization probes, called probe check. Probe check can actually detect if the hybridization probes have degraded in any way. It can also indicate if reagent reconstitution or reaction tube filling has occurred correctly. These features, in conjunction with manufacturing in a QSR compliant, ISO 13485 certified facility, mean no separate external positive and negative controls are required to obtain a valid result. False positive and false negative results are virtually eliminated. Furthermore, the use of the internal controls form key elements of a totally internal control scheme that means separate positive and negative controls are not required for routine operation. Calibration is required every 12 mo and is achieved by sending the unit to the vendor for calibration.
Response Time: Approximately 40 min. Dependent on specific agent assay protocol.
Data Analysis Time: Included within the 40 min specified in response time
Alarms: Visual alarm: Red—positive result; Green—negative result
Sensitivity: 33 CFU per ml for BA
Confidence Interval/Sensitivity: Greater than 95%
Specificity: See the report from the IntraAgency Working Group of the Office of Science and Technology Policy
Confidence Interval/Specificity: See the report from the IntraAgency Working Group of the Office of Science and Technology Policy

- **False Positives**: See the report from the IntraAgency Working Group of the Office of Science and Technology Policy. Based on usage rates, as of 11/30/2006, there will have been over 3.6 million tests run for anthrax with the USPS BDS with no false positive results.
- **False Negatives**: See the report from the IntraAgency Working Group of the Office of Science and Technology Policy

Resistance to Interferents: No known interferents
Testing Information: Report of the IntraAgency Working Group of the Office of Science and Technology Policy, "Review of the United States Postal Service's (USPS) Biohazard Detection Systems (BDS) Pilot Project" 2003

PHYSICAL PARAMETERS

Size: 36 cm x 29 cm x 30 cm (14 in x 11.5 in x 12 in)
Working Space: 0.9 m x 0.9 m (3 ft x 3 ft)
Weight: Approximately 23 kg (50 lb) for a 2 site system including the ruggedized travel case
Total Weight: 4 kg (9 lb) laptop computer. Assay kit to perform 10 assays approximately 0.7 kg (1.5 lb).
Power Requirements: 120 V to 240 V, 50 Hz to 60 Hz. 350 W; can be powered from a portable generator in a vehicle or in a boat

LOGISTIC PARAMETERS

Durability: Able to be transported quickly without protective packaging when transported with its portable transportation case
Ease of Use: The GeneXpert System combines cartridge-based sample preparation with amplification and detection functions in a fully integrated and automated nucleic acid analysis instrument. These products are designed to purify, concentrate, detect, and identify targeted nucleic acid sequences, delivering answers from unprocessed sample in less than 40 min. Current techniques for accomplishing the same complex series of procedures require extensive manual labor by skilled technicians and can take anywhere from 6 h to 3 d.
Environmental Conditions: 5 °C to 25 °C (41 °F to 77 °F)
Support Equipment: Laptop computer and barcode scanner (both provided with system)
Consumables: GeneXpert BT 3 Agent assay kit which includes 10 cartridges and pre-measured buffer bottles

Consumable Costs: $650 for a 10 BT3 Agent cartridge kit (detection of Antharx, Pestis, and Tularensis) including the buffer solutions
Maintenance: Standard service contract includes repair, parts, labor, shipping costs, internal modules, annual optical, and thermal calibration
Shelf Life (Equipment): Instrument can be store indefinately at room temperature
Shelf Life (Consumables): 12 mo at 5 °C (41 °F) and 6 mo at 25 °C (77 °F)
Maintenance Costs: Calibration and service contracts are offered starting at ~$1.5K per yr per module
Decontamination: Equipment can be wiped down with 70 % ethanol and/or 10 % bleach

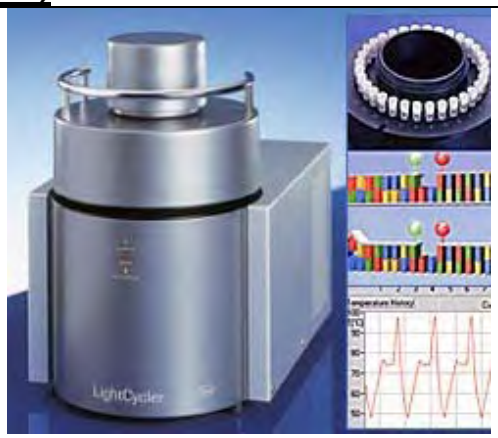
SPECIAL PARAMETERS

Skills Required: No special skills required. Ability to use pipetters and small buffer squeeze bottles and operate a laptop computer.
Training Required: Less than 1 h training required
Training Available: Training is provided by the manufacturer
Manuals Available: Manuals/CD are available
Data Storage: The connected computer retains all data from each assay performed
Communications: Through the laptop computer's communication ports
Security: Softwarwe can be password protected
Safety Requirements: Standard safety precautions when using laptop computer, laboratory instruments and possible biothreat agents
Applicable Regulations: All required PCR licenses have been obtained
Warranty: 12 mo for the instrument and through the expiration date for the cartridges. Expected life is dependent on usage and should be in excess of 5 yr.

GENERAL

LightCycler™ (Model 1.2)

Roche Applied Science
9115 Hague Road
Indianapolis, Indiana 46256
John R. Ogden, PhD
317–521–7569 (Tel)
317–521–7317 (Fax)
john.ogden@roche.com
Information Source: http://www.roche-diagnostics.com



Status: The vendor has not responded
Evaluated: Yes

Technology: Molecular
Portability: Mobile Laboratory Detection Equipment

Unit Cost: $57K, plus $250 set-up cost for pipetting device and $400 set-up cost for Master mix
Availability: The entire system is readily available. The LightCycler is shipped the same day an order is received for delivery and installation within 48 h. All reagents and consumables are off-the-shelf and require no special order. All are shipped overnight express.
Description: Real Time PCR—Capillary-based rapid cycler. Thirty-two samples in less than 20 min. Forced air driven temperature adjustment. Excite @ 470 nm: Read @ 53 0 nm, 640 nm, and 710 nm.
Application: The LightCycler was designed to perform very rapid (less than 20 min per run) real-time, quantitative PCR, and to perform sensitive melting curve analysis–tightly controlled temperature scan to detect single nucleotide mutations
Current Users: Diagnostic labs—used for esoteric testing for many parameters
Military—used by the military for biothreat agents
First responders—used in first response public health labs for the detection of biothreat agents
Scientific research labs—used for any kind of real time qPCR utilizing any fluorescent detection PCR chemistry
Hospitals—used for esoteric testing similar to diagnostic labs
Other:

- Pharmaceutical biotech for SNP validation work
- Food safety testing for detection of EHEC, salmonella and listeria
- Public health labs for detection of West Nile Virus
- Vet diagnostics labs with IDEXX kits
- Manufacturing companies for in-process QC for the presence of microbial contamination

OPERATIONAL PARAMETERS

BAs Detected: The LightCycler is capable of detecting any organism for which a workable primer/probe combination can be designed. Many organisms are being detected which we can not report because they are confidential to either a corporation or to the CDC. In most cases the detection level is much below a pfu or cfu. For most of the organisms below either a commercial kit or a publication is available. The LightCycler cannot be used to detect chemical agents or toxins.
Type of Sample: The nucleic acid must always be purified from the sample material prior to testing
Sample Preparation: RNA or DNA must be isolated and purified
SOP Sample Preparation: Time required for both manual and automated sample preparation is less than 2 h. Equipment for sample preparation includes centrifuge and pipettes (for manual or automated sample preparation) and MagNA (pure).
Start-up Time: Equipment start-up time—not applicable, just unpack and plug the instrument in
Detector start-up time—not applicable, just unpack and plug the instrument in
Calibration Requirements: Instrument requires one qualitative calibration at start-up of automated self-test—just click on button in software
Response Time: Immediate
Data Analysis Time: Data analysis takes about 1 min
Alarms: No alarm, but result is visually displayed
Sensitivity: Bacteria <1 CFU (dependant on primer/probe design)
Virus <1 PFU (dependant on primer/probe design)

Toxins—Not applicable
Target DNA—0.003 ng

Confidence Interval/Sensitivity: Not applicable
Specificity: Organisms or proteins that have been tested in cross-reactivity studies depends on the application
Confidence Interval/Specificity: Not applicable or parameter specific

- **False Positives**: Not applicable or parameter specific
- **False Negatives**: Not applicable or parameter specific

Resistance to Interferents: Known environmental interferents include—soil, cold temperatures, hot temperatures, high humidity, and other organisms or proteins
Testing Information: Springer Manuals and reprints are available upon request from the vendor. Since there are too many references to sight here, one can do a reference check for LightCycler.

PHYSICAL PARAMETERS

Size: 61 cm x 46 cm x 76 cm (24 in x 18 in x 30 in)
Working Space: 1.8 m x 0.9 m (6 ft x 3 ft)
Weight: LightCycler—13.1 kg (30 lb), no batteries
Total Weight: Laptop Computer—4.5 kg (10 lb); consumables—negligible
Power Requirements: Powered by ac only

LOGISTIC PARAMETERS

Durability: Must remain stationary; may be left in either cold or hot environment without effect
Ease of Use: Very easy. Steps include 1) load carousel, 2) place carousel in LightCycler, 3) close lid, and 4) push button to start run.
Environmental Conditions: Temperature between 15 ºC to 35 ºC (59 ºF to 95 ºF); 20 % to 80 % rh; pressure at 0 mmHg (0 Pa) and 2000 mmHg (2.67 E + 05 Pa)
Support Equipment: Lap top or desktop PC
Consumables: Capillaries, master mixes, multiple solutions, caustic solutions, flammable solutions, pipette tips, plastic trays, and probes and primers
Consumable Costs: $2 to $5 per test
Maintenance: Yearly CAP test. 24 h technical support is provided by the manufacturer or authorized agency, a loaner option is available. The equipment is upgradeable.
Shelf Life (Equipment): Yearly CAP test. Twenty-four (24 h) technical support is provided by the manufacturer or authorized agency, a loaner option is available, and the equipment is upgradeable.
Shelf Life (Consumables): Consumables do not remain in the instrument when it is not in use
Maintenance Costs: CAP test cost ~$2K
Decontamination: Not specified

SPECIAL PARAMETERS

Skills Required: Level of education—at least a high school diploma is required to accurately analyze raw data before a final result can be determined
Training Required: Less than 4 h training required (1 h or 2 h for basic training on how to use the instrument)
Training Available: Name of training course—LC Installation (basic training). Certification when completed—yes. Location of training—onsite (where equipment will be used or stored).
Manuals Available: User manual and training documents
Data Storage: Connected computer
Communications: Computer control and computer interface
Security: Password protected. Lock-down cables to prevent theft.
Safety Requirements: Not specified
Applicable Regulations: Not specified
Warranty: LightCycler—1 yr, can be extended up to 3 yr
PC—3 yr from computer manufacturer

GENERAL

Gen-Probe Leader 450i

Gen-Probe
10210 Genetic Center Drive
San Diego, California
92121–4362
858–410–8000 (Tel)
800–523–5001 (Tel)
cindyi@gen-probe.com
Information Source: http://www.gen-probe.com

Status: The vendor has not responded
Evaluated: No

Technology: Molecular
Portability: Fixed-Site Detection System

Unit Cost: Not specified
Availability: Commercially available
Description: Rolling Circle Amplification/rRNA
Application: DNA Probe—The Gen-Probe HPA technique uses a specific DNA
Current Users: Not specified

OPERATIONAL PARAMETERS

BAs Detected: Not specified
Type of Sample: Not specified
Sample Preparation: The Gen-Probe HPA technique uses a specific DNA probe, labeled with and an acridinum ester detector molecule that emits a chemilumescent signal. The DNA probe hybridizes with either the target rRNA in nonamplified test, or the amplicon produced in the Transcription mediated amplification reaction.
SOP Sample Preparation: Processing 250—twelve (12) 75 mm tubes, or processing 450—eight 40 mm tubes in one loading
Start-up Time: Not specified
Calibration Requirements: Not specified
Response Time: Not specified
Data Analysis Time: Not specified
Alarms: Not specified
Sensitivity: Not specified
Confidence Interval/Sensitivity: Not specified
Specificity: Not specified
Confidence Interval/Specificity: Not specified

- **False Positives**: Not specified
- **False Negatives**: Not specified

Resistance to Interferents: Not specified
Testing Information: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Working Space: Not specified
Weight: Not specified
Total Weight: Not specified
Power Requirements: Not specified

LOGISTIC PARAMETERS

Durability: Not specified
Ease of Use: Not specified
Environmental Conditions: Not specified

Support Equipment: A self-contained luminometer and microprocessor
Consumables: Not specified
Consumable Costs: Not specified
Maintenance: Not specified
Shelf Life (Equipment): 2 ºC to 25 ºC (35.6 ºF to 77 ºF)
Do not freeze these reagents
Stable until the experimentation date
Shelf Life (Consumables): Not specified
Maintenance Costs: Not specified
Decontamination: Not specified

SPECIAL PARAMETERS

Skills Required: Not specified
Training Required: Relatively inexperienced lab personnel
Training Available: Not specified
Manuals Available: Not specified
Data Storage: Stores up to 30 protocols. Allows the operator to program up to 11 different assays in 1 run. Allows "walkaway" processing of up to 250 samples.
Communications: Not specified
Security: Not specified
Safety Requirements: Not specified
Applicable Regulations: Not specified
Warranty: Not specified

GENERAL

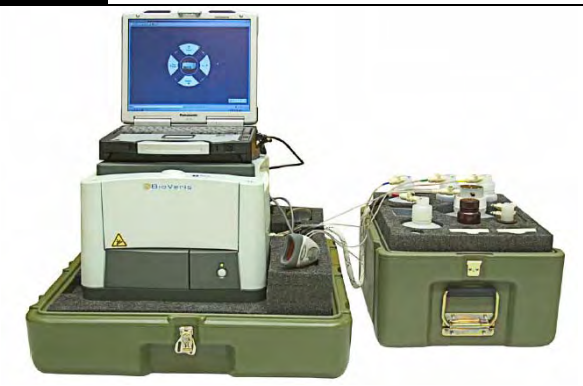
M-SERIES® M1M Analyzer

BioVeris Corporation
16020 Industrial Drive
Gaithersburg, Maryland 20877
800–336–4436 (Tel)
301–230–0158 (Fax)
Jill White
301–869–9800 (Tel) ext 1054
240–632–2206 (Fax)
jwhite@bioveris.com
bvcorp@bioveris.com

Information Source: http://www.bioveris.com

Status: The vendor has responded—10/21/2005

Evaluated: Yes



Technology: Immunochemical

Portability: Mobile Laboratory Detection Equipment

Unit Cost: Contact BioVeris Corporation for pricing information

Availability: Instruments are available in stock and take approximately 1 wk from time of order to ship

Description: Magnetic Bead Based—Electrochemiluminescence—reagents bound to magnetic bead "sandwich" emit light when voltage is applied. Does not necessarily need to be an antibody—can be DNA based

Application: The M1M Analyzer was designed for research and field applications. The M1M analyzer is currently being used by DOD, universities, Public Health laboratories, and private sector customers.

Current Users: DOD placements worldwide, laboratory, and research; CSTs in purchasing phase; USAMRIID as well as university research laboratories. Trauma center purchase for analysis of environmental samples.

OPERATIONAL PARAMETERS

BAs Detected: **NOTE: Instrumentation is used primarily by Government for detection of agents and detection limit may not be known for some; likewise, BioVeris does not have knowledge of all tests existing for equipment as provided by the government. Biological agent reagents can be obtained through the Critical Reagent Program, JPEO, and some through BioVeris. Reagents available through BioVeris indicated are in **bold**, as well as LDL data. CFU (colony forming unit); PFU (plaque forming unit); veg (vegetative).

Bacilus anthracis—100 spores/veg/mL to 1000 spores/veg/mL
Francisella tularenius—5000 cfu/mL
Salmonella typhimurium—1000 cfu/mL
Salmonella enteritidis—1000 cfu/mL
Salmonella typhi—1000 cfu/mL
E. coli O157:H7—500 cfu/mL
Orthopoxvirus—50 000 pfu/mL
Cryptosporidium spp—10 oocyst/mL to 50 oocyst/mL
Botulinum toxin—2 pg/mL to 5 pg/mL
Ricin—1 ng/mL to 10 ng/mL
Staphylococcal aureus enterotoxin B—0.5 pg/mL to 10 pg/mL

Type of Sample: Liquid state is required
Air—if liquefied
Solid—if rinsed with solution
Sludge—if diluted with solution
Surface wipes—if placed in liquid
Other—fecal, whole blood, serum, plasma, and food matrices

Sample Preparation: Sample, depending upon viscosity, matrix or particulate matter may need to be diluted with standard buffer and/or filtered. Sample preparation times are typically <30 s. In some instances, samples are heat killed for 10 min prior to testing to inactivate pathogens, however, this step is not required for detection.

SOP Sample Preparation: If not already liquid, sample is placed in buffer. Sample is filtered into analysis tube using a BV Filter Unit, a volume of diluent is added, and the sample is analyzed.

Start-up Time: Assembly—5 steps or less; calibration not required at start-up; <15 min detector start-up time (including calibration to initiating a run)

Calibration Requirements: Calibration is performed on a yearly basis. There is no need to calibrate the system more often unless a significant malfunction requiring service occurs. The system is QC tested once per wk to assure that all components are functioning within predetermined limits. QC testing takes approximately 20 min to perform. Instruments are shipped on a yearly basis to BioVeris Corporation for calibration and servicing. Calibration is performed by adjusting the signal generated to match a known set of quantitated standards. Instrument requires vendor support for quantitative calibration. Calibration is performed at:
BioVeris Corporation
16020 Industrial Dr.
Gaithersburg, MD 20877
Response Time: <30 min total time to analyze and give result
Data Analysis Time: <30 min total time to analyze and give result
Alarms: Auto, visible, and audible alarms
Sensitivity: Bacteria—The technology is capable of detecting as few as 20 cfu to 200 cfu per 100 µL sample. Without bead concentration, this sensitivity would equate to 200 cfu/mL to 2000 cfu/mL.

Virus—The technology is capable of detecting as few as 10^3 pfu per 100 µL sample. Without bead concentration, this sensitivity would equate to 10^4 pfu/mL.

Toxins—The technology is capable of detecting as few as 1 pg of toxin per 100 µL sample. Without bead concentration, this sensitivity would equate to 10 pg/mL.

Target DNA—The technology has been shown to be capable of detecting as few as 0.5 ng of target DNA using direct detection by DNA probes. Using an initial PCR amplification step, the technology is capable of detecting as little as a single copy of DNA in the reaction mixture.

In the levels of sensitivity reported above, sample sizes for the tests are typically 100 µL. However, because the magnetic microparticles used in the test can also be used to concentrate samples of 1 mL or more in volume, it is possible to increase the sensitivity per mL by as much as 5 to 8 fold by including an off-line sample capture and magnetic bead concentration step.
Confidence Interval/Sensitivity: Confidence levels are calculated based on dilution of quantitated standards to levels equivalent to the claimed sensitivity of the test and performing replicate testing. For assays currently manufactured by BioVeris Corporation, 2 to 3 different operators perform replicate testing on 3 different instrument systems over 3 d. The testing is performed on multiple kit lots as they become available. The following have a confidence level >95 %.
Staphylococcus aureus enterotoxins A and B—2 pg/mL to 3 pg/mL of purified toxin.
Clostridium botulinum neurotoxins A, B, E, and F—50 pg/mL of purified toxin.
Ricin—1 pg/mL to 5 pg/mL of purified toxin.
Bacillus anthracis—2 x 10^4 spores/mL.
Specificity: The instrument system itself does not have cross-reactivity with any organisms or proteins. The organisms or proteins that have been tested in cross-reactivity studies are assay dependent.
Confidence Interval/Specificity: All tests include positive controls that consist of simulants that react with the assay to assure that the tests are working within expected limits. Selectivity studies for tests manufactured by BioVeris Corporation are performed by testing large numbers of negative samples from various matrix types and applying the values from each sample against the cutoff value of the assay. The false positive rate is then calculated by determining the percentage of false positive results versus the total number of samples tested. Secondarily, a set of closely related organisms or proteins are tested at significantly higher levels than the cutoff of the assay to determine potential cross-reactivity with the test.
The following have confidence interval greater than 95 %:
Staphylococcus aureus enterotoxins A and B: detectable toxin.
Clostridium botulinum neurotoxins A, B, E, and F: detectable toxin.
Ricin: detectable toxin.
Bacillus anthracis: Detectable cfu or spores/mL.

- **False Positives**: Typically <1 %
- **False Negatives**: Typically <1%

Resistance to Interferents: The instrument system itself does not have cross-reactivity with any organisms or proteins. The organisms or proteins that have been tested in cross-reactivity studies are assay specific.
Testing Information: Not applicable

PHYSICAL PARAMETERS

Size: 37.6 cm x 37.6 cm x 29.7 cm (14.8 in x 14.3 in x 11.7 in)
Working Space: 0.9 m x 0.6 m (3 ft x 2 ft)
Weight: The M1M analyzer total weight is approximately 20 kg (44 lb). The buffers/reagents required to support the system weigh <2.7 kg (6 lb). Therefore, the entire weight of the system including consumables is approximately 22.7 kg (50 lb).
Total Weight: M1M Analyzer and computer—203 kg (44 lb)

BV-GLO—1 kg (2.2 lb)
BV-CLEAN—1 kg (2.2 lb)
BV-DILUENT and BV-STORE—0.5 kg (1.1 lb)
Positive calibrator—0.1 kg (0.2 lb)
Negative calibrator—90 kg (0.2 lb)
Test kits—45 g (0.1 lb)

Power Requirements: The electrical power requirements, fuse ratings, and output power of the M1M analyzer are as follows—90 to 250 V ac; 47 Hz to 63 Hz; can be operated off an external 24 V dc power supply

LOGISTIC PARAMETERS

Durability: The system can also be vehicle mounted and does not need to remain stationary. The instrument system is packaged into a ruggedized transport case for shipping. There is no need for specially trained or expert personnel to complete this function. For shipping the computer is packed in the transport case with the instrument and buffers required to operate the system are supplied in their own ruggedized transport case. Assembly time of the components at the destination is <5 min. Conversely, if the system is mounted on a mobile system, there is no need to disconnect the components and the system may be transported fully functional. The system does not need to be calibrated after being moved or dropped.

Ease of Use: The use of this system for the detection of BAs requires that a user be capable of manipulating a transfer pipet, that the user be capable of delivering sample diluent and sample to a microwell plate either dropwise or through the use of a pipet, and that the user be capable of operating the system through the use of a computer keypad or mouse. The ability to perform these manipulations will be dependent on the type of PPE being worn by the individual during testing. In general, there are 4 steps to completing an assay, 1) reagent addition—in some instances test reagents are supplied in lyophilized format in the tube negating the need for this step; 2) sample addition using a dropper format or pipetting; 3) instrument operation—through the use of a keypad or mouse; and 4) data management—requiring the use of the computer keypad or mouse.

Environmental Conditions: Adverse environmental conditions include: temperatures above 40 ºC (104 ºF) and temperatures below 5 ºC (41 ºF)—buffers can freeze at temperatures below 0 ºC (-32 ºF). Operates in 5 % to 98 % noncondensing rh; system has been operational outside of the conditions described above during DOD field trials.

Support Equipment: Pasteur pipettes are required for sample preparation M1M Analyzer tubes, if needed
Positive and negative calibrator

Consumables: BV-GLO, BV-CLEAN, BV-DILUENT, BV-STORE; BV Filter Units may or may not be required—depends upon matrix; and Test Kit

Consumable Costs: The cost of consumables needed to perform one assay is specific to each test. Please contact BioVeris Corporation for pricing.

Maintenance: Yearly preventative maintenance required. Please contact BioVeris Corporation for pricing of preventative maintenance contracts. Twenty-four (24 h) support is not provided, but there is a loaner option during maintenance or malfunctioning. As additional software features become available, the instrument will be upgraded to new software versions. Additional functionality is also being built into the hardware of the instrument system for future use. As new functionality becomes available, users can be upgraded.

Shelf Life (Equipment): System should not be stored longer than 1 yr without being serviced before it is used. Flow cell would suffer after 1 yr storage.

Shelf Life (Consumables): All reagent instrument consumables have specified expiration dating on their labels. The buffers used to operate the instrument system have expiration dating of 18 mo to 24 mo.

Maintenance Costs: Contact BioVeris Corporation for pricing information

Decontamination: The system can be decontaminated with 10 % bleach to remove the potential for biological hazards

SPECIAL PARAMETERS

Skills Required: No special skills but training required. A high school diploma is adequate level of education to operate the equipment. The operator does not have to analyze the raw data before a final result can be determined. The software is capable of automatically performing all functions required to determine whether or not an unknown sample is positive or negative without any user intervention. Positive results will alarm the system both visually and audibly. Expert users also have access to all sample and QC data to evaluate the sample results further.

Training Required: Less than 8 h training required

Training Available: Training to BioVeris Corporation customers is conducted on many different levels. BioVeris conducts a 3 d training course known as the Assay Development and Optimization Workshop that can be attended at various times throughout the year. The workshop can also be conducted on-site at a customer's location. The workshop includes an overview of the technology, instrument system, and a course in developing and optimizing assays on the instrument system. With each purchase of an instrument system, an BioVeris scientist visits the site, sets up the instrument system and spends as

many as two days familiarizing the customer with the operation and maintenance of the instrument system. During this time, training on specific assays important to the customer is also conducted. Additionally, the M1M Analyzer software includes a help section in the Users Manual to address issues that are commonly encountered. Additionally, the M1 software has a wizard function that guides a user that is unfamiliar with the process of running the system through the steps necessary to obtain a result. BioVeris Corporation also maintains a technical service phone number that will allow customers to talk directly with BioVeris technical staff to deal with instrument or assay specific issues. Classroom training (off site or on-site) results in certification:

- Assay Development and Optimization Workshop.
- Applications scientist visits. Training conducted on-site.

CD training does not result in certification:

- M1M Operator's Manual on CD.
- M1M Analyzer software "help" function.
- M1M Quick Start guide provided with instrument.
- M1M Training manual available "Train the trainer".
- BV Technology Presentation on CD.

Manuals Available: The M1 Analyzer User Manual includes all of the information to set up the instrument, perform the quality control and testing routines, and includes basic repair information that users can take care of on-site. The manual is illustrated and in CD format. Every test manufactured by BioVeris Corporation includes a set of instructions, packaged with the test, that instructs a user on how to run the test and includes information on sample processing, test performance, instrument set-up, and interpretation of results.

Data Storage: The user interface of the M1M Analyzer requires an external laptop computer that is supplied with the instrument at purchase. Software required to run the instrument system, collect and analyze the data, and perform instrument functions is contained within the laptop. Data can be printed from the laptop or transferred to computer disk for additional analysis. The data saved in the M1M Analyzer files cannot be manipulated, providing a lasting, unalterable record of all test results. The system is capable of being networked, optionally allowing data from tests to be sent directly to other computers that are on the operating system.

Communications: The M1M Analyzer can be used as a stand-alone system or can be networked on a standard Ethernet (10/100 Base T). Any device supported by Windows XP can be used with the system (printers, storage media, etc.). The system will be capable of driving or being driven by robotics for the purpose of automated sample handling and preparation.

Computer (control)—the M1M Analyzer is operated using a laptop computer that can be networked.

Computer interface—the M1M Analyzer uses a computer interface.

Data transfer capability (interface)—data can be exported from the M1M software to a Microsoft window environment such as an Excel or Word file on the operating computer. From there it can further manipulated.

Networking capability—the M1M Analyzer can be networked on a standard Ethernet (10/100 Base T).

Installed data processing equipment—the M1M Analyzer software has the ability to analyze samples and automatically return positive or negative results. Additionally it has the capability to display raw data for calculating mean values, standard deviation, % C.V., and signal to background ratios from which negative or positive sample determinations are made. If further manipulation is required, the data can be exported in spreadsheet format.

Security: Prior to each run and during the testing of each sample, the M1M Analyzer runs a series of instrument checks to validate that it is functioning within a range of predetermined operating conditions. Any effort that affects the ability of the system to operate within these conditions, intentional or not, are flagged by the instrument system and a visual warning is displayed to inform the user that the data generated is suspect. Additionally, a cause of the failure is reported. All instrument operating conditions are saved with every data set in an unalterable format so that all instrument runs can be referenced to make sure that the proper instrument settings were used for each test. A user cannot modify results in a data file at any time even during the read cycle. The system makes use of and extends Windows XP security. The computer is password protected and features of the software use the same password used by the operating system. The database is encrypted and password protected.

Safety Requirements: The M1M Analyzer has been designed to comply with all appropriate electrical safety standards. Although shielding and grounding is provided wherever applicable, laboratory personnel should never remove any covers of the analyzer that would expose electrical circuits.

Applicable Regulations: The M1M Analyzer conforms to the following safety standards: USA UL 3101–1/10.93 (TUV RL); Canada CAN/CSA–C22.2 No. 1010.1–92+A2:97 (TUV RL); and European compliance with the Low Voltage Directive. In addition, the analyzer conforms to the following EMC standards: CISPR 11 Class A Equipment; FCC Part 15, Class A Equipment; and compliance with EMC Directives. The M1M Analyzer has also been tested and has shown not to produce aerosols under normal operating conditions.

Warranty: Limited warranty is typically valid for 1 yr from date of installation.

GENERAL

M-SERIES® 384 Analyzer

BioVeris Corporation
16020 Industrial Drive
Gaithersburg, Maryland 20877
800–336–4436 (Tel)
301–230–0158 (Fax)
Jill White
301–869–9800 (Tel) ext 1054
240–632–2206 (Fax)
jwhite@bioveris.com
bvcorp@bioveris.com
Information Source: http://www.bioveris.com

Status: The vendor has responded—10/21/2005
Evaluated: No

Technology: Immunochemical
Portability: Fixed-Site Detection System

Unit Cost: Please contact BioVeris Corporation for pricing information
Availability: Instruments are available in stock and take approximately 1 wk from time of order to ship
Description: Magnetic Bead Based—Electrochemiluminescence—reagents bound to magnetic bead "sandwich" emit light when voltage is applied. Does not necessarily need to be an antibody—can be DNA based.
Application: The 384 Analyzer was designed for research applications. The 384 analyzer is BioVeris Corporation's high throughput instrument system. It is capable of reading a 96 well microtiter plate in approximately 15 min. It has the capability of integrating with an automated plate loader that can run up to 76 96-well plates without user intervention.
Current Users: Earlier version of the instrument is part of the ABATS System. A variety of instruments are in research labs in pharmaceutical and biotech companies—top 50 pharmaceutical companies have BV Technology. Pharmaceutical companies use the instrument for quality control testing of products.

OPERATIONAL PARAMETERS

BAs Detected: **NOTE: Instrumentation is used primarily by Government for detection of agents and detection limit may not be known for some; likewise, BioVeris does not have knowledge of all tests existing for equipment as provided by the government. Biological agent reagents can be obtained through the Critical Reagent Program, JPEO, and some through BioVeris. Reagents available through BioVeris are in **bold**. Data provided is LDL. CFU (colony forming unit); PFU (plaque forming unit); veg (vegetative).

Bacilus anthracis—1000 pores/veg/mL to 10 000 spores/veg/mL
Francisella tularenius—5000 cfu/mL
Salmonella typhimurium—1000 cfu/mL
Salmonella enteritidis—1000 cfu/mL
Salmonella typhi—1000 cfu/mL
Yersinia pestis—Unknown
E. coli O157:H7—500 cfu/mL
Orthopoxvirus—50 000 pfu/mL
Cryptosporidium spp—10 oocyst/mL to 50 oocyst/mL
Botulinum toxins—2 to pg/mL to 5 pg/mL
Ricin—1 ng/mL to 10 ng/mL
Staphylococcal aureus enterotoxin B—0.5 pg/mL to 1 pg/mL

Type of Sample: Liquid state is required

Air—if liquefied
Solid—if rinsed with solution
Sludge—if diluted with solution
Surface wipes—if placed in liquid
Other—fecal, whole blood, serum, plasma, and food matrices

Sample Preparation: Sample, depending upon viscosity, matrix or particulate matter may need to be diluted with standard buffer and/or filtered. Sample preparation times are typically <30 s. In some instances, samples are heat killed for 10 min prior to testing to inactivate pathogens, however, this step is not required for detection.

SOP Sample Preparation: If not already liquid, sample is placed in buffer. Sample is filtered into analysis tube using a BioVeris Filter Unit, a volume of diluent is added, and the sample is analyzed.
Start-up Time: Assembly—5 or less steps; <15 min calibration time; <30 min detector start-up time (including calibration to initiating a run)
Calibration Requirements: BioVeris recommends that the 384 be calibrated on a weekly basis. BioVeris recommends that a quantitatively QC plate be run at the beginning of each day to show that the system is operating within a defined set of parameters. Calibration is performed by adjusting the signal generated to match a known set of quantitated standards. These standards are supplied as a product. The standards are added to the wells of a 96-well plate in a specified order and the instrument is run. The system then calibrates automatically at the user's discretion according to the results of the run.
Response Time: <30 min to analyze and give results
Data Analysis Time: <30 min to analyze and give results
Alarms: Alarm capabilities include auto alarm and visible alarm
Sensitivity: Bacteria—The technology is capable of detecting as few as 20 cfu to 200 cfu per 100 µL sample. Without bead concentration, this sensitivity would equate to 200 to cfu/mL to 2000 cfu/mL.

Virus—The technology is capable of detecting as few as 10^3 pfu per 100 µL sample. Without bead concentration, this sensitivity would equate to 10^4 pfu/mL.

Toxins—The technology is capable of detecting as few as 1 pg of toxin per 100 µL sample. Without bead concentration, this sensitivity would equate to 10 pg/mL.

Target DNA—The technology has been shown to be capable of detecting as few as 0.5 ng of target DNA using direct detection by DNA probes. Using an initial PCR amplification step, the technology is capable of detecting as little as a single copy of DNA in the reaction mixture.

In the levels of sensitivity reported above, sample sizes for the tests are typically 100 µL. However, because the magnetic microparticles used in the test can also be used to concentrate samples of 1 mL or more in volume, it is possible to increase the sensitivity per mL by as much as 5 to 8 fold by including an off-line sample capture and magnetic bead concentration step.
Confidence Interval/Sensitivity: Confidence levels are calculated based on dilution of quantitated standards to levels equivalent to the claimed sensitivity of the test and performing replicate testing. For assays currently manufactured by BioVeris, 2 to 3 different operators perform replicate testing on 3 different instrument systems over 3 d. The testing is performed on multiple kit lots as they become available.
The following have confidence interval greater than 95 %:

Staphylococcus aureus enterotoxins A and B—2 pg/mL to 3 pg/mL of purified toxin.
Clostridium botulinum neurotoxins A, B, E, and F—50 pg/mL of purified toxin.
Ricin—1 ng/mL to 5 ng/mL of purified toxin.
Bacillus anthracis—2 x 10^4 spores/mL.

Specificity: The instrument system itself does not have cross-reactivity with any organisms or proteins. The organisms or proteins that have been tested in cross-reactivity studies are assay dependent.
Confidence Interval/Specificity: All tests include positive controls that consist of simulants that react with the assay to assure that the tests are working within expected limits. Selectivity studies for tests manufactured by BioVeris Corporation are performed by testing large numbers of negative samples from various matrix types and applying the values from each sample against the cutoff value of the assay. The false positive rate is then calculated by determining the percentage of false positive results versus the total number of samples tested. Secondarily, a set of closely related organisms or proteins are tested at significantly higher levels than the cutoff of the assay to determine potential cross-reactivity with the test.
The following have confidence interval greater than 95 %:
Staphylococcus aureus enterotoxins A and B: detectable toxin.
Clostridium botulinum neurotoxins A, B, E, and F: detectable toxin.
Ricin: detectable toxin.
Bacillus anthracis: Detectable cfu or spores/mL.

- **False Positives**: Typically <1%
- **False Negatives**: Typically <1%

Resistance to Interferents: Known environmental intereferents include cold temperatures (below freezing) and hot temperatures 100 °C (212 °F) or greater
Testing Information: Not applicable

PHYSICAL PARAMETERS

Size: 71 cm x 66 cm x 50 cm (28 in x 26 in x 19.6 in)
Working Space: 0.9 m x 0.6 m (3 ft x 2 ft)
Weight: The 384 Analyzer total weight is approximately 77 kg (170 lb). The buffers/reagents required to support the system weigh approximately 39 kg (85 lbs). Therefore, the entire weight of the system including consumables is approximately 116 kg (255 lb).

Total Weight: 384 Analyzer—77 kg (170 lb)
BV-GLO—19 kg (42 lb)
BV-CLEAN—19 kg (42 lb)
Positive calibrator—0.1 kg (0.2 lb)
Negative calibrator—0.1 kg (0.2 lb)
Microwell plate—45 g (0.1 lb)
Pipets—0.2 kg (0.5 lb)
Power Requirements: The electrical power requirements, fuse ratings, and output power of the 384 Analyzer are as follows—100 V to 120/200 to 240 V; 60/50 Hz; 10/5 A

LOGISTIC PARAMETERS

Durability: System must remain stationary to for analysis. It cannot be dropped from the counter height without effect. The instrument system is packaged into a shipping box for transport. There is no need for specially trained or expert personnel to complete this function. For shipping the buffers required to operate the system are disconnected and packed separately. Assembly time of the components at the destination is <5 min.
Ease of Use: The use of this system for the detection of BAs requires that a user be capable of manipulating a transfer pipette, that the user be capable of delivering sample diluent and sample to a 96-well plate, either dropwise or through the use of a pipette, and that the user be capable of operating the system through the use of a computer keypad or mouse. The ability to perform these manipulations will be dependent on the type of PPE being worn by the individual during testing. In general, there are 4 steps to completing an assay: 1) reagent addition—in some instances test reagents are supplied in lyophilized format negating the need for this step; 2) sample addition using a dropper format or pipetting; 3) instrument operation—through the use of a keypad or mouse; and 4) data management—requiring the use of the computer keypad or mouse.
Environmental Conditions: Validated for temperatures as between 25 ºC to 37 ºC (77 ºF to 98.6 ºF) but can operate in significantly lower and higher temperatures. Operates in 5 % to 80 % noncondensing rh. Buffers can freeze at temperatures below 0 ºC (32 ºF).
Support Equipment: Microwell plates, positive calibrator, and negative calibrator
Consumables: BV-GLO PLUS, BV-CLEAN PLUS, BV filter units, and test kits
Consumable Costs: The cost of consumables needed to perform one assay is specific to each test. Please contact BioVeris Corporation for pricing.
Maintenance: Yearly preventative maintenance is required. Please contact BioVeris Corporation for pricing of preventative maintenance contracts. Twenty-four (24 h) support is not provided, but there is a loaner option during maintenance or malfunctioning. The equipment is upgradeable (as additional software features become available, the instrument will be upgraded to new software versions).
Shelf Life (Equipment): The time that a system could be shut down is dependent on a number of factors. The system has a shut down protocol that if followed, will allow for a quick start-up when the system is brought back online. Systems can be kept on without running samples for extended periods of time. During extended storage times, the system can be set to use an automated prime sequence that maintains flow cell integrity when the system remains idle for extended periods.
Shelf Life (Consumables): Tricorders need to be serviced after 6 mo of storage. All reagent instrument consumables have specified expiration dating on their labels. The buffers used to operate the instrument system have expiration dating of 18 mo to 24 mo.
Maintenance Costs: Please contact BioVeris Corporation for pricing information
Decontamination: The system can be decontaminated with 10 % bleach to remove the potential for biological hazards

SPECIAL PARAMETERS

Skills Required: No special skills but training required. A high school diploma is adequate level of education to operate the equipment and to analyze the data.
Training Required: Less than 8 h training required. A user must divide the raw signal generated by a sample by the raw signal generated by the negative control to generate a signal to background ratio. If the signal to background ratio is above a threshold cutoff value, the sample is considered positive for the agent being tested. Data interpretation takes <1 min.
Training Available: Training to BioVeris Corporation customers is conducted on many different levels. BioVeris conducts a 3 d training course known as the Assay Development and Optimization Workshop that can be attended at various times throughout the year. The workshop can also be conducted on-site at a customer's location. The workshop includes an overview of the technology, instrument system, and a course in developing and optimizing assays on the instrument system. With each purchase of an instrument system, a scientist visits the site, sets up the instrument system and spends as many as 2 d familiarizing the customer with the operation and maintenance of the instrument system. During this time, training on specific assays important to the customer is also conducted. As discussed below, the 384 Analyzer has a comprehensive user manual that helps to reinforce the training and can be used as a reference guide in the future. The 384 Analyzer User's Guide

is provided in both a manual and a CD format. Additionally, the 384 Analyzer software includes a help section in the Users Manual to address issues that are commonly encountered. BioVeris Corporation also maintains a technical service phone number that will allow customers to talk directly with BioVeris technical staff to deal with instrument or assay specific issues.
Classroom training (off site or on-site) results in certification:

- Assay Development and Optimization Workshop.
- Applications scientist visits. Training conducted onsite.

Manual/CD training does not result in certification:

- 384 Operator's Manual on CD.
- 384 Analyzer software "help" function.
- BV Technology Presentation on CD.

Manuals Available: The 384 Analyzer User Manual includes all of the information to set up the instrument, perform the quality control and testing routines, and includes basic repair information that users can take care of on-site. The manual is illustrated and in CD as well as written format. Every test manufactured by BioVeris Corporation includes a set of instructions, packaged with the test, that instructs a user on how to run the test and includes information on sample processing, test performance, instrument set-up, and interpretation of results.
Data Storage: The user interface of the 384 Analyzer is a built-in computer that is part of the instrument system. Software required to run the instrument system, collect and analyze the data, and perform instrument functions is contained within the computer. Data can be printed from the system or transferred to computer disk for additional analysis. The data saved in the 384 Analyzer files cannot be manipulated, providing a lasting, unalterable record of all test results. The system is capable of being networked, optionally allowing data from tests to be sent directly to other computers that are on the operating system. All sample data are stored with the protocol name and plate bar code identification in standard ASCII file format and are ready to import into other external programs for data analysis and manipulation.
Communications: The 384 Analyzer can be used as a stand-alone system or can be networked on a standard Ethernet (10/100 Base T). Any device supported by Windows 98 can be used with the system (printers, storage media, etc.). The system is capable of driving or being driven by robotics for the purpose of automated sample handling and preparation.
Computer (control)—The 384 Analyzer is operated using an integrated internal computer system.
Computer interface—The 384 Analyzer uses a built-in computer interface. Minimally the computer is a 233 MHz microprocessor with 64 MB of RAM and a 6 GB hard drive, 4 MB flash drive, two RS-232 serial ports, parallel printer port, Windows 98 operating system, active matrix display, enhanced function keyboard, floppy drive, and a touch pad (or mouse) in a pullout drawer.
Data transfer capability (interface)—The system is capable of being networked, optionally allowing data from tests to be sent directly to other computers that are on the operating system. All sample data are stored with the protocol name and plate bar code identification in standard ASCII file format and are ready to import into other external programs for data analysis and manipulation.
Networking capability—The 384 Analyzer can be networked on a standard Ethernet (10/100 Base T).
Installed data processing equipment—The 384 Analyzer has the capability of displaying raw data. If further manipulation is required, the data can be exported in spreadsheet format in a Microsoft Windows program. Mean values, standard deviation, % C.V., and signal to background ratios to determine positive and negative samples can be calculated by hand or in the spreadsheet.
Security: Prior to each run and during the testing of each sample, the 384 Analyzer runs a series of instrument checks to validate that it is functioning within a range of predetermined operating conditions. Any effort that affects the ability of the system to operate within these conditions, intentional or not, is flagged by the instrument system and a visual warning is displayed to inform the user that the data generated is suspect. Additionally, a cause of the failure is reported. All instrument operating conditions are saved with every data set in an unalterable format so that all instrument runs can be referenced to make sure that the proper instrument settings were used for each test. A user cannot modify results in a data file at any time even during the read cycle. The system is password protected with multiple levels of password access to protect against inadvertent user changes to system software controls and protocol settings. The software conforms to 21 CFR Part ll.
Safety Requirements: The 384 Analyzer has been designed to comply with all appropriate electrical safety standards. Although shielding and grounding is provided wherever applicable, laboratory personnel should never remove any covers of the analyzer that would expose electrical circuits. If liquid is spilled on or in any part of the 384 Analyzer, there is an immediate electrical shock hazard. In such a case, the plug should be pulled from the outlet and the instrument thoroughly cleaned and inspected. Potential mechanical hazards exist when the operator is in contact with any moving parts of the instrument system. The operator should not touch any part of the analyzer while it is in motion.
Applicable Regulations: The 384 Analyzer conforms to the following safety standards in the U.S., Canada, and Europe: TUV Rheinland NRTL UL 3101–1 Laboratory Equipment and EN 61010–1 Laboratory Equipment; CE; CSA (pending). The system is in full compliance with EMC Directives and FCC part 15 for Class A Equipment and CISPER 11, for Class A Equipment. The 384 Analyzer has also been tested and has shown not to produce aerosols under normal operating conditions.
Warranty: Limited warranty is typically valid for 1 yr from date of installation

GENERAL

FACSCaliber

BD Biosciences Immunocytometry Systems
2350 Qume Drive
San Jose, California 95131
Janet Horta, Marketing Product Manager
408–954–2340 (Tel)
408–954–2391 (Fax)
Janet_Horta@bd.com
Information Source: http://www.bdfacs.com

Status: The vendor has not responded
Evaluated: No

Technology: Physical
Portability: Fixed-Site Detection System

Unit Cost: $120K, pricing varies with options. Also listed under GSA.
Availability: BD FACSCaliburs are in stock
Description: Flow Cytometry (physical) in conjunction with Fluorescence (optical)—Flow cytometry with select antibodies; 488 nm and 632 nm laser excitation sources; forward scatter, side scatter, and 4 fluorescence detectors. Can be used with antibodies, dyes, PNA probes, and other fluroescent reagents.
Application: The BD FACSCalibur analyzes particles in fluid by light scatter and fluorescence. The BD FACS Calibur is designed to meet a wide range of application, including antigen expression and biological responses in leucocytes, and soluble antigen concentrations using Cytometric Bead Arrays.
Current Users: The BD FACS Calibur has been commercially available for 9 yr. Several thousand units have been placed in hospital, government, industrial and research laboratories worldwide.

OPERATIONAL PARAMETERS

BAs Detected: Mammalian cells—Numerous assays available for lymphocytes, including immune function in response to pathogens (vaccine development).

Bacteria and spores—Viabiltiy kit available. Specific detection of pathogens such as B. anthracis and Salmonella has been demonstrated using commercially available and restricted reagents. Usable reagents include antibodies and PNA probes.

Proteins—Cytometric Bead Array (CBA) kits available for quantitation of protein concentrations in a variety of protein mixtures, including cytokines and immunoglobulin isotypes. CBA assays have been demonstrated with toxins such as ricin and staphylococcal enterotoxins using restricted reagents.

Viruses—Viruses can be detected using CBA assays. A CBA assay for Vaccinia has been demonstrated using restricted reagents.

Type of Sample: Samples are applied to the instrument in a liquid format. Aerosols must be collected into a liquid phase. Sludges and solids can be run if they can be suspended or dissolved in an aqueous phase.
Sample Preparation: Samples must be in a liquid suspension. Samples are generally reacted with reagents to associate fluorescence with antigens of interest. For cells, this generally involves incubation with dyes or fluorescently-conjugated antibodies for 5 min to 20 min. For proteins and viruses, the analytes are captured on fluorescent microspheres and then detected with a second reagent, generally requiring 1 h to 2 h.
SOP Sample Preparation: Standard procedures are provided with regular products and would be developed as part of any custom application. Sample preparation information is usually provided with specific reagents. In general, a specific volume of sample is reacted with a volume of reagent at ambient temperature. The amount of time required for the reaction is dependent on the reagent being used. Depending on the application, the sample may be pre-treated, such as lysis of erythrocytes, or post-treated, such as with a fixative. The sample is run on the detector without further preparation.
Start-up Time: The instrument laser requires a 15 min warm-up period at start-up. A calibraton run requires about 5 min.
Calibration Requirements: The instrument is calibrated manually with a calibration product. Instrument requires one quantitative calibration at start-up. Calibration is recommended once per day or shift.
Response Time: Samples can be analyzed in 0.5 min to 3 min, depending on the number of events to be collected and the concentration of the analyte in the sample
Data Analysis Time: Typically 1 min to 2 min for data collection and analysis. Data analysis is generally performed manually. For most analyses, results can be reported directly off the sample collection screen. In some cases, off-line

analysis of results files will be required, but can be performed in batch mode. It is possible to automate sample collection and analysis for specific applications.
Alarms: The associated computer has alarm capability. Data must be interpreted before it is recognized.
Sensitivity: Mammalian cells and bacteria can be efficiently detected down to 100 cells/mL. Proteins can be detected down to picograms per milliliter (pg/mL) concentrations using the CBA format.

Bacteria—100 cfu/mL
Virus—<1000 µg/mL
Toxins—<1000 µg/mL

Confidence Interval/Sensitivity: Depends on the number of events collected. At 10 000 events, the C.V. would be 1.0 %. Confidence interval testing has not been performed.
Specificity: Specificity depends entirely on the quality of the reagents used.
Monoclonal antibodies used in lymphocyte subsetting generally have no detectable cross-reaction with similar lymphocyte antigens. Specificity can be optimized where either a number of reagents can be screened or antibodies can be developed for a specific application. In the case of B. anthracis with restricted antibodies, the inactivated organisms and its endospores could be detected with essentially no cross-reaction on the simulant B. globigii.
Detector specifics include:

- Soil—possible scatter and autofluorescence
- pH—extreme pH can interfere with antibody interactions
- Blood—can interfere if not lysed or diluted
- Can differentiate between viable and nonviable organisms—depends on reagents used
- Can detect spores—depends on reagent specificity
- Cross reactivity with proteins or organisms—depends on quality of reagents used
- B. globigii have been tested in cross reactivity studies

Confidence Interval/Specificity: Confidence interval testing has not been performed

- **False Positives**: Highly dependent on the assay as developed
- **False Negatives**: Highly dependent on the assay as developed

Resistance to Interferents: Not specified
Testing Information: The FACS Calibur is cleared for In Vitro Diagnostic use. Instrumentation and reagents are manufactured in a GMP facility under ISO 2002.

PHYSICAL PARAMETERS

Size: Cytometer: 91 cm x 61 cm x 67 cm (35.9 in x 24.2 in x 26.5 in); computer: 48 cm x 41 cm x 54 cm (18. 9 in x 16.1 in x 21.3 in); printer: 48 cm x 41 cm x 54 cm (18.9 in x 16.11 in x 21.3 in)
Working Space: 2 m x 0.8 m x 1.4 m (78.7 in x 31.5 in x 49.2 in)
Weight: Cytometer: 109 kg (240 lb)
Computer: 50 kg (110 lb)
Total Weight: 20 L sheath cubitainer (consumable)—20 kg (44 lb)
Additional sample preparation equipment (pipetters, racks, vortex)—<2 kg (4.4 lb)
Power Requirements: U.S.—120 V ac ±10 %; 50/60 Hz ±2 Hz, 20 A maximum. Additional U.S. options—external transformer for 100 V ac ±10 %; 50/60 Hz ±2 Hz; or 220 V ac ±10 %; 50/60 Hz ±2 Hz, 20 A maximum.

LOGISTIC PARAMETERS

Durability: Good, thousands of instruments in routine use in laboratories world-wide. Factory calibration is required after transporting or rough handling.
Ease of Use: Moderate complexity; requires operator training. Sample preparation requires manipulation of micropipettes to add sample to tube and to add reagent to sample.
The BD FACS Calibur requires use of a keyboard and mouse to set up sample run initially (setting up instrument parameters, entering sample identifyers). Sample tube is mounted on the instrument and a mouse entry begins acquisition. Steps can be done wearing PPE as long as operator retains some dexterity.
Environmental Conditions: Temperature between 16 ºC to 29 ºC (61 ºF to 84 ºF)—under 16 ºC (61 ºF) there is a decrease in optical stability. 60 % to 90 % noncondensing rh—above 90 % relative humidity, there is possible damage to electronics.
Support Equipment: The cytometer is run by an accessory computer. In addition, sample preparation requires use of micropipettes, test tube racks, vortex, and squirt bottles for cleaning solutions.
Consumables: Sheath fluid (saline) for instrument, test tubes, specific reagent solutions, pipettes and pipette tips, fixative, and chlorine bleach for system cleaning
Consumable Costs: Generally $5 to $20 per test, depending on the assay

Maintenance: Service contract includes a preventive maintenance every 6 mo
- Daily cleaning
- Monthly, extended cleaning

Available: Twenty-four (24 h) technical support by authorized field service engineers, a loaner option during maintenance or malfunctioning, hardware option (new software and software updates when become available)
Shelf Life (Equipment): Instrument can be stored for extended periods if care is taken with instrument preparation, for example, care to avoid crystallization of the saline used for sheath fluid. After prolonged storage, the fluidic system may have to be flushed out.
Shelf Life (Consumables): Most reagents have limited shelf life. Most consumables can be stored under ambient conditions. Some reagents will require refrigeration 2 ºC to 8 ºC (35 ºF to 46 ºF).
Maintenance Costs: Cost of service contract—$12K per yr
Decontamination: Sample lines are routinely cleaned with 10 % household bleach. Other fluidics and surfaces can be decontaminated with 10 % household bleach.

SPECIAL PARAMETERS

Skills Required: General laboratory skills and specific training in use of equipment is generally required to prepare and run assays. For specific applications, tests and software could be structured to require less training.
Training Required: Most operators require 1 d to 2 d of hands-on training. B.S. level of education is required to accurately analyze the data from the equipment.
Training Available: Training courses routinely provided to 2 operators as part of equipment purchase.
Name of training course: BD FACS Calibur Operator's Course
Certification—yes
Location—off site (at manufacturer site)

Manual training available, but no certification
Manuals Available: Equipment manual is provided with the instrument. Reagent information provided for each product.
Data Storage: Data is generally stored on the associated computer in a standard flow cytometry data format as FCS files
Communications: Computer (control)—GPIO interface; computer provided with system
Networking capability—equipment has network and LIMS connection capability through the associated computer
Security: Restriction of computer access can be accomplished through third party applications on the associated computer
Safety Requirements: General lab procedures for handling hazardous biologicals per BMBL
Applicable Regulations: Not specified
Warranty: 1 yr, parts and service

GENERAL

BD FACSCount (Model 337858)

BD Biosciences Immunocytometry Systems
2350 Qume Drive
San Jose, California 95131
Janet Horta, Marketing Product Manager
408–954–2340 (Tel)
408–954–2391 (Fax)
Janet_Horta@bd.com
Information Source: http://www.bdfacs.com

Status: The vendor has responded—11/14/2005
Evaluated: No

Technology: Physical
Portability: Fixed-Site Detection System

Unit Cost: $35K. Also listed under GSA.
Availability: BD FACSCount systems are readily available for purchase and do not require special order
Description: Flow cytometry (physical) with select antibodies; 543 nm laser excitation; 2 fluorescence channels (optical) and a calculated size parameter. Can be used with BD FACSCount reagents and controls containing antibodies and reference beads.
Application: The BD FACSCount analyzes particles in fluid by fluorescence and size. The instrument was specifically designed for the automated enumeration of CD3+, CD4+, and CD8+ cells HIV/AIDS clinical blood samples.
Current Users: The BD FACSCalibur has been commercially available for over 10 yr. Hundreds of units have been placed in hospital, government, industrial and research laboratories worldwide. Medical labs working with HIV/AIDS patient blood; military medical labs working with HIV/AIDS patient blood; hospitals working with HIV/AIDS patient blood; and developing world country HIV/AIDS treatment programs

OPERATIONAL PARAMETERS

BAs Detected: Detection limit 100/mL: Bacilus anthracis, Brucella abortus, Brucella melitensis, Brucella suis, Brucella canis, Corynebacterium diptheria, Francisella tularenius, Burkholderia mallei, Burkholderia pseudomallei, Shigella spp., Salmonella typhimurium, Salmonella enteritidis, Salmonella typhi, Vibrio cholerae, Yersinia pestis, E. coli O157:H7, and Coxiella burnetii

Detection limit TBD: Rickettsia prowazekii, Rickettsia tsutsugamushi, Rickettsia rickettsii, and Chlamydia psittaci

Detection limit ng protein/mL (CBA assay): Arenavirus (Argentine Hemorrhagic Fever), Arenavirus (Bolivian Hemorrhagic Fever), Alphavirus, Nairovirus, Bunyavirus, Flavivirus, Arenavirus, Orthopoxvirus, Influenzavirus, Hepatitis A, Flavivirus, Filovirus (Marburg), Filovirus (Ebola), Alphavirus (Eastern Equine Encephalitis virus), Alphavirus (Western Equine Encephalitis virus), Alphavirus (Venezuelan Equine Encephalitis virus), Flavivirus (Russian Spring-Summer Encephalitis), Phlebovirus, Flavivirus: Yellow Fever, Cryptosporidium spp., Coccidiomycosis immitis, Histoplasma capsulatum, Clostridium botulinum, Botulinum toxins, Clostridium perfringens, Clostridium perfringens toxins, Clostridium tetani, Clostridium tetani toxin, Mycotoxins of the Trichothecene Group, Aflatoxin, Ricin, Staphylococcal aureus enterotoxin B, Microcysstins, Anatoxin A, Tetrodotoxin, Saxitoxin, Palytoxin, Abrin, and Modeccin

Type of Sample: Samples are applied to the instrument in a liquid format
Sample Preparation: 1.Add 50 µL whole blood collected in EDTA to each tube, vortex, and incubate 60 min to 120 min.
2. Add 50 µL fixative solution to each tube and vortex.
3. Vortex and run on the instrument.

Hands on time for sample preparation with BD FACSCount reagents is less than 15 min
Most cytometric bead assays require <2 h
Time to result is 70 min including 60 min incubation
SOP Sample Preparation: A User's Guide is provided with the instrument. FACSCount reagent is provided in a self-contained sealed vial. The vial is cored with a provided tool. Fifty (50) µL of blood are pipetted into the tube with a programmed pipettor. After a 60 min to 120 min incubation period, fixative is pipetted into the tube and the tube is run on the detector.
Start-up Time: The equipment must be setup by the manufacturer service engineer, requiring 3 h to 4 h. The instrument laser requires a 15 min warm-up period at start up. A calibration run requires about 5 min. Detector start up time, including calibration to initiating the run, is <30 min.

Calibration Requirements: Instrument requires one quantitative calibration at startup and is recommended once per day or shift. The daily control run is a linearity check on precision for calculating the target concentration. Three or four reagent tubes (depending on reagent being used) are prepared with (zero), low, medium, and high count control beads. Software prompts for the appropriate tube and calculates linearity of concentration at the end of the run. A calibration run is ~5 min.
Response Time: Samples can be analyzed in 30 s to 3 min, depending on the number of events to be collected and the concentration of the analyte in the sample.
Data Analysis Time: Typically <1 min. Data analysis is generally performed automatically by the on-board computer and software, and results are printed. New assays would require specific software to be developed.
Alarms: The on-board computer has visible alarm capability. Alarm in the format of warning messages when results are out of range.
Sensitivity: Refer to specific biological agents detected
Confidence Interval/Sensitivity: Confidence interval testing has not been performed.
Specificity: Detector specifics include:

- Soil—possible scatter and autofluorescence
- pH—extreme pH can interfere with antibody interactions
- Air pollutants—possibler scatter and autofluorescence
- Blood—can interfere if not lysed or diluted
- Excess environmental protein or DNA—not as long as viscosity is not extreme
- Cannot differentiate between viable and nonviable organisms
- Cannot detect spores
- There are no claims for cross reactivity with proteins or organisms

Confidence Interval/Specificity: Confidence interval testing has not been performed

- **False Positives**: Not performed
- **False Negatives**: Not performed

Resistance to Interferents: Not specified
Testing Information: The FACSCount is cleared for In Vitro Diagnostic use. Instrumentation and reagents are manufactured in a GMP facility under ISO 2002.

PHYSICAL PARAMETERS

Size: 43.2 cm x 59.9 cm x 38.1 cm (17 in x 23.6 in x 15 in)
Working Space: 100 cm x 80 cm x 5 cm (39.4 in x 31.5 in x 19.7 in)
Weight: 25.9 kg (57.1 lb)
Total Weight: 20 L Sheath cubitainer (consumable)—20 kg (44 lb)
Additional sample preparation equipment (pipettors, racks, vortex)—<2 kg (4.4 lb)
Power Requirements: U.S.—120 V ac ±10 %; 60 Hz ±5 %; additional U.S. options—100 V ac ±10 %; 60 Hz ± 5 %; or 220 V ac ±10 %; 50 Hz ±5 %

LOGISTIC PARAMETERS

Durability: Able to be left in hot or cold environments with little effect. Temperatures >35 ºC (95 ºF) decreases optical stability, and humidity above 95 % may cause possible damage to electronics. Factory calibration is needed if dropped.
Ease of Use: Sample preparation requires manipulation of micropipettes to add sample to tube and to add reagent to sample. The BD FACSCount requires use of a keypad and/or barcode reader to set up sample run and enter sample identifyers. Sample tube is mounted on the instrument and button begins acquisition. Steps can be done wearing PPE as long as operator retains some dexterity.
Environmental Conditions: Temperature between 10 ºC to 35 ºC (50 ºF to 95 ºF) at sea level, 10 ºC to 25 ºC (50 ºF to 77 ºF) at 1800 m [decreased optical stability above 35 ºC (95 °F)]. 5 %to 95 % rh, noncondensing (possible damage to electronics above 95 % relative humidity).
Support Equipment: Reagent preparation requires a coring tool provided with the system. Sample preparation requires the use of micropipettes and a vortexer.
Consumables: Sheath (saline system fluid), reagent in dedicated tube, pipette tips, fixative, and bleach (system cleaning)
Consumable Costs: $4 to $10, depending on volumes
Maintenance: Service contract includes a preventive maintenance every 12 mo

- Daily cleaning
- Monthly, extended cleaning
- Annual, preventative maintenance

Service is provided within 24 h in most locations world-wide. Technical phone support is provided during regular business hours. There is no loaner option during preventative maintenance. The FACSCount is a closed-end system with no functional modifications anticipated.
Shelf Life (Equipment): After 1 yr storage, the equipment may require fluidic system to be flushed out
Shelf Life (Consumables): Reagent shelf life guaranteed to be 6 mo, and up to 15 mo
Maintenance Costs: Approximately $5K to $10K/yr, depending on location and coverage (average $5.5K)
Decontamination: Sample lines are routinely cleaned with 10 % household bleach. Other fluidics and surfaces can be decontaminated with 10 % household bleach.

SPECIAL PARAMETERS

Skills Required: General laboratory skills and specific training in use of equipment generally required to prepare and run assays. Typically less than 4 h training required. Operator does not need to analyze raw data to determine a final result.
Training Required: Most operators require at least several hours of hands-on training (less than 4 h). A high school diploma is acceptable to run the equipment.
Training Available: On-site training (where the equipment will be stored or used), but no certification for this training. Computer based training provided with software. Videos on VHS or CD available, but no certification for training.
Manuals Available: Instrument manual provided with instrument, includes assay information.
Data Storage: Data is generally not stored
Communications: Integral computer (control). Networking—RS-232 port.
Security: There is currently no security associated with instrument use. Security could be programmed into the software.
Safety Requirements: General lab procedures for handling hazardous biologicals per BMBL
Applicable Regulations: Not specified
Warranty: 1 yr, parts and service

GENERAL

Agilent 2100 Bioanalyzer

Agilent Technologies
2850 Centerville Road
Wilmington, Delaware 19808
Mr. Tom Fenton
302–633–8160 (Tel)
609–714–3498 (Fax)
tom_fenton@agilent.com
Information Source: http://www.chem.agilent.com

Status: The vendor has responded—12/6/2006
Evaluated: No

Technology: Hybrid
Portability: Mobile Laboratory Detection Equipment

Unit Cost: Contact Agilent Technologies representative for quotation
Availability: COTS/GSA. Contact an Agilent Technologies representative for specific details.
Description: CE (Nucleic) and Optical (Laser induced fluorescence)
Application: Separation and detection (qualitative and quantitative) of DNA, RNA, and proteins. Qualitative detection is limited to size (bp length—DNA/RNA; MW—protein).
Current Users: Contact an Agilent Technologies representative

OPERATIONAL PARAMETERS

BAs Detected: The Agilent 2100 Bioanalyzer detects RNA, DNA, or protein. Any of the following may be detected as either extracted, or extracted and amplified RNA or DNA; or as extracted protein (if applicable).
Type of Sample: Liquid
Sample Preparation: Consult Reagent Kit Guide applicable to product of interest
Time for sample preparation: less than 15 min
Equipment required for sample preparation: microtube centrifuge, micropipette (0 µL to 2 µL, 0 µL to 10 µL, 0 µL to 20 µL, 0 µL to 200 µL, and 0 µL to 1000 µL), and hot plate 90 ºC (194 ºF)
SOP Sample Preparation: Reagent Kit Guide Protein 200 Plus Assay
Reagent Kit Guide Protein 50 Assay
Reagent Kit Guide DNA 500 and DNA 1000 Assay
Start-up Time: Equipment includes internal standards for calibration with sample run.* <10 min (first results), <3 min (consecutive results)
Calibration Requirements: Instrument is calibrated automatically with every run. Qualitative internal standard (size, i.e., bp or MW).
Response Time: 30 min for 12 samples
Data Analysis Time: Data analysis takes less than 15 min before a conclusion can be made
Alarms: Data must be interpreted before it is recognized
Sensitivity: Toxins—as protein, 20 ng/µL (as BSA in PBS)
Target DNA—0.5 ng/µL DNA
Confidence Interval/Sensitivity: Instrument detects DNA, RNA, or protein. Detection confidence depends on sampling parameters developed by user.
Specificity: Known environmental interferents: cold temperatures <5 ºC (41 ºF); hot temperatures >70 ºC (158 ºF); high humidity (condensing); and altitudes >1.24 mi
Confidence Interval/Specificity: Depends on sample extraction and amplification (if applicable) developed by user

- **False Positives**: Not specified
- **False Negatives**: Not specified

Resistance to Interferents: DNA resolution—5 bp (25 bp to 100 bp), 5 % (100 bp to 500 bp), 10 % (500 bp to 1500 bp), 20 % (1500 bp to 12 000 bp); protein resolution—10 % (MW)
Testing Information: See "Invitrogen Corporation PathAlert™ Detection Kits" Verification Report and Statement at: http://www.epa.gov/etv/verifications/vcenter1-32.html

PHYSICAL PARAMETERS

Size: 16 cm x 42 cm x 29 cm (6.4 in x 16.6 in x 11.4 in)—bioanalyzer only
Working Space: Space for above, plus standard PC, monitor, and printer (optional); priming station—10 cm x 12 cm x 10 cm (3.9 in x 4.7 in x 3.9 in)
Weight: Bioanalyzer—10 kg (22 lb)
Total Weight: >3 kg (6.6 lb)
Power Requirements: 100 V ac to 240 V ac, 50 Hz to 60 Hz, 60 VA

LOGISTIC PARAMETERS

Durability: Able to operate after being moved but with considerable regard to handling
Ease of Use: User must be able to operate PC keyboard and micropipettes
Environmental Conditions: Operate between 5 ºC to 104 ºC (41 ºF to 104 ºF). Avoid <-40 ºC to >158 ºC (-40 ºF to 158 ºF). Avoid condensing humidity. <4572 m (15 000 ft) during travel.
Support Equipment: All required support materials supplied with instrument and sample assay kits except micropipettes, and hot plate and bath
Consumables: Reagent kit appropriate to assay (contains supplies sufficient for approximately 250 samples)
Consumable Costs: Approximately $500 per assay kit. Contact Agilent Technologies representative for quotation.
Maintenance: There is a 24 h technical support provided by the manufacturer or authorized agency. There is a loaner option during maintenance or malfunctioning. Periodic consumables replacement by user; hardware repairs by the manufacturer. There is no upgradeable equipment.
Shelf Life (Equipment): Equipment can probably be stored several years without suffering
Shelf Life (Consumables): Reagent kits should not be stored greater than 6 mo
Maintenance Costs: Contact Agilent Technologies representative for quotation
Decontamination: Not specified

SPECIAL PARAMETERS

Skills Required: No special skills but training required Chemist or other scientific background preferred, at least B.S. Equipment requires the operator to analyze raw data before a final result can be determined.
Training Required: Less than 8 h training required
Training Available: Yes, on-site or off site
Manuals Available: Normal operation, maintenance, and trouble-shooting
Data Storage: PC required
Communications: PC standards
Security: PC standards
Safety Requirements: Laser safety class
Applicable Regulations: Not specified
Warranty: 1 yr hardware warranty—contact Agilent Technologies representative for details

GENERAL

HPLC Diode Array Detector 20/20

GROTON Biosystems
45 Discovery Way
Acton, Massachusetts 01720
Brian O'Flaherty
978–266–9222, ext 408 (Tel)
978–266–9223 (Fax)
oflbr@grotonbiosystems.com
Information Source: http://www.grotonbiosystems.com

Status: The vendor has not responded
Evaluated: No

Technology: Hybrid
Portability: Fixed-Site Detection System

Unit Cost: $10K
Availability: Detectors are available with a 1 wk delivery time. Consumables are readily available for purchase
Description: HPLC with diode array detector
Application: Principally used as a diode array detector for HPLC separations
Current Users: Contract labs, army research, government medical centers, VA medical, biotech and pharmacetical companies, and children's hospitals

OPERATIONAL PARAMETERS

BAs Detected: Aflatoxin, Saxitoxin, Microcysstins, and Anatoxin A
Type of Sample: Liquid
Sample Preparation: Detector is part of HPLC chromatographic system. Sample preparation could include extraction, and filtering. Time required for sample preparation—less than 1 h.
SOP Sample Preparation: Equipment required for sample preparation: centrifuge, pipette, hot plate, sonicator, membrane syringe filter, centrifuge tubes, pipette tips, and transfer pipettes
Start-up Time: There is no equipment start-up time, just unpack and plug the instrument in. Calibration requires 30 min warm up time (equipment includes internal standards for calibration with sample run).
Calibration Requirements: The protocol for calibration at startup requires linear calibration curve and standards. Type and frequency of calibration includes 1 qualitative calibration setting and 1 quantitative calibration setting.
Response Time: Not specified
Data Analysis Time: If data analysis is required, it takes less than 15 min to make a conclusion
Alarms: Data must be interpreted before it is recognized
Sensitivity: Target DNA—nanograms of DNA via dye, protein with tryptophan amino acids
Confidence Interval/Sensitivity: Not specified
Specificity: Known interferents include excess environmental protein, and excess environmental DNA. It cannot differentiate between viable and nonviable organisms, nor detect spores.
Confidence Interval/Specificity: Not specified

- **False Positives**: Not specified
- **False Negatives**: Not specified

Resistance to Interferents: Not specified
Testing Information: Not specified

PHYSICAL PARAMETERS

Size: 30 cm x 30 cm x 15 cm (1 ft x 1 ft x 0.5 ft)
Working Space: 30 sq cm (1 ft2)
Weight: 9 kg (20 lb)
Total Weight: Not specified
Power Requirements: Battery powered or ac

LOGISTIC PARAMETERS

Durability: Not specified
Ease of Use: Not specified
Environmental Conditions: Not specified
Support Equipment: Equipment required for sample preparation includes centrifuge, pipette, hot plate, sonicator, and membrane syringe filters
Consumables: Centrifuge tubes, pipette tips, and transfer pipettes
Consumable Costs: Cost is $700. Detector is a component of a larger system. Detector consumable cost is not significant. Possibly change a source every year with continuous use.
Maintenance: $3K, includes 2 visits but excludes travel (required yearly)
Twenty-four (24 h) technical support is not provided by the manufacturer or authorized agency, however, there is a loaner option during maintenance or malfunctioning
Shelf Life (Equipment): The equipment can be stored without being serviced before it is used
Shelf Life (Consumables): Consumables can be stored indefinitely
Maintenance Costs: $4K (required yearly)
Decontamination: Not specified

SPECIAL PARAMETERS

Skills Required: Special skills are required to operate the equipment; operator is required to analyze raw data before a final result can be determined. A B.S. is required to accurately analyze the data from the equipment.
Training Required: <8 h training required
Training Available: Training is available off site (at manufacturer site) or on-site (where the equipment will be used or stored)
Manuals Available: User manual
Data Storage: Results are either strip chart or computer
Communications: Equipment can be interfaced with computer
Security: Not specified
Safety Requirements: Not specified
Applicable Regulations: Not specified
Warranty: 1 yr parts and labor; expected lifetime is 10 yr

GENERAL

Agilent 6850; Agilent 6850 Series II Network GC

Agilent Technologies
2850 Centerville Road
Wilmington, Delaware 19808
Mr. Tom Fenton
302–633–8160 (Tel)
609–714–3498 (Fax)
tom_fenton@agilent.com
Information Source: http://www.chem.agilent.com

Status: The vendor has responded—12/6/2006
Evaluated: No

Technology: Hybrid
Portability: Mobile Laboratory Detection Equipment

Unit Cost: Configuration dependent
Availability: COTS/GSA
Description: GC—for BA identification. To confirm and identify BAs, such as anthrax, Agilent has teamed with MIDI, Inc., to provide a solution. The solution uses Agilent's state-of-the-art instrumentation with MIDI's bioterrorism reference library to quickly identify the bacteria and its strain. The reference library was developed in collaboration with the U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID). (http://www.midi-inc.com/pages/bioterrorism.html).
Application: To confirm and identify BAs, such as anthrax, Agilent has teamed with MIDI, Inc., to provide a solution. The solution uses Agilent's state-of-the-art instrumentation with MIDI's bioterrorism reference library to quickly identify the bacteria and its strain. The reference library was developed in collaboration with the U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID). (http://www.midi-inc.com/pages/bioterrorism.html).
Current Users: Contact POC above for information

OPERATIONAL PARAMETERS

BAs Detected: Bacillus anthracis (anthrax), Brucella melitensis (brucellosis), Burkholderia mallei (glanders), Burkholderia pseudomallei (melioidosis), Francisella tularensis (tularemia), Yersinia pestis (plague)
Type of Sample: Vapor and liquid
Sample Preparation: Not specified
SOP Sample Preparation: Not specified
Start-up Time: 2 h
Calibration Requirements: Yes
Response Time: Less than 30 min
Data Analysis Time: Not specified
Alarms: Audible alarm
Sensitivity: Not specified
Confidence Interval/Sensitivity: Not specified
Specificity: Not specified
Confidence Interval/Specificity: Not specified

- **False Positives**: Not specified
- **False Negatives**: Not specified

Resistance to Interferents: High selectivity but method dependent
Testing Information: Contact POC above

PHYSICAL PARAMETERS

Size: 58 cm x 30 cm x 30 cm (23 in x 12 in x 22 in)
Working Space: Not specified
Weight: Approximately 29 kg (65 lb) for the system
Total Weight: Not specified

Power Requirements: 100 V ac

LOGISTIC PARAMETERS

Durability: Able to operate after being moved but with considerable regard to handling
Ease of Use: Not specified
Environmental Conditions: -20 ºC to 35 ºC (-4 °F to 95 °F) at 0 % to 95 % rh (operating temperature)
Support Equipment: See required consumables
Consumables: Helium, hydrogen, nitrogen, GC columns, ferrules, injection port liners, and standards for calibration (both configurations). Sample preparation consumables (BA configuration).
Consumable Costs: Not specified
Maintenance: Periodic consumables replacement
Shelf Life (Equipment): Not applicable
Shelf Life (Consumables): Not applicable
Maintenance Costs: Configuration dependant
Decontamination: Not specified

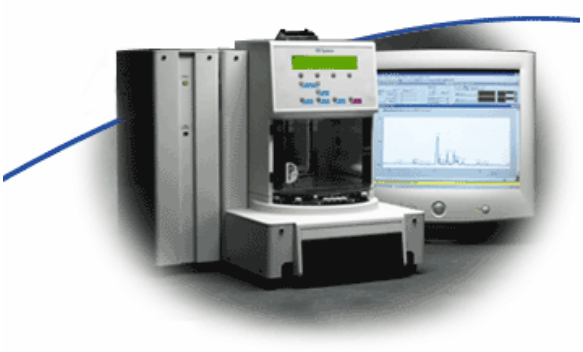
SPECIAL PARAMETERS

Skills Required: Biological sample handling (for BA identification)
Training Required: Instrument /data system operation (all configurations). Sample preparation (for BA identification).
Training Available: On-site or offsite (chemical agent system); off-site (BA identification)
Manuals Available: User manual
Data Storage: Not specified
Communications: Data system is Windows 2000 based. Can output results to Excel or database via TCP/IP or modem.
Security: Password protected
Safety Requirements: Not specified
Applicable Regulations: None
Warranty: 1 yr

GENERAL

Capillary Electrophoresis System (GPA100)

GROTON Biosystems
45 Discovery Way
Acton, Massachusetts 01720
Brian O'Flaherty
978–266–9222, ext 408 (Tel)
978–266–9223 (Fax)
oflbr@grotonbiosystems.com
Information Source: http://www.grotonbiosystems.com



Status: The vendor has not responded
Evaluated: No

Technology: Hybrid
Portability: Fixed-Site Detection System

Unit Cost: $30K
Availability: Detectors are available with a 1 wk delivery time. Consumables are readily available for purchase
Description: CE—System used for the separation and detection of oligonucleotides, proteins, peptides, and amino acids
Application: Optical detection—Ultraviolet, diode array, fluorescence, and laser induced fluorescence. Optical detection size: 25 cm x 30 cm (10 in x 12 in). Separation—Able to connect to commercially available MS systems. High separation of molecules in capillary tube under.
Current Users: Contract labs, army research, government medical centers, VA medical, biotech and pharmacetical companies, and children's hospitals

OPERATIONAL PARAMETERS

BAs Detected: Aflatoxin—<20 ppb and Saxitoxin—<20 ppb
Type of Sample: Liquid
Sample Preparation: Sample preparation could include extraction and filtering
SOP Sample Preparation: SOP provided by manufacturer—desalting of sample
Equipment required for sample preparation—centrifuge, pipette, hot plate, sonicator, membrane syringe filter, centrifuge tubes, pipette tips, transfer pipettes, and 0.2 µm membrane syringe filters
Start-up Time: There is no equipment start-up time, just unpack and plug the instrument in. Calibration requires 30 min warm-up time (equipment includes internal standards for calibration with sample run).
Calibration Requirements: The protocol for calibration at start-up requires linear calibration curve and standards. Type and frequency of calibration includes 1 qualitative calibration setting and 1 quantitative calibration setting.
Response Time: Not specified
Data Analysis Time: If data analysis is required, it takes less than 15 min to make a conclusion
Alarms: Data must be interpreted before it is recognized
Sensitivity: Target DNA—nanograms of DNA via dye, protein with tryptophan amino acids
Confidence Interval/Sensitivity: Not specified
Specificity: Known interferents include pH, excess environmental protein, and excess environmental DNA. It cannot differentiate between viable and nonviable organisms, nor detect spores.
Confidence Interval/Specificity: Not specified

- **False Positives**: Not specified
- **False Negatives**: Not specified

Resistance to Interferents: Not specified
Testing Information: Not specified

PHYSICAL PARAMETERS

Size: 60 cm x 60 cm x 91 cm (2 ft x 2 ft x 3 ft)
Working Space: 0.9 m^2 (3 ft^2)
Weight: 23 kg (50 lb)
Total Weight: Not specified
Power Requirements: Power is ac or battery powered

LOGISTIC PARAMETERS

Durability: Not specified
Ease of Use: Not specified
Environmental Conditions: Not specified
Support Equipment: Equipment required for sample preparation includes centrifuge, pipette, hot plate, sonicator, and membrane syringe filter
Consumables: Centrifuge tubes, pipette tips, transfer pipettes, and 0.2 µm membrane syringe filters
Consumable Costs: Cost is $700. Detector is a component of a larger system. Detector consumable cost is not significant. Possibly change a source every year with continuous use.
Maintenance: $3K, includes 2 visits but excludes travel (required yearly)
Twenty-four (24 h) technical support is not provided by the manufacturer or authorized agency, however, there is a loaner option during maintenance or malfunctioning
Shelf Life (Equipment): The equipment can be stored without being serviced before it is used
Shelf Life (Consumables): Consumables can be stored indefinitely
Maintenance Costs: $4K (required yearly)
Decontamination: Not specified

SPECIAL PARAMETERS

Skills Required: Special skills are required to operate the equipment; operator is required to analyze raw data before a final result can be determined. A B.S. is required to accurately analyze the data from the equipment.
Training Required: 2 d training required
Training Available: Training is available offsite (at manufacturer site) or on-site (where the equipment will be used or stored)
Manuals Available: User manual
Data Storage: Results are either strip chart or computer
Communications: Equipment can be interfaced with computer
Security: Not specified
Safety Requirements: Not specified
Applicable Regulations: Not specified
Warranty: 1 yr parts and labor; expected lifetime is 10 yr

GENERAL

HPLC Fluorescence Detector (FD500)

GROTON Biosystems
45 Discovery Way
Acton, Massachusetts 01720
Brian O'Flaherty
978–266–9222, ext 408 (Tel)
978–266–9223 (Fax)
oflbr@grotonbiosystems.com
Information Source: http://www.grotonbiosystems.com

Status: The vendor has not responded
Evaluated: No

Technology: Hybrid
Portability: Fixed-Site Detection System

Unit Cost: $10K
Availability: Detectors are available with a 1 wk delivery time. Consumables are readily available for purchase.
Description: HPLC and stand alone spectrofluorometer—fluorescence/emission
Application: Separation
Current Users: Contract labs, army research, government medical centers, VA medical, biotech and pharmacetical companies, and children's hospitals

OPERATIONAL PARAMETERS

BAs Detected: Aflatoxin— <1 ppb
Saxitoxin— <1 ppb
Type of Sample: Air, liquid, or solid
Sample Preparation: Detector is part of HPLC chromatographic system. Sample preparation could include extraction, and filtering.
SOP Sample Preparation: Equipment required for sample preparation:
Centrifuge, pipette, hot plate, sonicator, membrane syringe filter, centrifuge tubes, pipette tips, and transfer pipettes
Time required for sample preparation—less than 1 h
Start-up Time: There is no equipment start-up time, just unpack and plug the instrument in. Calibration requires 30 min warm-up time (equipment includes internal standards for calibration with sample run).
Calibration Requirements: The protocol for calibration at start-up requires linear calibration curve and standards. Type and frequency of calibration includes 1 qualitative calibration setting and 1 quantitative calibration setting.
Response Time: Not specified
Data Analysis Time: If data analysis is required, it takes less than 15 min to make a conclusion
Alarms: Data must be interpreted before it is recognized
Sensitivity: Target DNA—nanograms of DNA via dye, protein with tryptophan amino acids
Confidence Interval/Sensitivity: Not specified
Specificity: Known interferents include excess environmental protein, and excess environmental DNA. It cannot differentiate between viable and nonviable organisms, nor detect spores.
Confidence Interval/Specificity: Not specified

- **False Positives**: Not specified
- **False Negatives**: Not specified

Resistance to Interferents: Not specified
Testing Information: Not specified

PHYSICAL PARAMETERS

Size: 30 cm x 30 cm x 15 cm (1 ft x 1 ft x 0.5 ft)
Working Space: 30 sq cm (1 ft2)
Weight: 9 kg (20 lb)
Total Weight: Not specified

Power Requirements: Battery powered or ac

LOGISTIC PARAMETERS

Durability: Not specified
Ease of Use: Not specified
Environmental Conditions: Not specified
Support Equipment: Equipment required for sample preparation centrifuge, pipette, hot plate, sonicator, and membrane syringe filters
Consumables: Centrifuge tubes, pipette tips, and transfer pipettes
Consumable Costs: Cost is $700. Detector is a component of a larger system. Detector consumable cost is not significant. Possibly change a source every year with continuous use.
Maintenance: $3K, includes 2 visits but excludes travel (required yearly)
Twenty-four (24 h) technical support is not provided by the manufacturer or authorized agency, however, there is a loaner option during maintenance or malfunctioning
Shelf Life (Equipment): The equipment can be stored without being serviced before it is used
Shelf Life (Consumables): Consumables can be stored indefinitely
Maintenance Costs: $4K (required yearly)
Decontamination: Not specified

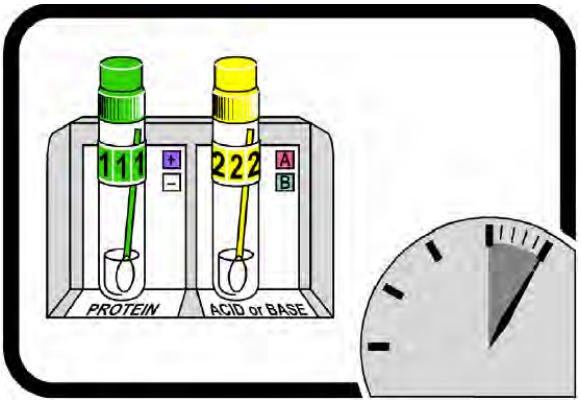
SPECIAL PARAMETERS

Skills Required: Special skills are required to operate the equipment; operator is required to analyze raw data before a final result can be determined. A B.S. is required to accurately analyze the data from the equipment.
Training Required: <8 h training required
Training Available: Training is available off site (at manufacturer site) or on-site (where the equipment will be used or stored)
Manuals Available: User manual
Data Storage: Results are either strip chart or computer
Communications: Equipment can be interfaced with computer
Security: Not specified
Safety Requirements: Not specified
Applicable Regulations: Not specified
Warranty: 1 yr parts and labor; expected lifetime is 10 yr

GENERAL

BioCheck™ Powder Screening Test Kit (GB 1001)

20/20 GeneSystems Inc.
9700 Great Seneca Highway
Rockville, Maryland 20850
866–572–2020 (Tel)
General Assistance:
240–453–6339 (Tel)
240–453–6208 (Fax)
Liz Marcus
240–453–6342 (Tel)
240–453–6208 (Fax)
Lmarcus@2020gene.com
Information Source: http://www.2020gene.com/
Status: The vendor has responded—10/26/2005
Evaluated: Yes



Technology: Screening/Immunochemical
Portability: Handheld Detection Equipment

Unit Cost: $19 to $25 per unit
Availability: Orders of up to 1000 units will ship within 3 wk of receipt of order. Three weeks is required for each 1000 units above the 1000 ordered, up to a total of 5000 (i.e., 3000 kits would require 9 wk to manufacture and ship). For orders of more than 5000 units, production would be accelerated through adjustments to the manufacturing process (e.g., outsourcing and automation).
Description: Immunochemical/Colorimetric/Optical—Visual inspection (by eye) for color changes. Proteomics and protein detection.
Primary intellectual property platform—Layered Gene Scanning (LGS)—was exclusively licensed from the National Institutes of Health (NIH) and is being co-developed between 20/20 and several NIH scientists. This technology provides drug companies and life scientists with a digital "snapshot" of the proteins in disease samples and is predicted to become the premier technology in diagnostic pathology within 4 yr.
Application: The BioCheck™ Powder Screening Kit provides a rapid screen for the possible presence of multiple bioterrorism agents including anthrax, botulinum, and ricin toxins while ruling out most of the ordinary substances that people have frequently feared to be possible weapons of mass destruction. A positive result with the kit indicates a need for further (agent-specific) testing (it does not necessarily mean a BWA is present); a negative suggests that a biological WMD active in visible, solid form (i.e., anthrax, ricin, botulinum toxin) is unlikely to be present. The kit is intended as a first step in evaluating a suspicious powder in the field. Its primary user group is first responders.
Current Users: Military—Defense Intelligence Agency, Commander, USA/RDECOM
First responders—More than 300 nationwide including Washington DC Fire and EMS, Orlando City (FL) Fire Department, Port of Seattle (WA) Fire Department, U.S. Marshals, and Federal Protective Services. Departments purchase 25 to 200 units per year depending upon the volume of calls.
Industrial or private sector clients including direct mail processors and IBM. To date there are about 15 of these users.

OPERATIONAL PARAMETERS

BAs Detected: Rapid screen for the possible presence of multiple bioterrorism agents such as B. anthracis, botulinum toxins, and ricin toxin (any WMD that is active in visible, solid powder form), while ruling out most of the ordinary substances that citizens have frequently feared to be possible WMD
Type of Sample: Detects all known biotoxins and pathogens dispersed as solid powders. First responders know almost immediately if they and those they protect are at risk of a BA.
Sample Preparation: Sample preparation is not required, therefore, average time is 0 s
SOP Sample Preparation: Not applicable
Start-up Time: Not applicable—instrument not required
Calibration Requirements: Instrument not required
Response Time: Not applicable—instrument not required
Data Analysis Time: Get results in less than 5 min. Procedure for analysis:

1. Remove screw caps from two test vials.
2. Collect a small amount of the sample on the two pre-wetted swabs provided.
3. Drop each swab into the appropriate vial.

4. Wait 5 min.
5. Read the result (examine two solutions for color changes).
6. ONLY if negative for protein (no color change in this vial): add second swab to the protein test vial. Wait 5 min and confirm color changed to purple (this step verifies that a negative result was a true negative).

Alarms: Visual
Sensitivity: Bacilus anthracis—>100 000 cfu/mL (visible quantity of spores: not liquid cultures)
Botulinum toxins—12 µg
Ricin—12 µg
Confidence Interval/Sensitivity: Bacilus anthracis—>100 000 spores (spores: any visible amount)
Botulinum toxins—12 µg
Ricin—12 µg
Specificity: The results are read as simple color changes and the kit can be used after minutes of training
Confidence Interval/Specificity: Not applicable. The equipment provides a generic test for protein and pH; it is not a specific agent test.

- **False Positives**: 13 % (based on field testing by DC fire and EMS, 87 % of materials that caused 911 calls did not contain protein)
- **False Negatives**: There is no known incident of a false negative

Resistance to Interferents: Cold temperatures—will slow reaction time
pH—strong acid pH (<pH 2)
Assay cross-reacts to any protein present at or above the threshold detection limit (the product is intended for use as a preliminary screen)
Flour, E. coli, bacillus thuringiensis (B. thuringiensis), yeast, yeast extract, bactotryptone, bacto agar, bovine serum albumin (BSA), cornmeal, nutmeg have been tested in cross-reactivity studies
Assay detects spores
Assay does not differentiate between viable and nonviable organisms
Testing Information: Battelle testing conducted in September 2002

PHYSICAL PARAMETERS

Size: Each kit is contained in a small box of ~10 cm x 10 cm x 5 cm (4 in x 4 in x 2 in)
Working Space: Beyond space to accommodate it, the equipment requires no transport or mobility support
Weight: The kit weighs 57 g (2 oz)
Total Weight: The kit weighs 57 g (2 oz)
Power Requirements: No power requirements

LOGISTIC PARAMETERS

Durability: Able to be transported quickly without protective packaging and dropped from counter height without effect. Able to be left in hot environment without effect; must be allowed to warm to room temperature if left in cold environment.
Ease of Use: The equipment can be readily deployed (and is routinely) by operators under challenging circumstances. Only 6 steps to run and complete an analysis (data analysis).
Environmental Conditions: Operating temperature range: 5 ºC to 90 ºC (41 ºF to 194 ºF). Close to boiling and boiling will cause evaporation and concentration changes to critical reagents compromising performance. Close to freezing and freezing will greatly slow the reaction time. If the solutions in the kit are frozen it cannot be used.
Support Equipment: Each kit is a self-contained unit with everything needed for sample assessment
Consumables: Each kit is a self-contained unit with everything needed for sample assessment
Consumable Costs: None required
Maintenance: The equipment is a one time use disposable product; therefore, preventative maintenance is not required and loaner option is not available. However, there is 24 h technical support for users in the field.
Shelf Life (Equipment): Product performance is not certain beyond 1 yr
Shelf Life (Consumables): The BioCheck™ product is stable for at least 1 yr
Maintenance Costs: Not applicable
Decontamination: Not applicable (disposable equipment). The equipment could be safely incinerated if required (e.g., used in detection of a BWA and thus needs to be destroyed).

SPECIAL PARAMETERS

Skills Required: No special skills but training required. The kit can be used after minutes of training. However, operator must have the ability to distinguish color (color-blind user could not deploy) since the results are read as simple color changes.

High school deiploma is sufficient level of education. Operator does not need to analyze raw data before a final result can be determined.
Training Required: No special skills but training required
Training Available: Training mmanuals are available
Manuals Available: Instruction sheet (provided with every piece of equipment)
Available upon request* [frequently asked questions, summary information flyer, detail on substances tested, and training presentation (PowerPoint)]*
Data Storage: Not applicable
Communications: Not applicable
Security: Security devices not provided or required. The positive control swab provided with the equipment is used to confirm its functionality.
Safety Requirements: Not applicable
Applicable Regulations: Not applicable
Warranty: Warranty not provided

GENERAL

KT1030 HazCat Anthrax Screening Test Kit

Haztech Systems, Inc.
PO Box 929
Mariposa, California 95338
Dawn L. Plunkett (Operations Manager)
800–543–5487 (Tel)
209–966–8089 (Fax)
sales@hazcat.com
Information Source: http://www.hazcat.com

Status: The vendor has responded—11/21/2006
Evaluated: Yes

Technology: Screening/Immunochemical
Portability: Mobile Laboratory Detection Equipment

Unit Cost: $614 plus shipping and handling
Availability: Product can be shipped within 7 d upon receipt of purchase order
Description: Immunoassay—The HazCat Anthrax Screening Kit as a stand-alone unit. It can be integrated with the HazCat Chemical Identification Kit to identify unknown industrial materials.
Application: The HazCat Anthrax Screening Test Kit solves the anthrax problem by proving the substance cannot be anthrax. The screen contains tests that eliminate broad families of compounds. Specific confirmation tests are also included, such as, the flour test, protein test, calcium test, etc. The HazCat Anthrax Screening Test Kit gives you the answers you need on scene. The results, plus contemporary emergency management strategy and tactics, equals an unbeatable combination to manage an emergency incident on more than a guess.
Current Users: States—California, Delaware, Florida, Idaho, Minnesota, Mississippi, New Jersey, North Carolina, Oregon, Utah, Pennsylvania, Virginia, and Washington.
U.S. Government Agencies—U.S. Army, U.S. Air Force, U.S. Coast Guard, U.S. Navy, U.S. Marines, EPA, Deptartment of Transportation, CIA, Los Alamos, Brookhaven National Lab, and NASA.
Canadian Government—Quebec-Ministry de l'Environment and Alberta-Department of Environment.
Cities—Los Angeles, California; Oakland, California; San Francisco, California; Salt Lake City, Utah; Seattle, Washington; Sacramento, California; Anchorage, Alaska; Akron, Ohio; El Paso, Texas; Phoenix, Arizona; Lansing, Michigan; New York, New York; Miami, Florida; Las Vegas, Nevada; Portland, Oregon; Gila River Indian Community, Arizona; Des Moines, Iowa; Cincinnati, Ohio; Overland Park, Kansas; Irving, Texas; Rapid City, South Dakota; Philadelphia, Pennsylvania; Syracuse, New York; and Boston, Massachusetts.

OPERATIONAL PARAMETERS

BAs Detected: Detects amino acid and protein. Screens nonbiological substances and pesticides. Immunoassay tests for anthrax, ricin, botulinum toxin, and soon for smallpox and plague. The kit eliminates an anthrax threat by positively identifying the sample as something other than anthrax—the usual outcome in the vast majority of cases.
Type of Sample: Solid and liquid
Sample Preparation: Wet, dry, and stain mounts. Occasional wash/extraction and mixing. Most tests may be performed on a swabbed sample.
SOP Sample Preparation: Results are ready as soon as the test is perfomed, using the step-by-step instructions. Anthrax may be eliminated as a threat by proving the substance does not produce test results expected from anthrax. Anthrax may appear as an almost white to tan to dirty, dark brown powder. Weapons grade anthrax is a fluid powder that flows like water. You cannot see individual spores. Suggests weapons grade anthrax spores coated with aluminum silicate. Anthrax cannot be eliminated; further testing required. Some pesticides may end up here. Usually they will be on an inert base such as magnesium carbonate. Try the Magnesium Test. Some anthrax is grown in blood extract and could be positive in the Iron Test, but may be negative if the anthrax culture was started in blood and then processed further as a method of growing greater amounts of bacteria.
Start-up Time: 15 min
Calibration Requirements: None
Response Time: 30 min
Data Analysis Time: Not specified

Alarms: The yellow liquids show a negative result in the Amino Acid Test and the user is told the unknown substance cannot be anthrax. The purple liquid is a positive result in the Amino Acid Test, and the user is directed to continue testing by following the path on the chart.
Sensitivity: Not specified
Confidence Interval/Sensitivity: Not specified
Specificity: Not specified
Confidence Interval/Specificity: Not specified

- **False Positives**: Not specified
- **False Negatives**: Not specified

Resistance to Interferents: Not specified
Testing Information: Not specified

PHYSICAL PARAMETERS

Size: 38 cm x 23 cm x 18 cm (15 in x 9 in x 7) in ABS plastic case
Working Space: Not specified
Weight: Not specified
Total Weight: Not specified
Power Requirements: Not specified

LOGISTIC PARAMETERS

Durability: It stores securely and all the components are accessed conveniently. The HazCat Anthrax Screening Test Kit is designed specifically for field use. It is completely portable and self-contained in a sturdy, easy-to-carry ABS plastic case.
Ease of Use: Not specified
Environmental Conditions: Above 0 ºC (32 ºF). Operates in most environments.
Support Equipment: Not specified
Consumables: Disposable test tubes, pipettes, scoops, test strips, slides, and reagents
Consumable Costs: Not specified
Maintenance: There are procedures for testing reagents every few months in the front of the user's manual
Shelf Life (Equipment): 90 % indefinitely; 10 % 1 yr to 3 yr
Shelf Life (Consumables): Some reagents are dated and will require replacing; most all reagents in the kit have an indefinite shelf life. Some hardware will need to be replaced as it is used.
Maintenance Costs: There is technical support and emergency support provided via telephone or e-mail
Decontamination: Not specified

SPECIAL PARAMETERS

Skills Required: High school education—no special skills, but training required
Training Required: Yes
Training Available: #S1803—4 d HazCat WMD Workshop, $750. Training results in certification.
Manuals Available: User manual and MSDS manual, flow charts, and field sheet packets
Data Storage: Not specified
Communications: Not applicable
Security: Equipment supplied in convenient lockable, durable plastic case
Safety Requirements: Not specified
Applicable Regulations: Not specified
Warranty: 1 yr parts and labor

GENERAL

KT1235 HazCat® WMD Kit

Haztech Systems, Inc.
PO Box 929
Mariposa, California 95338
Dawn L. Plunkett (Operations Manager)
800–543–5487 (Tel)
209–966–8089 (Fax)
sales@hazcat.com
Information Source: http://www.hazcat.com

Status: The vendor has responded—11/21/2006
Evaluated: Yes

Technology: Screening/Immunochemical
Portability: Mobile Laboratory Detection Equipment

Unit Cost: $4.16K plus shipping and handling
Availability: Product can be shipped within 7 d upon receipt of purchase order
Description: ELISA Test Kits plus Microscopy
Application: Field reagents chemistry/qualitative analysis. KT1235 WMD Kit Solid/Liquid Field Chemical Identification. The HazCat WMD Kit may be fortified with the RTAK MicroCat—a field microscopy system with digital linking to on-duty microbiologists.
Current Users: Los Angeles PD, Sacramento Fire Department, Tempe Fire Department, Roseville Fire Department, FBI, FedEx, and CSTs.

OPERATIONAL PARAMETERS

BAs Detected: Detects amino acid and protein, screens nonbiological substances and pesticides, immunoassay tests for anthrax, ricin, botulinum toxin, and soon for smallpox and plague
Type of Sample: All
Sample Preparation: Occasional wash/extraction and mixing. Most tests may be performed on a swabbed sample.
SOP Sample Preparation: Not specified
Start-up Time: 15 min
Calibration Requirements: No calibration required after the equipment is moved
Response Time: 30 min
Data Analysis Time: Not specified
Alarms: Not specified
Sensitivity: 0.01 mg of Bacillus globigii (about 100 000 spores)
Confidence Interval/Sensitivity: Not specified
Specificity: Not specified
Confidence Interval/Specificity: Not specified

- **False Positives**: Not specified
- **False Negatives**: Not specified

Resistance to Interferents: Minimal
Testing Information: HazCat manual supplies details on quality checks of reagents on an annual basis

PHYSICAL PARAMETERS

Size: 24 cm x 29 cm x 30 cm (9.5 in x 11.5 in x 11.75 in); 48 cm x 28 cm x 28 cm (19 in x 11 in x 11 in) ABS plastic case
Working Space: Not specified
Weight: 9 kg (20 lb)
Total Weight: Not specified
Power Requirements: 9 V battery

LOGISTIC PARAMETERS

Durability: It stores securely and all the components are accessed conveniently. The HazCat Chemical Identification System is designed specifically for field use.
Ease of Use: Not specified
Environmental Conditions: Above 0 ºC (32 ºF). Operates in most environments.
Support Equipment: Not specified
Consumables: Disposable test tubes, pipettes, scoops, test strips, slides, and reagents
Consumable Costs: Not specified
Maintenance: There are procedures for testing reagents every few months in the front of the user's manual
Shelf Life (Equipment): 90 % indefinitely; 10 % 1 yr to 3 yr
Shelf Life (Consumables): Some reagents are dated and will require replacing; most all reagents in the kit have an indefinite shelf life. Some hardware will need to be replaced as it is used.
Maintenance Costs: $100—there is technical support and emergency support provided via telephone or e-mail
Decontamination: Not specified

SPECIAL PARAMETERS

Skills Required: High school education—no special skills, but training required
Training Required: Yes
Training Available: #S1803—4 d HazCat WMD Workshop, $750. Training results in certification.
Manuals Available: User manual and MSDS manual, flow charts, and field sheet packets
Data Storage: Not specified
Communications: Not applicable
Security: Equipment supplied in convenient lockable, durable plastic case
Safety Requirements: Not specified
Applicable Regulations: Title 29 CFR 1910.120 Req. for I.D., IATA shipping confirmation
Warranty: 1 yr parts and labor

GENERAL

KT1040 HazCat® MicroCat/WMD

Haztech Systems, Inc.
PO Box 929
Mariposa, California 95338
Dawn L. Plunkett (Operations Manager)
800–543–5487 (Tel)
209–966–8089 (Fax)
sales@hazcat.com
Information Source: http://www.hazcat.com

Status: The vendor has responded—11/21/2006
Evaluated: Yes

Technology: Screening/Microscopy
Portability: Mobile Laboratory Detection Equipment

Unit Cost: $22K plus shipping and handling
Availability: Product can be shipped within 7 d upon receipt of purchase order
Description: Microscopy—Field Digital Phased Microscopy
KT1040 MicroCat/WMD Kit, Solid/Liquid Field Chemical Identification
Leica DMLS clinical microscope; LED illumination (80 h battery); Plan phase optics (10x, 40x, 100x).
Application: Field reagents chemistry. KT1040 MicroCat /WMD Kit, Solid/Liquid Field Chemical Identification.
Current Users: Los Angeles PD, Sacramento Fire Department, Tempe Fire Department, Roseville Fire Department, FBI, FedEx, CSTs, and Dugway Proving Grounds.

OPERATIONAL PARAMETERS

BAs Detected: Detects amino acid and protein, screens nonbiological substances and pesticides, immunoassay tests for anthrax, ricin, botulinum toxin, and soon for smallpox and plague.
Microscopy—CDC Category A Diseases/Agents and CDC Category B Diseases/Agents
Type of Sample: Solid and liquid
Sample Preparation: Wet, dry, and stain mounts. Occasional wash/extraction and mixing. Most tests may be performed on a swabbed sample.
SOP Sample Preparation: Samples are first screened for radioactive hazards with radiation monitor. Nonradioactive materials are screened for biological threats with simple tests on small amounts of sample, using the amino acid test, which detects protein. Supporting tests screen compounds that are incompatible with biologic agents. If an agent is not ruled out by the screen, specific immunoassay tests are used for bacteria, spores, and toxins.
Start-up Time: Microscope—between 61 s and 5 min; detection kit—15 min
Calibration Requirements: None
Response Time: Collect a sample—10 s
Analyze the sample—between 61 s and 2 min
Identify the sample and get results—2 min
Detection kit—30 min
Data Analysis Time: Analyze the sample—between 61 s and 2 min
Identify the sample and get results—2 min
Alarms: Not applicable
Sensitivity: Detects microscopic structure to a view of 100x. Capable of viewing biological and crystalline structure.
Confidence Interval/Sensitivity: Not specified
Specificity: Not specified
Confidence Interval/Specificity: Not specified

- **False Positives**: Not specified
- **False Negatives**: Not specified

Resistance to Interferents: Not applicable
Testing Information: Manual Detection Limits, 05Mar03.doc

PHYSICAL PARAMETERS

Size: 36 cm x 48 cm x 61 cm (14 in x 19 in x 24 in)
Working Space: Not specified
Weight: 23 kg (50 lb)
Total Weight: Not specified
Power Requirements: Battery or ac powered. Uses 2 D cell batteries for up to 8 h continuous use.

LOGISTIC PARAMETERS

Durability: No calibration required after the equipment is moved. Rugged high impact case, foam lined. Custom case for protection and transport—microscope.
Ease of Use: Not specified
Environmental Conditions: Above 0 ºC (32 ºF). Operation is restricted to certain environments (climate controlled).
Support Equipment: Forensic collection kit and assessment algorithm
Consumables: Disposable test tubes, pipettes, scoops, test strips, reagents, slides, covers, stains, and some hardware
Consumable Costs: Not specified
Maintenance: Annual testing of reagents by owner suggested
Shelf Life (Equipment): 1 yr—reagents are expected to last indefinitely. MicroCat is expected to last indefinitely.
Shelf Life (Consumables): Some reagents are dated and will require replacing; most all reagents in the kit have an indefinite shelf life. Some hardware will need to be replaced as it is used.
Maintenance Costs: Not specified
Decontamination: Not specified

SPECIAL PARAMETERS

Skills Required: No special skills, but training required
Training Required: Yes
Training Available: #S1803—4 d HazCat WMD Workshop, $750. Training results in certification and recertification. Training is offered either at manufacturers or where equipment is used or stored. Certified training available.
Manuals Available: Yes
Data Storage: Digital camera with USB connection for microscope
Communications: Computer interface; RF communication—wireless digital image transmission equipment for remote MicroCat image transmission; networking capability and hardware capability
Security: End user may secure with padlocks
Safety Requirements: Not specified
Applicable Regulations: Title 29 CFR 1910.120 Req. for I.D., IATA shipping confirmation
Warranty: 1 yr parts and labor

GENERAL

HazMatID (Model 023–1001)

Smiths Detection Danbury
21 Commerce Drive
Danbury, Connecticut 06810
203–207–9700 (Tel)
888–473–6747
203–207–9780 (Fax)
Bob Bohn
bob.bohn@smithsdetection.com
Information Source: http://www.hazmatid.com/

Status: The vendor has responded—1/12/2007
Evaluated: Yes

Technology: Screening
Portability: Mobile Laboratory Detection Equipment

Unit Cost: $62.5K
Availability: 60 d to 90 d
Description: FTIR—HazMatID is a highly specific tool that measures how chemical samples interact with IR light. Each chemical has its own unique IR fingerprint, which when automatically analyzed by the onboard computer results in an identification in less than 20 s. HazMatID's new Bio-CheckIR™ software will analyze the spectrum of the unknown and can alert the user when a possible biological material is present allowing the responder to choose the next course of action.
Application: The HazMatID™ is intended to provide initial determinations and be used as an information resource in the field, and not for absolute or conclusive identifications of unknown substances. The results provided by the HazMatID should be verified by using other appropriate techniques. Smiths Detection makes no recommendations nor does it assume any liability for how the information is utilized. The system can easily be carried on-scene making it an ideal tool for First Responders in an emergency situation.
Current Users: First responders—Mobile labs can support First Responders by discriminating biological from nonbiological microscopic particles as well as identifying the chemistry of the nonbiological particles.
Military—Naval Criminal Services, San Diego as well as the 6th and 44th CST-WMD mobile labs can support First Responders by rapidly discriminating biological from nonbiological microscopic particles as well as identifying the chemistry of the nonbiological particles.

OPERATIONAL PARAMETERS

BAs Detected: HazMatID instantly compares the IR fingerprint against an onboard database to provide the identity of the unknown. Database libraries include the following:

- WMD—Nerve and Blister Agents
- Toxic industrial chemicals
- Forensic drugs and clean lab precursors
- White powders
- Explosives
- WMD precursors
- Common chemicals

Type of Sample: HazMatID allows the responder to resolve simple mixtures through an automated "subtraction" feature in the software
Sample Preparation: Simply place a drop or a few grains of the unknown on the small diamond sensor and a simple touchscreen program walks the responder through the complete analysis in seconds. No sample preparation is required.
SOP Sample Preparation: HazMatID's new Bio-CheckIR™ software will analyze the spectrum of the unknown and can alert the user when a possible biological material is present allowing the responder to choose the next course of action
Start-up Time: The system is operational in <2 min
Calibration Requirements: User calibration is not required, and no consumables are needed to operate the system
Response Time: Results in an identification in <20 s
Data Analysis Time: Results in an identification in <20 s
Alarms: Flashing display indictaes the precense of protien peaks
Sensitivity: 5 % to 10 % by weight of the sample; lower with sample preparation

Confidence Interval/Sensitivity: Not specified
Specificity: Indicated presence of protein
Confidence Interval/Specificity: Not specified

- **False Positives**: Not specified
- **False Negatives**: Not specified

Resistance to Interferents: Not specified
Testing Information: Ongoing work with AFIOH

PHYSICAL PARAMETERS

Size: 46 cm x 28 cm x 18 cm (18 in x 11 in x 7 in)
Working Space: Not specified
Weight: 10 kg (23 lb)
Total Weight: Not specified
Power Requirements: Power—internal battery, mains, or cigarette lighter; battery runs for 2 h; charge time is 3 h

LOGISTIC PARAMETERS

Durability: Indoor and outdoor capability. The system is waterproof to allow it to pass through the decon line. The beam splitter uses a ZnSe substrate which is resistant to environmental conditions encountered in the field.
Ease of Use: The HazMatID is simple to use. HazMatID was designed to be used in Level A gear.
Environmental Conditions: Operational in extreme weather and temperatures ranging from -10 ºC to 50 ºC (14 °F to 122 °F). Humidity ranging from 0 % to 100 %. Operational in the hot zone and sub freezing temperatures.
Support Equipment: Not specified
Consumables: None
Consumable Costs: Not applicable
Maintenance: Smiths Detection has instituted a 24 h, 7 d per wk reachback capability. This will provide assistance in the identification of compounds as well as support on system operation and troubleshooting by Smiths Detection spectroscopists, chemists, electrical engineers, and software engineers. Additionally, Smiths Detection guarantees that a replacement unit will be shipped for overnight delivery if your system requires service. Lastly, all HazMatID purchasers will receive software upgrades and access to a password protected website forum where responders can share spectra.
Shelf Life (Equipment): Able to be stored for extended periods of time. Battery will discharge over time and need to be recharged prior to use.
Shelf Life (Consumables): Not applicable
Maintenance Costs: $4.5K per year after 4 yr
Decontamination: The system is waterproof to allow it to pass through the decon line. The system can be exposed to decontamination solution either by spraying the unit or dunking it with the cover open.

SPECIAL PARAMETERS

Skills Required: None required, basic technician preferred
Training Required: 1 d basic course
Training Available: Standard 1 d training course in Danbury, Connecticut or optional on-site training. Training results in certification.
Manuals Available: User manuals and CD
Data Storage: External data storage: Full USB support, flash devices, floppy drives, and CD-RWs
Input/output devices: Mouse and keyboard compatible and ethernet capable. Reachback is provided 24/7. This allows you access to Smiths Detection's scientists for data interpretation if required as well as hardware and software technicians to answer any operating questions. Additionally, Smiths Detection guarantees that a replacement unit will be shipped for overnight delivery if your system requires service. Lastly, all HazMatID purchasers will receive software upgrades and access to a password protected website forum where responders can share spectra.
Communications: User interface—The HazMatID software is a streamlined, touchscreen application specifically designed to be easy to use but very powerful in its capability.
A complete identification of an unknown simply requires the user to advance each screen as it is presented.
Network enabled. Requires security authorization to access Windows® operating system.
Wireless capability—Up to 11 Mbps high-speed transfer rate with automatic fallback to 802.11b (the standard wireless ethernet networking technology), 2.4 GHz compliant.
Security: Supports up to 128-bit WEP encryption security. All HazMatID purchasers will receive software upgrades and access to a password protected website forum where responders can share spectra.

Safety Requirements: Not specified
Applicable Regulations: Not specified
Warranty: Standard 1 yr Partnership Program, optional 3 yr and 5 yr Partnership Programs available. Includes 24/7 Reachback, loaner and other features. The people at Smiths Detection pride themselves on being able to respond to all inquiries as quickly, and completely as possible. Here in the support section we have developed a database of information that is literally "right at your fingertips." In the FAQ subhead we have listed the most frequently asked questions about our products and how they work. If your question is more complex check out "Tech Support" where you can find email and telephone support lines, as well as a downloadable version of our latest user manual. It is our intention to provide our customers with the most complete support possible, if you have any comments or suggestions on how we might better serve you, please do not hesitate to email our help desk.

GENERAL

IlluminatIR ML Package (Model 006–2019)

Smiths Detection Danbury
21 Commerce Drive
Danbury, Connecticut 06810
203–207–9700 (Tel)
888–473–6747
203–207–9780 (Fax)
Ben Twombly
Ben.Twombley@smithsdetection.com
Information Source: http://www.hazmatid.com/

Status: The vendor has responded—1/12/2007
Evaluated: Yes
Availability: 60 d

Technology: Screening
Portability: Vehicle mounted or Fixed-Site Detection System

Unit Cost: $94K
Description: FTIR—The core technology of the system is FTIR mid-IR- micro-spectroscopy. This is a technology that has been in use for more than 20 yr and is legally acceptable as scientific evidence in a court of law.
Optical—The IlluminatIR microscope system can determine the chemical identity of particles as small as 10 µm in size.
Other—By measuring the mid-IR absorption of the sample, the system will produce a visual spectral fingerprint and match the unknown to a spectral library database.
Application: This microscope technology has both first responder and public health lab applications, in addition to many other commercial applications such as drug analysis, micro-contamination, chemical and polymer analysis, etc. System should be mounted inside a mobile van.
Current Users: Mobile labs can support first responders by discriminating biological from nonbiological microscopic particles as well as determining the chemical identity of the nonbiological particles.
Naval Criminal Services, San Diego, as well as the 6th and 44th CST-WMD mobile labs can support first responders by rapidly discriminating biological from nonbiological microscopic particles as well as determining the chemical identity of the nonbiological particles.
The Departments of Health in the states of Florida, Kansas, Michigan, New York, Oklahoma, and Washington can easily and quickly identify hundreds of toxic or nontoxic microscopic particles as well as all forms of asbestos.
Research Labs at Pfizer, Gentec, and the Universities of New Haven and South Florida can easily and quickly confirm the chemical identity of liquids and solids at the microscopic level.

OPERATIONAL PARAMETERS

BAs Detected: The IlluminatIR detects the presence of microscopic proteins but cannot identify species
Type of Sample: Liquid—single drop
Solid—single granule of powder
Sludge—single drop
Sample Preparation: If a generic biological is detected at the scene of a suspicious incident, the nonprepared sample is placed on a microscope glass slide then covered and sealed by a cover slip. Less than 15 min for sample preparation.
SOP Sample Preparation: If no generic biological is indicated at the scene of a suspicious incident, no sample preparation is required to do analysis with the IlluminatIR. If a generic biological is indicated at the scene of a suspicious incident, using the SealIR Disposable Sealed Cell Kit, P/N 006–4049, a small amount of powder or liquid is placed onto the glass slide and sealed by an IR transmissive Barium Fluoride cover slip.
Start-up Time: Less than 5 min
Calibration Requirements: Equipment must be setup by manufacturer. Instrument is calibrated automatically with every run (qualitative and quantitative). Automatic software/hardware alignment visually indicates on the computer monitor that the system is optimally calibrated and properly functioning.

Response Time: Less than 5 min	**Data Analysis Time**: Less than 5 min

Alarms: No alarm, but result is visually displayed. Data does not have to be interpreted before it is recognized.
Sensitivity: Identification of toxins
Confidence Interval/Sensitivity: Not applicable
Specificity: Known environmental interferents include soil, presence of environmental bacteria, cold temperatures, and hot temperatures. The assay cross-reacts to all organisms or proteins.

Confidence Interval/Specificity: Not applicable

- **False Positives**: Not applicable
- **False Negatives**: Not applicable

Resistance to Interferents: Not applicable
Testing Information: Not applicable

PHYSICAL PARAMETERS

Size: 58 cm x 38 cm x 64 cm (23 in x 15 in x 25 in) instrument size in addition to laptop computer
Working Space: 0.9 m^2 (1 yd^2) with laptop computer
Weight: 23 kg (50 lb) **Total Weight**: Not available
Power Requirements: ac powered (indicated V and Hz) 120/240 V, 60/50 Hz

LOGISTIC PARAMETERS

Durability: System should be mounted inside a mobile van. Able to be left in hor or cold environment without effect.
Ease of Use: Technician can be trained to use the system in less than 1 d
Environmental Conditions: <40 ºC (104 ºF); >10 ºC (50 ºF); <80 % noncondensing relative humidity
Support Equipment: Laptop computer
SealIR Disposable Sealed Cell Kit, P/N 006–4049 or E-Glass Microscope Slides, P/N 006–4013.
SealIR Disposable Sealed Cell Kit, P/N 006–4049 or E-Glass Microscope Slides, P/N 006.
SealIR Disposable Sealed Cell Kit, P/N 006–4049 or E-Glass Microscope Slides, P/N 006–4013.4013.
Consumables: Liquid nitrogen to cool detector
Consumable Costs: $15 or less per assay; $1.5K per yr cost
Maintenance: There is 24 h of technical support provided by the manufacturer or authorized agency. There is no loaner option during maintenance or malfunctioning. Equipment is upgradeable (microscope objectives, polarizers, etc., as well as automatation can be added). Microscope optics need to be cleaned every 6 mo.
Shelf Life (Equipment): Not specified
Shelf Life (Consumables): Source, laser, and laser power supply may require replacement every 2 yr to 3 yr
Maintenance Costs: $4.5K every 2 yr to 3 yr
Decontamination: Not specified

SPECIAL PARAMETERS

Skills Required: No special skills but training required. High school education or above. IlluminatIR's QualID software makes analysis simple, even for users unfamiliar with spectroscopy. A simple push-button initiates a measurement and resultant information is displayed in clear, concise format.
Training Required: Less than 8 h training required
Training Available: Standard 1.5 d training course in Danbury, Connecticut or optional on-site training. Optional off-site training available. Training results in certification.
Manuals Available: User manuals and CD
Data Storage: Laptop and QualID software: External data storage—full USB support, flash devices, floppy drives, and CD-RWs. Input/output devices—mouse and keyboard compatible. Ethernet capable. Reachback is provided 24 h/d, 7 d/wk that allows access to Smith Detection's scientists for data interpretation if required as well as hardware and software technicians to answer any operating questions. All IlluminatIR purchasers will receive software upgrades and access to a password protected website forum where responders can share spectra.
Communications: IlluminatIR's QualID software makes analysis simple, even for users unfamiliar with spectroscopy. A simple push-button initiates a measurement and resultant information is displayed in clear, concise format.
Security: Supports up to 128-bit WEP encryption security. All IlluminatIR purchasers will receive software upgrades and access to a password protected website forum where responders can share spectra.

Safety Requirements: None	**Applicable Regulations**: None

Warranty: The people at Smiths Detection pride themselves on being able to respond to all inquiries as quickly, and completely as possible. The support section has developeded a database of information that is literally "right at your fingertips." In the FAQ subhead we have listed the most frequently asked questions about our products and how they work. If your question is more complex check out "Tech Support" where you can find email and telephone support lines, as well as a downloadable version of our latest user manual. It is our intention to provide our customers with the most complete support possible, if you have any comments or suggestions on how we might better serve you, please do not hesitate to email our help desk.

GENERAL

HMB Portable Biohazard Detector (HMB V–PS)

BioVigil
3610 Graustark St.
Houston, Texas 77006
Marcus Duffel
713–494–7997 (Tel)
713–807–9919 (Fax)
marcus@biovigil.com
info@biovigil.com
Information Source: http://www.biovigil.com

Status: The vendor has responded—11/22/2006
Evaluated: Yes

Technology: Screening
Portability: Handheld Detection Equipment

Unit Cost: $2K; unique consumables cost—$350 per test kit
Availability: HMB V–PS equipment and consumables are readily available, no lead-time
Description: Biomass Readout (BMR)—Aerobic organisms, both bacteria and fungi, produce a category of enzymes called peroxidases while metabolizing, producing peroxidases that are measured by the HMB test. Peroxidases are produced in proportion to the rate of biological activity. Thusly, the quantity of enzyme present in a sample is a measure of the current total biological activity. In the HMB procedure, the reagent reacts with the enzyme to produce oxygen. The oxygen produced is measured by the HMB and converted to Biomass Readout (BMR).
Application: Instrument was originally designed to rapidly measure metabolic activity of aerobic organisms in industrial/commercial applications. These companies primarily use the instrument for QC and employee health monitoring applications. First responders utilize the HMB to make rapid assessment of biological activity based on objective facts rather than subjective circumstances. This enables them to quickly categorize an emergency as a false alarm or secure the area for further analysis.
Current Users: 1) First responders—Fort Worth Fire Department, Ft. Worth, Texas; Birmingham Fire Department, Birmingham, Alabama; and Fauquier County Virginia Sheriffs Department
2) Scientific research labs—Sierra Environmental Services, Inc.
3) Commercial applications—metalworking fluid analysis (Alcoa Aluminum, Boeing Aircraft Company, Reynolds Metals); waste water treatment plant management [Eastman Chemical (Kodak)]; and cooling tower water management (Nalco Chemical Company)

OPERATIONAL PARAMETERS

BAs Detected: Organisms based on their chemical makeup and metabolic activity of the following organismes, they should be detectable by the HMB instrument: Bacilus anthracis, Brucella abortus, Brucella melitensis, Brucella suis, Brucella canis, Corynebacterium diptheria, Francisella tularenius, Shigella spp., Salmonella typhimurium, Salmonella enteritidis, Salmonella typhi, Vibrio cholerae, Yersinia pestis, E. coli O157:H7, Coxiella burnetii, Chlamydia psittaci, Coccidiomycosis immitis, and Staphylococcal aureus enterotoxin B.
The following organisms are either unknown to Biotech or do not exhibit the characteristics detectable by the HMB: Burkholderia mallei, Burkholderia pseudomallei, Rickettsia prowazekii, Rickettsia tsutsugamushi, Rickettsia rickettsii, and ricin (probably not yet tested).
Type of Sample: Liquid, solid, sludge, surface wipes, and powders
Sample Preparation: Collect a pinch of the sample to be tested and place in the pre-dispensed test tube in the HMB kit. Sample preparation is not required.
SOP Sample Preparation: Test procedure:

1. Put sample into a tube containing reactant
2. Stopper the tube, shake, and then remove the stopper
3. Add +/- 12 drops of HMB 50R (hold at an angle) and return the stopper
4. Pierce the stopper for 1s to 2 s with vent
5. Mix the tube and let stand upright for 10 min
6. After 10 min tap the tube lightly on the bottom
7. Make sure the HMB is set at 0.000 and impale the topper with the meter

8. Note the reading

Start-up Time: Not applicable (unpack and plug the instrument in)
Calibration Requirements: No calibration required at startup, equipment autocalibrates. Instrument is automatically quantitatively calibrated with every run.
Response Time: Immediated after 10 min test procedure
Data Analysis Time: Less than 1 min
Alarms: Auto, visible, and audible alarm
Sensitivity: Bacteria—1000/mL
Target DNA*—not applicable
Biotech has not had the opportunity to test viruses and toxins
Confidence Interval/Sensitivity: Bacteria—1000/mL (greater than 95 %)
Specificity: Known environmental interferents include the presence of environmental bacteria (i.e., bacteria sample specific). It differentiates between viable and nonviable organisms, and it detects spores. It is not applicable for cross reactivity to proteins.
Confidence Interval/Specificity: Bacteria—1000/mL (greater than 95 %)
Stimulants are available to assure operations capability prior to use for some bacteria

- **False Positives**: Sample specific
- **False Negatives**: None

Resistance to Interferents: Sample specific
Testing Information: USDA, Fort Worth Fire Department, and Sierra Environmental Services, Inc.

PHYSICAL PARAMETERS

Size: 19 cm x 13 cm x 2.5 cm (7.5 in x 5 in x 1 in)
Working Space: 61 sq cm (2 ft2)
Weight: 0.34 kg (12 oz); 0.45 kg (16 oz) with batteries
Total Weight: 1.4 kg (48 oz)
Power Requirements: One 9 V battery (battery should allow many days of continual use)

LOGISTIC PARAMETERS

Durability: Very rugged: Calibration is not required after moving, dropping, or leaving in hot or cold environments. Able to be transported quickly without protective packaging.
Ease of Use: Test procedures can be conducted wearing PPE; 8 steps required for test procedure
Environmental Conditions: Not in temperatures below 0 ºC (32 ºF)—liquid samples will freeze
Support Equipment: Test kit components include a venting device and a measuring scoop. Eye protection is recommended.
Consumables: One pre-dispensed tube from the HMB kit and 12 drops of 50R reagent. The reagents for the performance of the HMB test have been developed by BioTech for the use of the HMB. Internal manufacturing Quality Control (QC) of testing reagents and materials is a crucial element in achieving accurate and repeatable results. Customers who have tried to duplicate these reagents, or who have used alternative reagents for their testing, have gotten erroneous results. For best results from your testing, use reagents and testing materials manufactured by BioTech only.
Consumable Costs: $3.50 per test
Maintenance: Calibration is recommended every 2 yr
There is 24 h of technical support provided by the manufacturer or authorized agency, and there is a loaner option during maintenance or malfunctioning. Equipment is not upgradeable.
Shelf Life (Equipment): Batteries should not be stored more than 1 yr
Shelf Life (Consumables): Reagents (pre-dispensed tubes) should not be stored more than 1 yr
Maintenance Costs: Not applicable
Decontamination: Not specified

SPECIAL PARAMETERS

Skills Required: No special skills or training required. High school diploma or less—elementary age students have performed the HMB test before. Equipment requires the operator to analyze raw data before a final result can be determined.
Training Required: Less than 4 h training required
Training Available: Classroom/online training: HMB—First Responder Training. Either off site or on-site. Training does not result in certification.
Manual/CD/Video: HMB—First Responder Training or Public Safety Manual. Training does not result in certification.
Manuals Available: User manual with training procedures

Data Storage: Data can be stored and downloaded at a later time via USB port or adapter. Data stored is time and date stamped.
Communications: Computer interface with USB port for transfer capability
Security: Other than keeping equipment in a secure area, no security is necessary
Safety Requirements: Caution: Wear eye protection when making these tests or when handling reagents. The reagents used in these procedures would be harmful to eye tissue if direct contact is made. 1N HCl is a strong acid. HMB 50R contains a high level of hydrogen peroxide. If either come in direct contact with eyes, immediately flush with copious amounts of water and seek medical attention. Contact with skin is to be avoided, but is not dangerous in small amounts. A small tingling or burning and some bleaching may occur, but will disappear in less than an hour.
Applicable Regulations: Not specified
Warranty: BioTech International, Inc., warrants the HMB V-PS against defects in material and workmanship for a period of 1 yr from the date of delivery when used in accordance with the instructions in this HMB V Public Safety Application manual. The liability of BioTech International is limited to replacement or repair, at its option, of any product.

GENERAL

PROFILE® 1 (Model 3560)

New Horizons Diagnostics Corporation
9110 Red Branch Road
Columbia, Maryland 21045
David Trudil
410–992–9357 Ext. 235 or 232 (Tel)
410–992–0328 (Fax)
nhdiag@aol.com
nhdetect@aol.com
Information Source: http://www.nhdiag.co

Status: The vendor has responded—11/29/2006
Evaluated: Yes

Technology: Optical
Portability: Handheld Detection Equipment

Unit Cost: $4K
Availability: Reagents in stock readily available. Instruments available may require 2 wk to 4 wk lead time for large orders.
Description: ATP Bioluminescence—The PROFILE® 1 Bioluminometer is a handheld instrument capable of determining the presence of low levels of bacteria. PROFILE® 1 is able to differentiate microbial from somatic cells, yeast from bacteria, and can eliminate interfering (quenching) substances from the sample. Correlates to culture with no interference from foreign substances. To maximize specificity, a series of simple, patented, steps are used to remove ATP arising from human cells and other interfering compounds. PROFILE® 1 will detect only viable organisms. Studies performed by the USDA, Agriculture Canada, DOD, University of Michigan, and others have shown an excellent correlation to standard culture methods. Results are read on the LCD display.
Application: Detection of bacteria and spores from human, animal, food, water, powders, fuel and other environmental samples. Core instrument (model 4700 luminometer) utilized successfully in NDI BIDS. The conditions under which samples were collected included controlled aerosol chamber; outdoor field trials with intentional releases; and ad hoc background aerosols. Sampling times varied as per the exercise protocol, typically 1 min to <1 h.
NATO validated by Polish Government—utilized in Iraq and other locals (Dr. Mike Bartosczce obwwihe@man.pulawy.pl.
WHO water ref lab tested for water samples.
First responder validated via APG study (Dr. P. Stopa peter.stopa@us.army.mil).
U.S. DOD tested for spore and bacteria detection.
USDA field validated for food (animal carcass) (Dr. G. Siragusa. siragusa@ssa.ars.usda.gov)
Current Users: Commercial (human, food, and environmenta); military (domestic and international); first responder (domestic and international); university scientific research laboratories; and hospitals

OPERATIONAL PARAMETERS

BAs Detected: Bacilus anthracis, Brucella abortus, Brucella melitensis, Brucella suis, Brucella canis, Corynebacterium diptheria, Francisella tularenius Burkholderia mallei, Burkholderia pseudomallei, Shigella spp., Salmonella typhimurium, Salmonella enteritidis, Salmonella typhi, Vibrio cholerae, Yersinia pestis, E. coli O157:H7, Coxiella burnetii, Rickettsia prowazekii, Rickettsia tsutsugamushi, Rickettsia rickettsii; Clostridium botulinum; Clostridium tetani; and Clostridium tetani toxin
Type of Sample: Air, liquid, solid, sludge, surface wipes, human, and food
Sample Preparation: No sample preparation—food sample may require standard USDA method collection
Reagent quality control: The system is prepared for use by reconstituting the Luciferin-Luciferase (L-L) reagent at least one-half hour before use. The activity of the enzyme is then measured by assaying it with the ATP standard solution supplied with the kit. The resulting value is then compared to the ATP and the relative luminescence units should be within the range specified on the vial. If not, then a new vial of enzyme should be used.
SOP Sample Preparation: Sample (50 µL to 1 mL) is added to a Filtravette(tm) and is washed with 4 to 5 drops of Somatic-Cell Releasing Agent (SRA) included in the kit. The liquid is then expressed by the use of a pressurizing device to force the liquid through the membrane. The wash with SRA is repeated. This step removes nonbacterial sources of ATP and any interfering substances. The Filtravette™ is removed and placed into the sample drawer of the instrument. Two drops of Bacterial Cell Releasing Agent (BRA) is added to the Filtravette™ to lyse the bacterial cells. It is immediately followed by 50 µL of the L-L reagent. The sample is then mixed quickly by re-expressing the liquid 4 times with the pipet. The sample drawer is then closed and the luminescence [relative luminescence unit (RLU)] is recorded. Tables are then used to convert the RLUs to either ATP or bacterial concentration.

Start-up Time: None—unpack and plug in; no calibration time required
Calibration Requirements: Not applicable (unpack and plug the instrument in). Instrument is qualitatively and quantitatively calibrated automatically with every run.
Response Time: Spores are detectable after 5 min of incubation at a concentration of 10^6 CFU/mL; however, we routinely used a 15 min incubation because better agreement with classical plate counting techniques was observed
Data Analysis Time: 10 s
Alarms: No alarm, but result is visually displayed; data must be interpreted
Sensitivity: All bacteria at 300 CFU/mL to10 000 CFU/mL with >50 µL sample size
Confidence Interval/Sensitivity: >95 %
Specificity: Generic screen for any bacteria; thousands of organisms have been tested in cross-reactivity studies
Confidence Interval/Specificity: 100 % of bacteria and spores detected with 0 % false positives

- **False Positives**: None
- **False Negatives**: None

Resistance to Interferents: No intereference for nonbacterial/spore samples (dust, dirt, powders, etc.)
Testing Information: 1. Cutter C, Dorsa W, Siragusa G. A rapid microbial ATP bioluminescence assay for meat carcasses. Dairy, Food Environ. San. 1996:16 (11) p. 726–736.
2. Siragusa G, Cutter C, Dorsa W, Koohmaraie M.Use of a rapid microbial ATP bio- luminescence assay to detect contamination on beef and pork carcasses.J. Food Protec.1995:58 (7), p.770–775.
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5. Trudil, David. "Rapid bioluminescence-based urine screen", New Horizons Diagnostics Corp.. FDA Cert. No. 302–09–1997, 1997.
6. Stopa, P,Coon P, Seitzinger A, Paterno D, Tiemanm D, Milton M. Proc. 6th CBW Int. Symp: 1998:suppl. 229.
7. Stopa P., et al, Detection of Bio aerosols by lumin techniques,Field Analytical Chem & Tech 1999; 3;283–290.
8. Deininger RA, Lee JY.Rapid determination of bacteria in drinking water using an ATP assy. Field Anal Chem Technology, 2001: 5(4):1–5.
9. Lee, JL, Deiniger RA, Rapid quantification of viable bacteria in water using an ATP assay, New Products, October 2001.
10. Delahaye, E. , et al, An ATP-based method for monitoring the microbial drinking water in a distribution network, Water Research Vol 37 (2003) pp 3689–3696, Elsevier Science Ltd.
11. Lee, JL, Deiniger, RA, Rapid screening method for the detection of viable spores in powders using bioluminescence, Luminescence, 2004; 19.

PHYSICAL PARAMETERS

Size: 5.08 cm x 8.89 cm x 15.24 cm (2 in x 3.5 in x 6 in)	**Weight**: 340 g (12 oz)
Working Space: <0.09 m^2 (1 ft^2)	**Total Weight**: <1021 g (36 oz)

Power Requirements: Battery or ac powered (9 V battery)

LOGISTIC PARAMETERS

Durability: Weather resistant, transportable, rugged, and no calibration required after moving
Ease of Use: Small, compact, and is easy to use while wearing PPE; 8 steps with medium level of accuracy
Environmental Conditions: 0 °C to 45 °C (32 °F to 113 °F)—humidity not a factor
Consumables: LLL reagent, BRA reagent, SRA reagent, flitravettes, pipette tips, and blotter paper

Consumable Costs: <$6 per test	**Support Equipment**: None
Maintenance: Wipe clean daily; loaner option is available	**Shelf Life (Equipment)**: Not applicable
Maintenance Costs: None	**Shelf Life (Consumables)**: >1 yr LL reagent

Decontamination: Not specified

SPECIAL PARAMETERS

Skills Required: No special skills but training required	**Training Required**: <4 h training required
Data Storage: Not available	**Communications**: Not available
Security: Not applicable	**Safety Requirements**: Not applicable
Applicable Regulations: Not applicable	**Warranty**: 1 yr

Training Available: Profile general use course available (classroom both offsite or onsite). Training results in certification.
Manuals Available: User manual; for repair send to manufacturer

GENERAL

Defender TSR (Test Strip Reader) System (P–502)

Alexeter Technologies
830 Seton Court
Suite #6
Wheeling, Illinois 60090
847– 419–1507 (Tel)
847–419–1648 (Fax)
Tom Fryzel
tfryzel@alexeter.com
service@alexter.com
Information Source: http://www.alexeter.com

Status: The vendor has responded—11/21/2006
Evaluated: Yes

Technology: Immunochemical
Portability: Handheld Detection Equipment

Unit Cost: $14.6K, including 200 test strips, training strips, collection materials and on-site training anywhere in the U.S. Cost per assay of total consumable is $24.
Availability: Lead time is generally 2 wk
Description: Lateral Flow Immunochromatography—Advanced mono- and polyclonal sandwich assays
The Defender TSR is the next-generation for field portable biological analysis. Completely compatible with our current BioThreat Alert Tests, the Defender offers added functionality and sensitivities as compared to our table-top Guardian Reader. Our HazCommand™ and BioCommand™ software directs the user step-by-step through sample credibility evaluation, protein screening, and full BioThreat Test menus. The Defender offers true hand-held detection and increased sensitivity.
Application: Field detection of biological agents from environmental samples
Current Users: State and federal health diagnostic laboratories; Army, Navy, Marines, and Coast Guard; over 1200 Hazmat teams; and most "three letter" security agencies in Washington, including the FDA

OPERATIONAL PARAMETERS

BAs Detected: B. anthracis, Brucella abortus, Brucella melitensis, Brucella suis, Brucella canis, Francisella tularenius, Yersinia pestis, orthopoxvirus, botulinum toxins, ricin, and S. aureus enterotoxin B
Type of Sample: Defender TSR (Test Strip Reader) System is capable of testing for all types of samples including liquid, solids, surface wipes, and airborne particulates suspended in a liquid
Sample Preparation: The sample preparation requires mixing the substance to be tested with a proprietary buffer solution. A dilution may need to be performed depending on the viscosity of the solution, or type of screening test being used. Sample preparation time is <1 min.
SOP Sample Preparation: Powders and granular solids—Wet a swab with buffer solution and take a swipe sample. Mix with 1 mL of buffer solution. Add 5 drops of this mixture to a test strip.
Liquids—Sample the liquid with a dry swab. Mix with 1 mL of buffer solution. Add 5 drops of this mixture to a test strip.
Aerosol samples—Concentrate the aerosol using a particle concentrator such as the BioCapture 650. Add 5 drops of the concentrated sample to a test strip. Note: Depending on the concentration of particles in the air, this method may not yield a sample sufficiently concentrated for evaluation with an immunoassay. Follow up negative results with microbiological evaluation at a qualified laboratory.
Detailed SOPs are provided by Alexeter Technologies
Start-up Time: There are no start-up requirements, just unpack and plug in). The Defender TSR System auto-calibrates using an internal standard. Upon power-up, the Defender TSR System takes approximately 30 s to perform a series of self-tests to ensure a successful automatic calibration has taken place.
Calibration Requirements: Defender TSR System performs a quantitative calibration every time a test in run using internal tiles (NIST traceable standards). No user interaction is required.
Response Time: <5 min
Data Analysis Time: <15 min
Alarms: Visible and audible
Sensitivity: Bacterial tests are generally sensitive at 10^5 CFU/mL
Our only virus test (orthopox) is sensitive to 500 ng/mL
Toxin tests are sensitive from 5 ng/mL to 20 ng/mL

B. anthracis—10^5 CFUs/mL
Brucella abortus—10^5 CFU/mL
Brucella melitensis—10^5 CFU/mL
Brucella suis—10^5 CFU/mL
Brucella canis—10^5 CFU/mL
Francisella tularenius—10^5 CFU/mL
Yersinia pestis—10^5 CFU/mL
Orthopoxvirus—250 ng to 500 ng
Botulinum toxins—20 ng/mL
Ricin—5 ng/mL
S. aureus enterotoxin B—12 ng/mL

Confidence Interval/Sensitivity: Greater than 95 %

Specificity: Test for anthrax does not cross-react with near neighbors BT (Bacillus thuringiensis) or BG (Bacillus globigii). All other tests shall demonstrate at least 95 % specificity across a standard battery of at least 20 other potential interfering substances.

Confidence Interval/Specificity: Greater than 95 %

- **False Positives**: Defender TSR System is currently running at a <0.02 % false positive rate
- **False Negatives**: None to date

Resistance to Interferents: Environmental interferents include soil and pH variations. Spores can be detected. Organisms or proteins the assay cross-react to are very specific, call Alexeter for details. Organisms or proteins that have been tested in cross-reactivity studies are included in multiple studies, call Alexeter for details.

Testing Information: Independent test results are available from Alexeter by request to http://www.alexeter.com/feedback.htm or by calling Alexeter's customer service department at 847–419–1507

PHYSICAL PARAMETERS

Size: 20 cm x 10 cm x 9 cm (8 in x 4 in x 3.5 in)

Working Space: Can be operated while in the palm of your hand. Therefore, in both field and lab settings, minimal space is required, i.e., 0.2 m^2 (2 ft^2) would suffice for table-top use.

Weight: <1.5 kg (1 lb); weight in carrying case—1.8 kg (4 lb)

Total Weight: The Defender, power supply, and test strips weigh about 2.7 kg (6 lb) in the case. Tetracore's BioThreat Alert™ test kit [1 box of 25 tests is 283 g (10 oz)].

Power Requirements: 120 V ac to 240 V ac, an international power adaptor is supplied (line power is not required); internal lithium-ion batteries (<8 h of continual use)

LOGISTIC PARAMETERS

Durability: Easily hand-carried to any location in the field. It is supplied in a watertight case. It is not recommended that the Defender be dropped, but it can be moved without protective packaging, and can be left in cold or hot environments without effect.

Ease of Use: Can be used up to Level A protective gear

Environmental Conditions: Operating temperature range: 4 ºC to 41 ºC (40 ºF to 105 ºF)
Storage temperature range: -29 ºC to 60 ºC (-20 ºF to 140 ºF)
Not above 80 % humidity
Keep out of direct sunlight, rain, and snow

Support Equipment: None required

Consumables: Sample swab, vials and buffer solution, all provided with the test kits

Consumable Costs: Each test strip costs approximately $24, including all consumables required. Quantity discounts are available.

Maintenance: Preventative maintenance is not required. Alexeter provides worldwide technical support 24/7. Any malfunctioning unit will be replaced while under warranty. Extended warranties are available. Because the Defender TSR is software-driven, upgrades are simply flashed to nonvolatile memory inside the unit. For example, new biological agents and changing test parameters can be easily accommodated.

Shelf Life (Equipment): Battery in the reader can be stored up to 5 yr; equipment's estimated life span is 10 yr

Shelf Life (Consumables): Not applicable

Maintenance Costs: Not applicable

Decontamination: Wipe down outer surfaces. Paraformaldehyde gas decontamination has also been employed

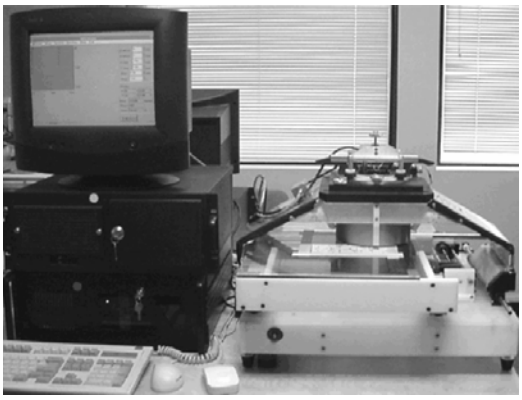
SPECIAL PARAMETERS

Skills Required: Hazmat technician level training, or high school diploma, is adequate. The operator is not required to analyze raw data to determine a final result.
Training Required: No special skills but <8 h formal training is required
Training Available: Alexeter System Training is offered onsite (where equipment will be used or stored). Manual training is also available. Training does not result in certification.
Manuals Available: Full manual shipped with each unit. Updates area always available on Alexeter's website.
Data Storage: Internal data storage and printout provided for last 200 tests. All test results are written directly to an RFID contained in each test strip. All test results can be exported to a PC via serial cable. Optional increased memory and hazmat database applications.
Communications: Serial communication interface provided for data transfer capability (interface). Connectivity is near-universal with dual-wireless capabilities (802.11b and Bluetooth™) and USB interface.
Security: RFID secures test data. Secure data transmission capability for technical support and documentation.
Safety Requirements: Consult OSHA regulations
Applicable Regulations: No regulations currently apply to environmental testing
Warranty: 1 yr warranty standard, extended warranties available. Equipment's estimated life span is 10 yr.

GENERAL

MPD-based BW Detector (P-chip/MPD/2004)

BioTraces, Inc.
13455 Sunrise Valley Drive
Suite 200
Herndon, Virginia 20171
Fairfax, Virginia
A.K. Drukier
703–793–0907 (Tel)
703–793–1550 (Tel) ext 108
703–793–1564 (Fax)
AKD@biotraces.com
Information Source: http://www.biotraces.com/
ECBC Market Survey
Status: The vendor has responded—11/21/2006
Evaluated: Yes



Technology: Immunochemical
Portability: Handheld Detection Equipment

Unit Cost: $5K for portable MPD in series of 1000
Availability: 3 mo
Description: Enhanced Immunoassay—Multianalyte Bioassay
Immunochemical—ELISA, lateral flow, and protein array
Optical detection—Colorimetry
MultiPhoton detection—P-chip/MPD® technology permits measurement of biological and chemical substances with unprecedented sensitivity, making possible the detection of as few as a hundred labelled molecules. Methodologies have been developed to achieve this sensitivity with robust, low cost instrumentation, and remarkably, at levels of radiation below background. This powerful combination of attributes has been captured in a strong fundamental patent position, which BioTraces continues to expand.
Developed through NIST program
Application: Super-sensitive detection of proteins specific to BWA
Current Users: 20 users world wide include: 2 diagnostic labs in Europe, 2 military organizations in Europe, 7 scientific research labs (3 national labs, 4 academic labs), 3 large hospitals, and 2 biotech companies

OPERATIONAL PARAMETERS

BAs Detected: B. anthracis—1 bacteria/mL
Corynebacterium diptheria—0.1 pg/mL
Salmonella typhimurium—1 bacteria/mL
Salmonella enteritidis—1 bacteria/mL
Rickettsia tsutsugamushi—10 copies/mL
Rickettsia rickettsii—10 copies/mL
Histoplasma capsulatum
Botulinum toxins
Clostridium perfringens toxins
Mycotoxins of the Trichothecene group
Aflatoxin
S. aureus enterotoxin B
Type of Sample: Air, liquied, sludge, surface wipes, and airborne particulates suspended in a liquid
Sample Preparation: Air condensation, filtering. Average time for sample preparation is <1 h.
SOP Sample Preparation: Available on request; very similar to standard ELISA
Start-up Time: Assembly requires 3 steps; assembly requires tools
<15 min start-up time—includes calibration to initiating a sample run
<30 min calibration, response time, and analysis interpretation
Calibration Requirements: Self-calibrating. Instrument is automatically quantitatively calibrated with every run. Instrument requires one quantitative calibration at startup. Equipment does not require calibration each time it is moved. Protocol for calibration will be provided upon request.
Response Time: 15 min to 30 min per assay

Data Analysis Time: 5 min to 10 min past assay
Alarms: Auto, visible, and audible alarms
Sensitivity: Bacteria—<1 CFU/mL
Virus—<10 viruses/mL
Toxins—0.1 pg/mL
Confidence Interval/Sensitivity: 10 fg/mL of epitope
Specificity: 1:1000 between B. globigii and B. kursaki at 10 pathogens/mL
Confidence Interval/Specificity: Better than 1/10 000 false positive rate for bacteria/spores. Fully qualitative with sensitivity/LOD about 100x better than current protein based methods.

- **False Positives**: Current 0.0001
- Target 0.00001
- **False Negatives**: Current 0.001
- Target 0.0001

Resistance to Interferents: Detects spores; cross reacts to some close strains, e.g., B. anthracis vs. B thurigeusis
Testing Information: Sensitivity for viruses ≤10 viruses/mL, ≤1 bacteria/mL, and ≤0.1 pg/mL. See www.biotraces.com.

PHYSICAL PARAMETERS

Size: 12.7 cm x 10.2 cm x 7.6 cm (5 in x 4 in x 3 in); detector is palm-size
Working Space: Can be carried in backpack
Weight: P-chip/MPD reader—2.3 kg (5 lb)
Total Weight: As in typical immunoassay
Power Requirements: <4 h continual use with 2 x A4 batteries; <12 h continual use with a solar battery

LOGISTIC PARAMETERS

Durability: Handheld detection equipment (portable) is very durable. It autocalibrates after being moved, and it can be left in cold or hot environment with no effect. Can be operated under any environmental conditions.
Ease of Use: User friendly
Environmental Conditions: 0 ºC to 50 ºC (32 ºF to 122 ºF)
Support Equipment: Air handling system
Consumables: As with other immunoassays: multiple solutions and pipette tips
Water, blocker, Abs
Consumable Costs: <$1 at 10 bacteria/mL level
Maintenance: Portable MPD—bi-monthly (about 30 min time required)
There is 24 h technical support provided by the manufacturer or authorized agency; there is a loaner option during maintenance or malfunctioning; and it is upgradeable (with automated wetware)
Shelf Life (Equipment): Bi-alkali batteries would deteriorate after several years of storage
Shelf Life (Consumables): Abs can be stored up to 6 mo; buffers can be stored up to 1 yr
Maintenance Costs: Not specified
Decontamination: Washing

SPECIAL PARAMETERS

Skills Required: General proctice with air handling equipment. Operator does not need to analyze raw data before final result can be determined. A high school diploma or BS is sufficient education.
Training Required: Less than 4 h informal training
Training Available: Classroom or video training is available
Manuals Available: SOPs and technical specifications are available
Data Storage: Currently via portable computer; mid-2007 via palm computer
Communications: Command control communications, computer interface, data transfer capability (interface), interoperability, networking capability, and installed data processing equipment
Security: May be encrypted upon request
Safety Requirements: None
Applicable Regulations: None
Warranty: 1 yr

GENERAL

QTL Biosensor (Model 2000 and 2200)

QTL Biodetection
1040 Eberly Way, Suite 100
Lemont Furnace, Pennsylvania 15456
Brian Oswalt
724–430–0603 (Tel)
724–430–0605 (Fax)
boswalt@qtlbio.com
Information Source: http://www.qtlbio.com

Status: The vendor has responded—12/4/2006
Evaluated: Yes

Technology: Immunochemical
Portability: Handheld Detection Equipment

Unit Cost: Model 2000—$9.9K and Model 2200—$10.9K (U.S. list price)
Availability: Available immediately up to 100 units. Larger orders 3 wk to 4 wk lead time.
Description: Magnetic Bead Based Immunoassay with a Proprietary Dynamic Surface Generation and Imaging system
Application: The QTL Biosensor Detection instrument is a self contained handheld qualitative testing device for the detection of weaponized bioagents (BA). It is a ruggedized field ready unit for hazmat, military, and first responders. The unit can be operated from ac power or from a rechargeable internal battery pack. Personal protection equipment (PPE) can be worn while operating the QTL Biosensor. Time to result is less than 5 min and requires no interpretation by the operator.
Current Users: First responders, hazmat teams, police departments, military, and scientific laboratories

OPERATIONAL PARAMETERS

BAs Detected: B. anthracis— $\leq 10^4$ spores; Botulinum toxins—5 ng; Ricin—5 ng; and SEB—0.05 ng
Type of Sample: Liquid, solid, and surface wipes
Sample Preparation: Dry sample is swabbed, placed in buffer tube, liquid extracted, and syringed into cartridge. Time <2 min.
SOP Sample Preparation: Pick up sample with included swab (for liquid sample add 300 µL of sample to wet sampling tube).

Place swab into small buffer tube with prep buffer.
Remove 150 µL of sample with syringe and place into instrument detection cartridge.
Shake the cartridge for 1 min following count down timer
Place the cartridge into the QTL Biosensor.
Pellet for 3 min.
Depress wash syringe on the cartridge.
Press the read button and results will be given as follows: Green light—no target is present; Red light and beeping—target is present.

Start-up Time: There are no start-up requirements. Power on button is pushed and instrument is ready for operation. Instrument can operate on internal rechargeable battery pack, ac power or external 12 V dc.
Calibration Requirements: Instrument can be calibrated periodically (every 6 mo recommended). Calibration can be performed by the end user. Insert a calibration cartridge as a baseline check.
Response Time: Less than 6 min total time from sample collection to final result. The final result is a direct read with no interpretation needed.
Data Analysis Time: There is no additional analysis time beyond the response time. The instrument gives a direct readout with no data interpretation.
Alarms: Visible and audible
Sensitivity: Bacteria—10^4 spores; Toxins—0.05 ng
Confidence Interval/Sensitivity: Not applicable
Specificity: No Cross-reactivity at concentration of >1x 10^6 with—Bacillus (megaterium, subtilis, thuringensis, kurstakii, canis, melitensis, and suis) strains, Clostridium botulinum(A,B,E, and F) strains, Francisella tularensis, and Yersinia pestis
Confidence Interval/Specificity: Not applicable

- **False Positives**: 1 in 1 million
- **False Negatives**: 1 in 10 thousand

Resistance to Interferents: No Interference with the standard panel of powders from the U.S. Army Critical Reagent Program. These include: Talcum powder, powdered milk, spackling powder, chalk, foot powder, flour and Kaolon, and Bentonite clays.
Testing Information: Performance Verification of the QTL Biosensor—University of Alabama (UAB), New York Departmant of Health Wadsworth Biodefense Laboratory (NYDOH), and U.S. EPA Environmental Technology Verification Program (EPA/ETV). Available upon request.

PHYSICAL PARAMETERS

Size: 28 cm x 25 cm x 13 cm (11 in x 10 in x 5 in) **Working Space**: 30.5 cm x 30.5 cm (1 ft x 1 ft)
Weight: 2.95 kg (6.5 lb)—with handle for hand carrying. Batteries are internal rechargeable (included in the weight).
Total Weight: 2.95 kg (6.5 lb)
Power Requirements: NiMH battery—75+ tests per battery charge; can also use ac power or external 12 V dc

LOGISTIC PARAMETERS

Durability: The QTL Biosensor is a self contained battery operated handheld instrument ruggedized for field use. Instrument does not need calibration if dropped or left in extreme environments.
Ease of Use: It is designed for use while wearing Class A or lower PPE protection. The instrument has large bright colored buttons the can be pushed with gloved hands. There is a wizard that walks an operator through the steps if they are unfamiliar with the equipment or have not used it recently. The signals for detection are a red light and a warning beeping from a positive result. This can be heard in a noisy environment or other challenging conditions. There are approximately six steps from swabbing to result. The unit does not require a high level of operator precision to get an accurate result.
Environmental Conditions: Up to 50 °C (122 °F)
Support Equipment: NO support equipment is needed and NO lock down is required
Consumables: Cartridge pack(includes test cartridge and sampling kit). The test cartridges are for one time use and are barcoded for archiving or further testing.
Consumable Costs: $29 per single test detection cartridge
Maintenance: Preventative maintenance—6 mo interval. There is 24 h technical support provided by manufacturer; there is a loaner option during malfunctioning or maintenance.
Shelf Life (Equipment): Usable lifetime approximately 10 yr with proper periodic maintenance
Shelf Life (Consumables): Consumables shelf life is 1 yr at room temperature
Maintenance Costs: Less than $50 field serviceable (2 calibration cartridges per year)
Decontamination: The unit is certified to IP67. May go through a full decontamination procedure by submersion in decon solution, bleach wipe down, or by vapor hydrogen peroxide (VHP) and can be reused immediately after a positive result. Testing showed no indication that the reader was affected by available decontamination techniques.

SPECIAL PARAMETERS

Skills Required: High school education or equivalent. Operator does not have to interpret results.
Training Required: <1 h training
Training Available: Training is available from QTL Biosensor training video or optional onsite certification available. Onsite training does result in vendor sponsored certification for operation of equipment.
Manuals Available: QTL Biosensor Training Manual; QTL Operator Manual; QTL Biosensor Quick Start Guide; and QTL Biosensor Training Video
Data Storage: 100 test results can be stored directly in the detector's on board memory. Test results can be uploaded to an external computer connected to the detector via serial port.
Communications: Computer interface—direct via serial port.
Data transfer capability (interface)—direct via serial port.
Interoperability—any computer with serial port.
Commonality— any computer with serial port.
Networking capability—can be connected to network via PC.
Hardwire capability—serial port.
Installed data processing equipment—results completely processed onboard unit to give result without the need for a computer.
Security: The detector is a clamshell case that can be locked on the outside so entry can be controlled
Safety Requirements: No requirements
Applicable Regulations: No requirements
Warranty: 1 yr warranty parts and labor. See warranty agreement for details.

GENERAL

Prime Alert® Biodetection System (Model 096–3130)

GenPrime, Inc. (Manufacturer)
Scott Health & Safety (Distrubutor for First Responder Community)
4320 Goldmine Road
Monroe, North Carolina 28110
Bryon Gordon, Product Manager
800–247–7257 (Tel)
704–291–8420 (Fax)
scottmarketing.scotths.us@tycoint.com
Information Source: http://www.scotthealthsafety.com

Status: The vendor has responded—11/27/2006
Evaluated: Yes

Technology: Immunochemical/Optical
Portability: Handheld Detection Equipment

Unit Cost: The complete Prime Alert® Biodetection System, which includes all the equipment and five Complete Microbe and Toxin Screens costs $10.5K retail.
Availability: The Prime Alert Biodetection System is available for shipment within 4 wk to 6 wk. All consumables and components necessary to run Microbe Screens and Toxin Screens are included in the Prime Alert System. Consumables can be ordered separately as needed. No support equipment is required.
Description: Lateral Flow Immunochromatography and Fluorescence/Emission—Toxin screens for ricin and botulinum are lateral flow antibody tests. Microbe screen is a fluorescent-based assay using binding dyes and a hand held fluorometer.
Application: The Prime Alert Biodetection System allows first responders to perform a rapid, on-site test to determine if a substance is a potential biohazard or merely a hoax. The simple and reliable technology alerts the responder to the presence of suspicious levels of any microbe in one five-minute test. A negative result is quickly followed by tests for ricin and botulinum toxins. In less than 10 min reliable information is obtained, allowing the first response team to make an informed decision regarding incident closure. The Microbe Screen™ is performed using a proven fluorescent-based technology in a hand-held reader and the Toxin Screens™ are carried out using lateral flow antibody tests.
Current Users: First Responders—Chicago Fire Department, Seattle Fire Department, Washington DC Special Operations, Atlanta Fire Department, Dekalb County Fire Department, Spokane City Fire Department, Glendale Fire Department, Bellevue Fire Department, Brunswick Fire Department, Columbus Fire Department, Denver Fire Department, Massachusetts Department of Fire Services, Prince William County Fire Department, Rochester Fire Department, Rapid City Fire Department, Athens-Clarke Co. Fire Department, Augusta Richmond County Fire Department, Berks County Emergency Management Agency, Beverly Hills Fire Department, Brunswick Fire Department, Cecil County Emergency Management, Cherokee County Fire Department, Dublin Fire Department, County of Los Angeles Fire Department, Forest Park Fire Department, Greenwood Fire Department, Mankato Fire Department, Robeson Co. Emergency Management, Savannah Fire Department, Vancouver Fire Department, and Virginia Fire Marshalls Office
Diagnostic Labs—Environmental Hydrogeological Consultants
Military—Navy Regional Fire Rescue, Fairchild Air Force Base, Defense Forces of Ireland, U.S. Army Aberdeen Proving Ground, and Singapore Civil Defense Forces
Scientific Research Labs—U.S. Army Dugway Proving Ground and Krel Laboratories
Hospitals—Baylor Medical Center and Williamsport Hospital
United States Postal Inspection Service, U.S. Coast Guard, LSU Academy of Counter Terrorism, Houston Chronicle, Northern Trust Company, U.S. Steel Corporation, Chicago Fire Training Academy, KAPL Lockheed, and Progressive Insurance Company
U.S. Coast Guard, LSU Academy of Counter Terrorism, Houston Chronicle, Northern Trust Company, U.S. Steel Corporation, Chicago Fire Training Academy, KAPL Lockheed, and Progressive Insurance Co.

OPERATIONAL PARAMETERS

BAs Detected: Bacillus anthracis, Brucella abortus, Brucella melitensis, Brucella suis, Brucella canis, Corynebacterium diptheria, Francisella tularenius, Burkholderia mallei, Burkholderia pseudomallei, Shigella spp., Salmonella typhimurium, Salmonella enteritidis, Salmonella typhi, Vibrio cholerae, Yersinia pestis, E. coli O157:H7, Coxiella burnetii, Rickettsia prowazekii, Rickettsia tsutsugamushi, Rickettsia rickettsii, Chlamydia psittaci, Clostridium botulinum, Botulinum Toxins, Clostridium perfringens, Clostridium tetani, and ricin
Type of Sample: Powder

Sample Preparation: No sample preparation is required. Sample powder is collected with tools provided and suspended in buffer provided. No additional support equipment is required for the Prime Alert. Sample collection takes less than 1 min.
SOP Sample Preparation: No sample preparation is required. A specific volume of sample is required and collection tools are provided.
Start-up Time: 2 min equipment set-up time (unpack and calibrate). 2 min start up for microbe screen. No start up time necessary for toxin screen.
Calibration Requirements: Instrument requires one quantitative calibration at startup. Manual calibration required for each microbe screen. No calibration required for toxin screen. Equipment includes internal standards for calibration with sample run. Calibration is a simple 3 step process and takes less than 2 min: 1) blank the instrument, 2) calibrate the instrument, and 3) verify calibration. Calibration time <5 min.
Response Time: 5 min (microbe screen), 10 min (toxin screen)
Data Analysis Time: <1 min for analysis and interpretation
Alarms: No alarm, but result is visually displayed
Sensitivity: Microbe screen: Detects bacterial spores ranges from 1.1×10^5 cfu/mg to 2.2×10^6 cfu/mg depending on the species
Toxin screen: Sensitivity for ricin is 50 ng/test (400 ng/mL); sensitivity for Botulinum toxin is 50 ng/test (400 ng/mL)
Confidence Interval/Sensitivity: Confidence Interval for sensitivity (at the limit of detection)—98 % for microbe screen and 100 % for toxin screen. The determination of the reproducibility and sensitivity of the assay was carried out by the Battelle Memorial Institute, Columbus, Ohio. The Prime Alert fluorescent results were compared with colony forming units as determined by standard plate counts using Bacillus subtilis spores, Bacillus thuringiensis spores, and Bacillus subtilis var. niger spores. Standard statistical tests were carried out and the correlation coefficient for these studies was R2 = 0.9853 with a CV of 1.3 %.
Specificity: Not specified
Confidence Interval/Specificity: Confidence Interval for Sensitivity (at the limit of detection)—98 % for microbe screen, 100 % for toxin screen. The determination of the reproducibility and specificity of the assay was carried out by the Battelle Memorial Institute, Columbus, Ohio. The Prime Alert fluorescent results were compared to non biological powders, those not containing bacteria or bacterial spores. The confidence interval for specificity of the microbe screen is 96 %.

- **False Positives**: Less than 4 % for microbe screen; 0 % for toxin screen
- **False Negatives**: 0 % at sensitivity threshold for microbe screen; 0 % at sensitivity threshold for toxin screen

Resistance to Interferents: Environmental interferents include escess environmental DNA. The assay detects spores and the assay does not cross-react with proteins or other organisms.
For the toxin screen, the following substances were tested for cross-reactivity—sodium chloride, bovine serum albumin, nondairy creamer, sugar, household dust, talcum powder, nonfat dry milk, flour, baking soda, baking powder, laundry detergent, and purified water.
For the microbe screen, the following substances were tested for cross-reactivity—cultured buttermilk, buttermilk pancake mix , unbleached flour, bleached flour , whole grain brown rice flour, nonfat dry milk, vanilla ensure, coffee mate coffee creamer, Western Family Coffee Creamer, All Kitchens nonDairy Creamer, Vanilla Pudding mix, chicken gravy, chicken bouillon, beef bouillon, instant dry mashed potatoes, corn starch, corn meal, gelatin, pure cane sugar, powdered sugar, equal sweetener (aspartame), Sweet 'N Low (saccharin), sugar in the raw, brown sugar, corn sugar (dextrose), iodized table salt, meat tenderizer, Ever Fresh, baking soda, baking powder, soy protein powder, garlic salt, paprika, white pepper, black pepper, ground mustard, taco seasoning, Good Host iced tea mix, ground cinnamon, ground ginger, Cascade dishwashing detergent, Tide with bleach, Western Family laundry detergent, Comet, Johnson & Johnson Baby Powder, Western Family talcum powder, Desenex, Gold Bond, General Foods International French Vanilla Instant coffee mix, General Food International Hazelnut instant coffee mix, General Foods International Mocha instant coffee mix, hot cocoa mix, sawdust, bentanite, crushed asprin, powdered make-up, crushed yeast, malt extract, tryptic soy broth, granulated solidifying agar, Lactobacillus growth medium (Americana medium), B. thuringeinsis bacteria, B. thuringeinsis spores, B. subtilis bacteria, B. subtilis spores, Lactobacillus, Lactococcus, E. coli, L. rhamnosus R-011, L. casei R-256, L. plantarum R-202, L. acidophilus, B. longum BB536, and B. breve R-070.
Testing Information: The Prime Alert Microbe Screen was validated by the Battelle Memorial Institute, Columbus, Ohio

PHYSICAL PARAMETERS

Size: 41 cm x 33 cm x 18 cm (16 in x 13 in x 7 in)
Working Space: Test can be performed in a 0.6 m x 0.6 m (2 ft x 2 ft) workspace. No support equipment is required.
Weight: Total wt of equipment kit, that includes carrying case, sampling tools, hand-held reader, and consumable test kits, is 5.4 kg (12 lb). Total weight including batteries is 2.1 kg (12 lb 2 oz).
Total Weight: Consumable test weighs 0.17 kg (6 oz).
Power Requirements: 4 AAA batteries (6V, 0.3W)

LOGISTIC PARAMETERS

Durability: The Prime Alert equipment kit is contained in a 40 cm x 33 cm x 18 cm (16 in x 13 in x 7 in) hard shell pelican case, which can be packed and moved by a single person with little training. The Prime Alert can be transported quickly and does not require recalibration. The Prime Alert reader can be dropped from counter height and left in cold or lhot environment without effect, but recalibration is recommended.
Ease of Use: The Prime Alert is easy to operate and can be carried out by a single individual in a level A suit
The Prime Alert Microbe Screen is carried out in 4 basic steps:

1. Mix solutions.
2. Collect sample and place in solution
3. Insert sample into reader and obtain result
4. Verify result

The Prime Alert Toxin Screen is carried out in 3 basic steps

1. Collect sample and place in solution
2. Transfer solution to test strip
3. Obtain result

Environmental Conditions: Can be used under any environment conditions; humidity does not affect operation
Support Equipment: No support equipment is required
Consumables: The Prime Alert consumable comes complete with all the necessary components to run a microbe screen and a toxin screen
Consumable Costs: One complete screen, which includes a microbe screen and ricin and Botulinum toxin screens, costs $210 retail
Maintenance: Maintenance is not required. Batteries should be changed yearly. There is 24 h technical support provided by the manufacturer or authorized agency. Loaner option during maintenance or malfunctioning. Upgrades including new testing and ad-on software capabilities may be added.
Shelf Life (Equipment): The equipment kit including the reader should not suffer for at least 5 yr
Shelf Life (Consumables): There is a 1 yr shelf life for all consumables
Maintenance Costs: Not specified
Decontamination: All components of the Prime Alert can be decontaminated or disposed of after use. O-ring seals in the reader make the unit completely submersible in alcohols, 10 % bleach, liquid detergents, and other appropriate decontamination solutions.

SPECIAL PARAMETERS

Skills Required: No specific skill level and no specialized training beyond hazmat training are required to learn how to use the Prime Alert. A person with a high school education can learn to use the equipment. Operator is not required to analyze raw data.
Training Required: Informal training—Each Prime Alert Equipment kit comes with a comprehensive training video and CD, a written user guide and quick reference cards. Training can be accomplished in less than 30 min.
Training Available: Formal training is available from the manufacturer. Training from the manufacturer can be accomplished with the training video and CD included with the equipment. In addition, Scott Health & Safety offers group "train the trainer" sessions at customer's facility. Training results in certification.
Manuals Available: Comprehensive instruction manual, quick reference cards, training video, and CD are included with each equipment kit at no charge.
Data Storage: The Prime Alert reader for microbe screens can store up to 1000 data points
Communications: The data points stored in the Prime Alert reader for Microbe Screens can be transferred to an Excel spreadsheet on any PC via an RS–232 serial port
Security: No special security mechanisms are required with the Prime Alert. The reader maintains internal parameters set by the manufacturer, which can be checked by the operator. All consumables are packaged in tamper proof pouches in order to maintain integrity of all components.
Safety Requirements: No safety requirements apply to the possession of the Prime Alert Biodetection System
Applicable Regulations: No regulations apply to the possession of the Prime Alert Biodetection/Threat Verification System
Warranty: The Prime Alert® Biodetection Threat Verification System comes with a 1 yr warranty. Loaner replacement units are included as part of the warranty. Extended warranties are available. The expected useful lifetime of the equipment is in excess of 5 yr.

GENERAL

RAZOR® System (RAZR-ASY–0010)

Idaho Technology, Inc.
390 Wakara Way
Salt Lake City, Utah 84108
Michael T. Hurley, Bio-Defense Programs
801–556-3234 (Tel)
801–588–0507 (Fax)
mike_hurley@idahotech.com
Information Source: http://www.Idahotech.com
ECBC Market Survey

Status: The vendor has responded—11/28/2006
Evaluated: Yes

Technology: Molecular
Portability: Handheld Detection Equipment

Unit Cost: $34.8K—commercial list. RAZOR system includes RAZOR unit plus rechargeable battery pack, carrying case, battery charger, power supply, carrying straps, cord/cables, maintenance kit, user manual, and training DVD
$180—RAZOR pouch freeze-dried reagent kits with sample preparation kit (12 reactions per pouch; multiple agents tested per pouch)
Availability: Immediate availability, commercially available off the shelf (COTS) since Spring 2005
Description: Real Time PCR—RAZOR utilizes PCR technology to amplify specific DNA sequences. In addition, fluorescent probes monitor the reaction and report results in real-time.
Application: Detection and identification of biological organisms by real-time PCR
Current Users: Military—U.S. Special Operations Command and international customers (Australia and Finland)
First Responders—Orlando Fire HazMat, Salt Lake United Fire Authority HazMat, and Kansas City Fire HazMat
Scientific Research Labs—Armed Forces Institute of Pathology and Naval Medical Research Laboratory

OPERATIONAL PARAMETERS

BAs Detected: Commercially available freeze-dried assays manufactured by Idaho Technology Inc.
Bacilus anthracis, Brucella spp., Francisella tularenius, Salmonella spp, Yersinia pestis, E. coli 0157 , Cryptosporidium spp., Clostridium botulinum Type A, Rcininus communis, Variola, Avian Influenza H5 subtype, Influenza Type A, Listeria monocytogenes.
Type of Sample: Air, liquid, solid, sludge, and surface wipes
Sample Preparation: The RAZOR System uses a simple "Dilute and Go" sample preparation method, which is designed to prepare liquid and dry samples for loading into RAZOR pouches and to dilute out potential inhibitors to PCR. The System is also compatible with DNA extracted and purified from more sophisticated methods. Sample preparation is <15 min.
SOP Sample Preparation: A sampling kit is included with the RAZOR pouch freeze-dried reagent kit. Each sampling kit contains swabs, transfer pipettes, and sample bottles pre-filled with buffer and labeled. This allows for both dry and liquid samples to be prepared for analysis.

1) Swabs included in the RAZOR sampling kit are used to collect powder, liquid, or surface swipe samples. Touching a powder with a dry swab or using a damp swab to swipe a surface acquires the sample. The swab is then transferred to the "Sample" bottle. The tip of the swab is broken off into the bottle and the contents are shaken vigorously for ~30 s.
2) Graduated transfer pipettes can be used to collect an aliquot of a liquid sample for testing. To accommodate for bulky protective gear, a single squeeze by the user aspirates and holds the correct volume into the pipette. After the transfer, the contents are shaken for approximately 30 s to mix. The samples are then ready to be loaded into the RAZOR pouch.
3) Samples are inserted into the pouches with cannula tipped syringes. The syringe is inserted into the pouch, and the sample liquid is drawn by vacuum pressure into wells containing the freeze-dried reagent. This design ensures that the correct volume of sample liquid is used to automatically resuspend the dried reagents. The user then depresses plungers on the fitment to disperse the reaction mixtures to their proper sample slot.

Start-up Time: 2 min—unpack and plug the instrument in
Calibration Requirements: 2 min for autocalibration. Instrument quantitatively autocalibrates with each run. The RAZOR instrument runs a series of self-test diagnostics to ensure proper working condition of critical systems.
Response Time: Under 30 min

Data Analysis Time: Less than 1 min—no operator analysis required
Alarms: Visual alarm (detector) appears at the conclusion of the run
Sensitivity: The RAZOR System is able to reliably detect to 100 fg of amplifiable DNA material in a single reaction, this is approximately 20 copies of bacterial DNA

Bacteria— ~200 CFU/mL
Virus— ~2000 CFU/mL
Toxins—not applicable
Target DNA—100 fg (femtograms = 10e-12)

Confidence Interval/Sensitivity: >95 % at 100 fg
Every assay is tested over a dynamic range (dilution series) to determine detection sensitivity. LOD is defined at the lowest DNA concentration where greater than 95 % of the reactions return a positive result.
Specificity: The RAZOR System uses DNA assays designed for detection of a specific agent. The assays undergo rigorous specificity testing against panels of related and unrelated agents. The assays show 0 % cross-reactivity with agents in the tested panels. Specific DNA assays have not shown cross-reactivity. Organisms or proteins that have been tested in cross-reactivity studies varies for specific assay. For example, anthrax target 1 assay has been tested against the following: B. c. 3A, B. c. 4342, B. c. D17, B. c. S2-8, B. t. 97-27, B. t. al Hokum, B. t. HD571, B. c. F1-15, Clostridium botulinum F, Listeria innocua, Corynebacterium diphtheriae, Corynebacterium jeikeium, Clostridium botulinum A, Clostridium botulinum B, Burkholderia mallei, Burkholderia pseudomallei, Clostridium perfringens A, Staphylococcus aureus A, Staphylococcus aureus E, WHMC 8-12, WHMC 34-27, WHMC 35-14, WHMC 35-72, WHMC 32-35, WHMC 36-35, WHMC 6-43, WHMC 7-62, WHMC 18-4, WHMC 9-4, WHMC 7-28, WHMC 35-66, WHMC 34-73, Clostridium botulinum E, Staphylococcus aureus C, F. tularensis SHU4, Yersinia pestis CO92, Vibrio cholerae, Deinococcus radiodurans, B. t. Kurstaki, Bacillus subtilis 6051, B. t. Israeliensis 35646, Bacillus cereus 11778, B. megaterium 14581, Bacillus sphaericus 4525, Bacillus mycoides 6462, Bacillus globigii DPG, Clostridium perfringens B, Staphylococcus aureus B, Brucella melitensis, Brucella suis, and Brucella abortus.
Confidence Interval/Specificity: 0 % cross-reactivity with organisms in testing panel

- **False Positives**: None known
- **False Negatives**: None known

Resistance to Interferents: Some organic acids or salts can interfere if at high concentrations in the sample. Can be removed by dilution or sample purification.
Testing Information: 1. Biologic Air-Borne Particle Detection, Sampling, and Identification. March 2005. Summarizes study conducted at MesoSystems Technology's test facility for aerosolized agents. Report available from Idaho Technology
2. Test Report—Idaho Technology Inc.'s RAZOR™ System. March 2005. Summarizes specificity study conducted at the Defense Science and Technology Organization (DSTO) in Melbourne, AU and at the Queensland Health Pathology and Scientific Services laboratory in Brisbane, AU. Report available from Idaho Technology.
3. Final Report for Performing Verification of PCR Reliability and Verification of the RAZOR System Within Extreme Environmental Conditions. July 2003. Summarizes environmental testing of RAZOR II+ instrument (previous version). Executive Summary available from Idaho Technology.

PHYSICAL PARAMETERS

Size: 17 cm x 11 cm x 23 cm (6.6 in x 4.4 in x 9.1 in)
Working Space: 0.1 m^2 (1 ft^2) battery operated; 0.2 m^2 (2 ft^2) ac power
Weight: 4.1 kg (9.1 lb) including battery
Total Weight: Storage case/accessories 4.5 kg(10 lb); assay kits 0.2 kg (8 oz)
Power Requirements: Battery—at least 4 complete 30 min runs on a battery charge; generator powered (indicated output kW); ac powered 100 V to 240 V 47/63 HZ

LOGISTIC PARAMETERS

Durability: Instrument (with battery) can be easily carried via hand strap or shoulder strap. RAZOR® System was designed for field/portable use. It is a hand-portable, ruggedized unit that has passed vibration, pressure, and blowing sand tests. In addition, this unit also can operate on-the-move at hot and cold temperatures. It can be dropped without effect if in its storage case.
Ease of Use: Easy to use. The RAZOR® System does not require prior laboratory experience or advanced computer skills. The instrument was ergonomically designed to assist users in advanced PPE (i.e., Level A HazMat suits or MOPPs gear). There are four primary steps to obtain a result: sample, prepare, load pouch, and run RAZOR. The level of accuracy needed is minimal because the tools used either eliminate the need for user accuracy or are robust enough to allow for error without compromising results.

Environmental Conditions: RAZOR® System can be operated between 0 ºC to 40 ºC (32 °F and 103 °F). Slow cooling of air shuts the machine off. The recommended relative humidity instrument operation is below 95 %.
Support Equipment: None required
Consumables: RAZOR pouch freeze-dried assay kits with sample prep kits (12 reactions per pouch, multiple agents tested per pouch)
Consumable Costs: RAZOR pouch freeze-dried assay kits with sample prep kits: $180 (12 reactions per pouch, multiple agents tested per pouch)
Maintenance: The RAZOR® instrument does not require regular service/maintenance, however periodic user maintenance is recommended. Loaner option during maintenance or malfunctioning is available, and 24 h technical support is provided by the manufacturer. The RAZOR is supported with Software upgrades, new assay upgrades and part upgrades (filters, etc.). Loaner options are determined by length of maintenance downtime and limited to instrument availability.
Shelf Life (Equipment): Instrument can be stored for up to 10 yr without being serviced before it is used
Shelf Life (Consumables): Shelf life for RAZOR pouch freeze-dried reagent kits is 6 mo
Maintenance Costs: $0
Decontamination: 10 % bleach is recommended to surface decontaminate the RAZOR ® System

SPECIAL PARAMETERS

Skills Required: High school level education or higher is appropriate. General biology knowledge is helpful but not necessary. Operator requirements include familiarity and general knowledge of RAZOR® System user manual (instrument operation, sample prep and reagent set-up). Operator does not need to analyze raw data before a final result can be determined.
Training Required: 2 h of instruction and practice time is sufficient to learn equipment operation. Frequent practice will reinforce learning and maintain proficiency and readiness. Optional on-site 6 h training course is available upon special arrangement.
Training Available: A training DVD is sent with the instrument upon purchase. In addition Idaho Technology offers onsite training for the RAZOR® System (RAZOR System Training). Training program includes instrument set-up, sample preparation and reagent set-up, concepts of operations, and troubleshooting.
Manuals Available: User Technical Manual (hardcopy and electronic) is included with the RAZOR® System. The Technical Manual includes instructions to set-up, run and report results (common user). Technical Manual also includes instructions to use advanced Software options (run programming and advanced data analysis) along with troubleshooting and maintenance sections. In addition, a training DVD is shipped with the System.
Data Storage: Data is stored in the RAZOR System's onboard CPU. The data can be downloaded to a computer where it can be sent via email, exported to storage media, or saved in the RAZOR software's database.
Communications: RAZOR desktop software allows control directly from a computer. Designed for use with Windows 2000 Operating System (compatible with XP). Data downloaded to desktop software can be sent via email, file sharing, or electronic storage media.
Security: Not applicable
Safety Requirements: The RAZOR System meets the Machinery Safety, Electromagnetic Compatibility, and Low Voltage directives for CE approval
Applicable Regulations: Not specified
Warranty: Idaho Technology offers a 1 yr warranty on parts and labor as well as 24/7 technical support. Additional extended warranties are also available.

GENERAL

Uni-Lite NG

Biotrace International, Ltd.
1106 E. Seymour St.
Muncie, Indiana 47302
Ken Davenport
513–266–8873 (Tel)
616–588–6096 (Fax)
kdavenport@biotrace.com
Information Source: http://www.biotrace.co.uk/

Status: The vendor has responded—11/21/2005
Evaluated: Yes

Technology: Optical
Portability: Handheld Detection Equipment

Unit Cost: $3K; PC ($2K)
Availability: Lead time depends on volume ordered. Two hundred instruments available in stock 2 wk to 3 wk; larger orders will require 3 mo to 6 mo lead time
Description: ATP Bioluminescence
Application: The Uni-Lite NG was designed as a hand-held luminometer for the detection of microbial biomass on surfaces or in solutions. The equipment and software was designed with the food and beverage manufacturing market as well as catering/food service markets.
Current Users: Military—Patuxant Naval Air Station
Scientific research labs—Numerous labs
Hospitals—Innova Fairfax Hospital
Industry—Coke, Pepsi, Kraft, Philip Morris, Nestle, and Hershey

OPERATIONAL PARAMETERS

BAs Detected: Bacilus anthracis, Brucella abortus, Brucella melitensis, Brucella suis, Brucella canis, Corynebacterium diptheria, Francisella tularenius, Burkholderia mallei, Burkholderia pseudomallei, Shigella spp., Salmonella typhimurium, Salmonella enteritidis, Salmonella typhi, Vibrio cholerae, Yersinia pestis, E. coli O157:H7, Coxiella burnetii, Rickettsia prowazekii, Rickettsia tsutsugamushi, Rickettsia rickettsii, Chlamydia psittaci, Cryptosporidium spp., Coccidiomycosis immitis, Histoplasma capsulatum, Clostridium botulinum, Clostridium perfringens, and Clostridium tetani
Type of Sample: Liquid, surface wipes, and airborne particulates suspended in a liquid
Sample Preparation: Sample preparation is not required
SOP Sample Preparation: Not applicable
Start-up Time: None (unpack and plug in); <1 min
Calibration Requirements: Equipment auto-calibrates. Instrument is calibrated automatically (qualitative and quantitative) with every run. Protocol for calibration—-turn on the instrument (press and hold red button).
Response Time: <1 min
Data Analysis Time: <1 min
Alarms: No alarm, but result is visually displayed. Also auto, visible, and audible.
Sensitivity: Bacteria—1000 CFUs/mL to 10 000 CFUs/mL
Confidence Interval/Sensitivity: Biomass confidence interval >95 %—2 femtomoles of ATP
Zero sample controls performed, 20 swabs each from 3 lots
Standard ATP solutions were spotted directly on swabs and read
Threshold is 3 standard deviations above the background
Specificity: Not specified
Confidence Interval/Specificity: Not specified

- **False Positives**: Not specified
- **False Negatives**: Not specified

Resistance to Interferents: Environmental interferents include high humidity, low humidity, pH, air pollutants, excess environmental protein, and excess environmental DNA; can differentiate between viable and nonviable organisms in liquid; can detect spores; cross-reacts to all biomass

Testing Information: Not specified

PHYSICAL PARAMETERS

Size: 10 cm x 23 cm x 8 cm (4 in x 9 in x 3 in)—fits in pants-pocket; single tests are slightly bigger than a sharpie pen
Working Space: Refrigerated storage <0.3 m^3 (1 ft^3) for 100 tests. No bench space required.
Weight: <500 g (18 oz); <500 g (18 oz) with batteries
Total Weight: <0.91 kg (2 lb)
Power Requirements: Battery powered; <12 h of continual use with X—Lithium ion

LOGISTIC PARAMETERS

Durability: Able to be transported quickly without protective packaging, able to be dropped from counter height without effect, able to be left in hot or cold environment without effect, and Military specs are available
Ease of Use: 4 step tests—swab/dip; press test handle down; insert in NG; and press one button to activate reading
Environmental Conditions: Not in temperatures above 37 ºC (98.6 ºF)—low readings. Not in temperatures below 5 ºC (41 ºF)—low readings. Humidity has no effect.
Support Equipment: Charging cord and PC communication cable
Consumables: Biotrace reagent kits—Clean-Trace (surfaces) and Aqua-Trace (solutions)
Consumable Costs: ~ $3 per test cost per assay of total consumable
Maintenance: Monthly—positive control check $4. Yearly—factory check $500. There is a 24 h technical support provided by the manufacturer or authorized agency, there is a loaner option during maintenance or malfunctioning, and equipment is upgradeable.
Shelf Life (Equipment): 1 yr—battery will require charging
Shelf Life (Consumables): 6 mo—Clean-Trace Reagents; 1 yr—Aqua-Trace reagents
Maintenance Costs: $300/yr preventative maintenance contract
Decontamination: Not immersable—can use most cleaning solutions

SPECIAL PARAMETERS

Skills Required: No advanced skills required. Operator does not need to analyze raw data before a final result and high school diploma is sufficient education.
Training Required: No special skills and less than 4 h formal training required
Training Available: Classroom/Online—Biotrace Autotrack Training—Offsite (at manufacturer site) or onsite (where equipment will be used or stored) results in certification. Manual, CD, and video training does not result in certification.
Manuals Available: User manual
Data Storage: 20 000 data points can be stored
Communications: Computer interface—proprietary Biotrack software; data transfer capability (interface)—RS232 port
Security: Units can be set up to be password protected. Software is PC based and depends on PC settings for security.
Safety Requirements: No hazardous waste (with the exception of biological weapon contamination) or restrictions
Applicable Regulations: With the possible exception of NIOSH/OSHA regulations on the lifting of the equipment, there are no regulations regarding the use of the equipment
Warranty: 1 yr parts and labor warranty; 5 yr unit life

GENERAL

Autotrack (Continuous Flow ATP Detector)

Biotrace International, Ltd.
1106 E. Seymour St.
Muncie, Indiana 47302
Ken Davenport
513–266–8873 (Tel)
616–588–6096 (Fax)
kdavenport@biotrace.com
Information Source: http://www.biotrace.co.uk/

Status: The vendor has responded—11/21/2005
Evaluated: Yes

Technology: Optical
Portability: Mobile Laboratory Detection Equipment

Unit Cost: $66K
Availability: Lead time depends on volume ordered. There are 30 to 50 instruments available in stock; larger orders will require 3 mo to 6 mo lead time.
Description: ATP Bioluminescence/Continuous Flow Lluminometer
Application: Designed for field detection of airborne biomass. The Autotrack was designed as a second part of an air sampling system, the Biotrace Biological Detection System comprised of the Inelligent Air Cyclone, which collects particulates from 750 L air/min and concentrates it into a continuous effluent stream. The liquid stream is then analyzed by the Autotrack for free and total ATP in a continuous process. The free ATP represents nonmicrobial ATP (background) while the total ATP represents the total signal. The total minus the free represents the microbial ATP—the higher the difference between total and free, the larger the amount of biomass in the feed stream or airborne biomass if used in conjunction with the Intelligent Air Cyclone.
Current Users: UK Military as part of IBDS program

OPERATIONAL PARAMETERS

BAs Detected: Bacilus anthracis, Brucella abortus, Brucella melitensis, Brucella suis, Brucella canis, Corynebacterium diptheria, Francisella tularenius, Burkholderia mallei, Burkholderia pseudomallei, Shigella spp., Salmonella typhimurium, Salmonella enteritidis, Salmonella typhi, Vibrio cholerae, Yersinia pestis, E. coli O157:H7, Coxiella burnetii, Rickettsia prowazekii, Rickettsia tsutsugamushi, Rickettsia rickettsii, Chlamydia psittaci, Cryptosporidium spp., Coccidiomycosis immitis, Histoplasma capsulatum, Clostridium botulinum, Clostridium perfringens, and Clostridium tetani
Type of Sample: Liquid and airborne particulates suspended in a liquid
Sample Preparation: Airborn biomass detection requires use of the Biotrace Intelligent Air Cyclone or similar continuous air sampling system. Potable water testing does not require sample preparation.
SOP Sample Preparation: See cyclone manufacturer for detail. For water sampling (no sample preparation required):

1. Ensure the water source is free of visible clay, mud, etc.
2. Place sample intake tube in the water
3. Turn on the pumping mechanism

Start-up Time: <15 min, including calibration. Assembly requires 5 or less steps—attach tubing, clip rubber tubing into peristaltic pumps, resuspend luciferase reagent, and insert tubing into bottles.
Calibration Requirements: Instrument requires one calibration at startup (qualitative and quantitative)
Response Time: <1 min
Data Analysis Time: <5 min
Alarms: No alarm, but result is visually displayed. Also auto, visible, audible, and visible and audible.
Sensitivity: Bacteria—1000 CFUs/mL to 10 000 CFUs/mL
Confidence Interval/Sensitivity: Not specified
Specificity: Not specified
Confidence Interval/Specificity: Not specified

- **False Positives**: Not specified
- **False Negatives**: Not specified

Resistance to Interferents: Environmental interferents include soil, high and low humidity, pH, air pollutants, excess evironmental protein, and excess environmental DNA. Instruments differentiates between viable and nonviable organisms, detects spores, and cross-reacts to all biomass.
Testing Information: All current data for the autotrack with BWA is classified by the UK military. Biotrace is currently conducing these types of experiments with a UK-based testing agency.

PHYSICAL PARAMETERS

Size: 48 cm x 30 cm x 28 cm (19 in x 12 in x 11 in)
Working Space: Refrigerated storage <0.2 m^2 (2 ft^2) for 100 tests; support equipment (computer/lap-top connection); reagent preparation—<0.1 m^2 (1 ft^2) shelf space
Weight: 20 kg (44 lb); 23 kg (50 lb)—weight of support equipment and consumables; 1 or 2 person portability
Total Weight: Not applicable
Power Requirements: V ac power required. Typically vehicle mounted.

LOGISTIC PARAMETERS

Durability: Meets Mil Specs for durability. The equipment is protected by a stainless steel case.
Ease of Use: Not specified
Environmental Conditions: Not in temperatures above 37 ºC (98.6 ºF)—low readings. Not in temperatures below 5 ºC (41 ºF)—low readings. Humidity has no effect.
Support Equipment: Replacement tubing and flow cells. All tools are standard screwdriver/hex key.
Consumables: Biotrace reagent kits
Consumable Costs: Difficult to compare as this is continual usage rather than single assays.
Reagent cost is ~ $1.5K to $3K per day with constant use
Maintenance: Daily—positive control check $4. Yearly—factory check $500. There is a 24 h technical support provided by the manufacturer or authorized agency, there is a loaner option during maintenance or malfunctioning, but equipment is not upgradeable.
Shelf Life (Equipment): 1 yr—rubber tubing for peristaltic pump would suffer with prolonged storage
Shelf Life (Consumables): 1 yr—Luciferase reagents
Maintenance Costs: $1K
Decontamination: Remove tubing and flow cell to remove internal contamination. External contamination requires replacement of all electronic components.

SPECIAL PARAMETERS

Skills Required: Ability to use MS Excel, operator is not required to analyze raw data to conclude a final result, and high school diploma is sufficient education
Training Required: Less than 4 h formal training required or less than 8 h informal training required
Training Available: Classroom/Online—Biotrace Autotrack Training—Offsite (at manufacturer site) or onsite (where equipment will be used or stored) does not result in certification. Manual training.
Manuals Available: User manual and repair manual
Data Storage: Data is uploaded to a computer using Biotrace software. This software transfers data directly to MS Excel, and files can easily be stored on the user's PC.
Communications: Computer interface—proprietary software; data transfer capability (interface)—RS232 port
Security: Hacker/unauthorized user protection depends on the settings of the PC used for interface
Safety Requirements: No hazardous waste (with the exception of biological weapon contamination) or restrictions
Applicable Regulations: With the possible exception of NIOSH/OSHA regulations on the lifting of the equipment, there are no regulations regarding the use of the equipment
Warranty: 1 yr parts and labor warranty

GENERAL

VeroTect

Biral
P.O. Box 2
Poerishead
Bristol BS20 7JB
UK
Steve Evans
+44 1275 847787 (Tel)
+44 1275 847303 (Fax)
Sevans@biral.com
Information Source: http://www.biral.com

Status: The vendor has responded—11/29/2006
Evaluated: Yes

Technology: Optical
Portability: Mobile Laboratory Detection Equipment

Unit Cost: Unit cost of detector £65 400 (approximately $90K). Volume discounts on application.
Availability: Availability Q2, 2005. Lead time 12 wk from receipt of order.
Description: Optoelectronic—Fluorescence/Emission—280 nm excitation. 2 channel emission detection
Particle shape and size via laser light elastic scattering. There is known to be far more information embedded within the spatial distribution of the scattered light. In recent years, developments in optoelectronic device performance, coupled with the inexorable advances in low-cost computer power, have presented exciting opportunities for real-time particle analysis.
Application: Military and civil applications for real time bio-detection trigger/alerter. Standalone point detection or as part of a network of sensors.
Current Users: Military—Selected for UK MoD Integrated Sensor Management System (ISMS)

OPERATIONAL PARAMETERS

BAs Detected: The VeroTect detector provides real time, generic detection, i.e., the ability to discriminate bio aerosols from nonbio aerosols. It detects that a potential threat agent is present, but it does not provide specific identification of the exact threat agent.
Type of Sample: Air
Sample Preparation: None
SOP Sample Preparation: Not applicable
Start-up Time: Detector startup time (including calibration to initiating a run) <5 min
Assembly requires 3 steps

- Connect sampling inlet
- Connect power and data cables
- Apply power and allow startup sequence to complete

Calibration Requirements: Calibration not required at startup. Instrument requires vendor support for quantitative calibration. Manual calibration is carried out in the factory at predefined service intervals, normally 12 mo or 24 mo dependent on the level of confidence checks undertaken in the field or storage depot.
Response Time: <30 s
Data Analysis Time: Real time
Alarms: Auto, visible, and audible. Network connection capability.
Sensitivity: The VeroTect detector provides real time, near generic detection, i.e., the ability to discriminate bio aerosols. It does not provide specific identification of the threat agent.
Confidence Interval/Sensitivity: Not applicable
Specificity: Not applicable
Confidence Interval/Specificity: Not applicable

- **False Positives**: Low—reduced by interferents discrimination capability
- **False Negatives**: Low—high probability of bioaerosol event detection by numerous particle characterisation methods, i.e., size, shape, concentration, and flourescence

Resistance to Interferents: Known environmental interferents include presence of environmental bacteria, cold temperatures, hot temperatures, high humidity, low humidity, pH, air pollutants, excess environmental protein, and excess environmental DNA; fuel oils and pollens; differentiates between viable and nonviable organisms; and detects spores

Testing Information: No publishable data available at this time

PHYSICAL PARAMETERS

Size: 960 mm x 460 mm x 500 mm (3.1 ft x 1.5 ft x 1.64 ft)
Working Space: None
Weight: <30 kg (66 lb)
Total Weight: 10 kg (22 lb) transit case
Power Requirements: 200 W, 110 V ac or 220 V ac, 47 Hz to 63 Hz, or can be powered by 18 V dc to 36 V dc

LOGISTIC PARAMETERS

Durability: Vehicle transported, 2 man lift including transit case, 1 man deployment
Able to be dropped from counter height without effect—Mil Spec DEF STAN 00–35
Able to be left in cold environment without effect—Mil Spec DEF STAN 00–35
Able to be left in hot environment without effect—Mil Spec DEF STAN 00–35
Ease of Use: Deployable by operator wearing PPE
Environmental Conditions: Not in temperatures above 55 ºC (131 ºF)—Mil Spec DEF STAN 00–35
Not in temperatures below -33 ºC (-27.4 ºF)—Mil Spec DEF STAN 00–35
Not above humidity of 95 %—Mil Spec DEF STAN 00–35
Support Equipment: None
Consumables: None
Consumable Costs: None
Maintenance: The only maintenance task required to be carried out by the user is the replacement of the sampling nozzle in the event of it becoming blocked during operation. Technical support available during UK office hours only. No preventive maintenance required. There are no field replaceable parts.
Shelf Life (Equipment): Infinite shelf life but limited in practice to 2 yr for calibration interval
Shelf Life (Consumables): Not applicable
Maintenance Costs: To be defined under scope of any supply contract
Decontamination: Under UK MoD review

SPECIAL PARAMETERS

Skills Required: No special skills or training required. The operator does not need to analyze raw data before a final result can be determined. High school diploma is sufficient education.
Training Required: Minimal
Training Available: Commercial standard user manual supplied with the equipment
Manuals Available: Commercial standard User Manual supplied with the equipment
Data Storage: On board data storage facility provided. Will support 72 h battlefield mission.
Communications: Computer (control), computer interface, data transfer capability (interface), networking capability, hardwire capability, and installed data processing equipment
Security: Authentication password required for entry; physical spoof proofing measures employed—interlocks on access panels
Safety Requirements: CE marked and MoD Safety Case approval
Applicable Regulations: UK Export Control Act 2002
Warranty: 12 mo standard manufacturer warranty

GENERAL

4 WARN Sentry 3000 (Model 718866–901)

General Dynamics Canada
1020 68th Ave NE
Calgary, Alberta, T2E 8P2
Mike Boryski
403–730–1246
mike.boryski@gdcanada.com
Information Source: http://www.gdcanada.com

Status: The vendor has responded—10/24/2005
Evaluated: Yes

Technology: Optical
Portability: Mobile Laboratory Detection Equipment

Unit Cost: This product is approximately $100K USD, depending upon configuration and quantities
Availability: Product is available in 16 wk to 20 wk depending on quantities
Description: Fluorescence—The optics and associated detection circuitry is based on fluorescent particle detection technology utilizing a Continuous Wave (CW) Ultra Violet (UV) laser diode. Particles are pulled into the unit by a particle concentrator which filters out particles less than 1 µ and greater than 10 µ. The particles then pass through an optical cell encased within a narrow stream of air, which is directed through the path of the laser beam. If the particle is biological in nature, it will contain Nicotinamide Adenine Dinucleotide (NADH), which when illuminated by the UV laser, will fluoresce. The fluorescence is detected using Photo Multiplier Tubes (PMT) and the signal passed to the Sentry's central processor unit. GD Canada's proprietary software then passes the information to a tested and proven algorithm that determines if the agent is indeed biological in nature. If a biological agent is detected, the Sentry processor will trigger the dry sampler as discussed previously. An alarm message is simultaneously sent to the operator via the SMS along with an audible alarm.
Application: The detector is intended to be used as a remote area-monitoring device for the purpose of warning authorities of a biological attack. With sufficient warning, authorities can initiate response plans to minimize causalities and contain an attack. The Sentry 3000 provides near real-time detection, notifying the operator of a biological event within 20 s of being exposed to the agent. Once an agent is detected and an alarm has been issued, the unit immediately and automatically collects a sample of the aerosol using a dry sampler. The dry sampler utilizes a filter paper that traps particles of interest for laboratory analysis at a later time. A liquid sample can also be prepared in the field from the dry sample paper for use with identification technologies, such as handheld immunoassay tickets. Placing the filter in distilled water and shaking prepare a liquid sample. The Sentry 3000 can be used alone or in a network of several Sentry 3000 units, all-communicating with a central System Management Terminal to provide perimeter protection of a high value asset. The Sentry 3000 can also be used by the first responder as a point source location device when connected to an optional battery pack and Supplementary Airflow Unit (SAU) which has 6 m (20 ft) (can be longer if required) of flexible hose and a wand. The Sentry 3000 may also be used in building applications to monitor the air in ventilation systems. It is also capable of being installed and operated in a vehicle, such as air monitoring vehicles, for fast response to emergency situations. The Sentry 3000 is portable, and may also be used for reconnaissance because of its real time response. Thus, it can be used to survey containers by sampling air through pressure valves and can be used to survey buildings to detect residual contamination after an attack. It can be used to locate the release point of biological attacks.
Current Users: Military—In use by the Canadian Military.
First Responders—Being investigated by the Calgary Hazardous Materials division and Canadian Customs and Revenue Agency. In use in United Kingdom by The Home Office.
Other*—Bubble Technology

OPERATIONAL PARAMETERS

BAs Detected: The 4WARN Sentry 3000 is a generic detector that can detect any agent that is biological in nature. It is not agent specific. The term "detect" here means that the system determines that a biological agent is in the air. The Sentry 3000 does not identify the agent. However, it does collect a dry sample that can be used for laboratory analysis, or can be concerted to a liquid sample by introducing it into distilled water and agitating. The liquid sample can than be used with identification technologies that require wet samples. The primary advantage of the Sentry 3000 is immediate notification that a biological attack has occurred without having to wait hours or days for laboratory analysis to determine if a biological event has taken place.

Type of Sample: Air
Sample Preparation: The Sentry does not require sample preparation for detection as it monitors and detects biological agents within aerosols
SOP Sample Preparation: Not applicable
Start-up Time: Less than 1 min when started up with a network cable. Less than 5 min when started up with a network cable connected. Unpack and plug in as a single detector. Assembly requires 3 steps for remote monitoring or networking:

1. Connect Sentry and computer with Ethernet cable OR connect modem to computer and antenna to Sentry for wireless communications
2. Connect GPS antenna to Sentry
3. Power up Sentry and SMT computer and launch SMS application

Calibration Requirements: Equipment auto-calibrates—sets alarm based on background sample. The Sentry 3000 does not require field calibration. There is not protocol for calibration.
Response Time: <20 s from time agent enters optics until an alarm is issued
Data Analysis Time: Results are presented to operator as either an alarm or no alarm. Practically no interpretation time.
Alarms: Visual and audible alarms; automatic alarm
Sensitivity: Bacteria—whole cell in CFUs (colony forming units)/mL—20 ACPLA, <10 ACPLA at tets at Battelle
Virus—particles in PFUs (plaque forming units)/mL—20 ACPLA, <10 ACPLA at tets at Battelle
Toxins—micrograms of toxin/mL—<5 ng/ml ovalbumin, ~ 20 ACPLA
Confidence Interval/Sensitivity: Standard test protocol used at ABT at Battelle with detector in automatic alarm mode. Over 50 test runs at 5 to 80 ACPLA, 3 days of tests, including interferrents
Spores, Bacteria—Greater than 95 %—10 ACPLA at ABT in Battelle, based on simulants
Viruses, Toxins—Greater than 90 %—20 PFU / ml or 20 ACPLA at ABT in Battelle, based on simulants
Specificity: Bacilus anthracis—<10 ACPLA in some instances
Brucella abortus, Brucella melitensis, Brucella suis, Brucella canis, Corynebacterium diptheria, Burkholderia mallei, Burkholderia pseudomallei, Shigella spp., Salmonella typhimurium, Salmonella enteritidis, Salmonella typhi, Vibrio cholerae, Yersinia pestis, E. coli O157:H7, Coxiella burnetii, Rickettsia prowazekii, Rickettsia tsutsugamushi, Rickettsia rickettsii, Chlamydia psittaci, Cryptosporidium spp., Coccidiomycosis immitis, Histoplasma capsulatum, Clostridium botulinum, Botulinum toxins, Clostridium perfringens, Clostridium perfringens toxins, Clostridium tetani, Clostridium tetani toxin, and ricin
Francisella tularenius—Not tested for sensitivity against real agents so detection limit is based on data from stimulant testing
** Based on positive detection of ovalbumin as simulant
Clostridium tetani toxin, Mycotoxins of the Trichothecene Group, Aflatoxin, Staphylococcal aureus enterotoxin B, Microcysstins, Anatoxin A, Tetrodotoxin, Saxitoxin, Palytoxin, Abrin, and Modeccin
Confidence Interval/Specificity: Not applicable

- **False Positives**: The Sentry 3000 has been shown to consistently detect and alarm on Bacillus Globigii (BG) concentrations of 10 ACPLA and higher in tests at multiple locations. A recent test of 68 trials ranging in BG concentrations of 8 to 80 ACPLA, the Sentry detected all 68 releases and alarmed on all but 5, all of which were below 15 ACPLA.
- **False Negatives**: The Sentry 3000 has been shown to consistently detect and alarm on Bacillus Globigii (BG) concentrations of 10 ACPLA and higher in tests at multiple locations. A recent test of 68 trials ranging in BG concentrations of 8 to 80 ACPLA, the Sentry detected all 68 releases and alarmed on all but 5, all of which were below 15 ACPLA.

Resistance to Interferents: Hot and cold temperatures—operates from 0 ºC to 30 ºC (32 ºF to 86 ºF)
Humidity—operates up to 95 % rh, noncondensing
Air pollutants—no false alarms with diesel test dust, smokes, and salt water, and does alarm on extinguished rubber
It can differentiate between viable and nonviable organisms—viable biological particles fluoresce
It can detect spores—viable biological spores fluoresce
Testing Information: Technical Notes and independent third party test results available upon formal request

PHYSICAL PARAMETERS

Size: Sentry 3000 detector—21.2 in x 16.0 in x 8.3 in (l, w, h); laptop—1.2 in x 12.4 in x 10.1 in (h, w, d)
Working Space: No support equipment required
Weight: Sentry 3000—18 kg (39 lb); laptop—2.1 kg (4.7 lb) weight of laptop includes battery
Total Weight: Package of sample filter papers weigh a few ounces; spare HEPA filter weighs a few ounces
Power Requirements: Power required—100 to 240 V ac, 50/60 Hz
Battery powered—optional battery pack complete with inverter and charger; <8 h of continual use with rechargeable deep cycle battery pack

LOGISTIC PARAMETERS

Durability: The Sentry enclosure is made from a high impact material; hence the equipment need only be unplugged for transport. The Sentry is shipped from the factory in a transport case that is made from high impact material and is fitted with wheels and a handle. If desired, the Sentry can be installed in the case and transported, or it can be moved by one person and transported in a vehicle as is (without an additional transport case). The Sentry is tested to a custom wheeled profile using MIL-STD–810 methods (4 h per axis), and it can be dropped several times from a height of 46 cm (18 in) without effect.
Ease of Use: Personnel wearing PPE can use the Sentry detector. The dry sample module was designed such that a person wearing NBC gloves can easily remove it. There are no controls on the Sentry other than the power switch
Environmental Conditions: Not in temperatures above >30 ºC (86 ºF)—laser will shut down. Not in temperatures below <0 ºC (32 ºF)—laser will not turn on. Not above humidity of 95 % non condensing—effects not known.
Support Equipment: No special tools are required
Consumables: No consumables are required for detection. Each dry sample uses a single 5 cm (2 in) sample filter.
Consumable Costs: Not applicable, this product does not use assays. The system is provided with a bottle of PSL beads, a package of 100 dry sample filters and one HEPA filter. No other consumables are required for immediate use.
Maintenance: HEPA filter—3000 h to 5000 h of operation, depending on the environment
Concentrator cleaning—2000 h of operation or as required
Tech support line operated 0800 to 1700 MST, Monday through Friday
At present a loaner program does not exist. This is something that could be explored.
The system has been designed to be completely modular, and hence can easily accept new processing electronics as parts (processors) become obsolete and can accept new florescent detection technology as it becomes available
Shelf Life (Equipment): No parts of the equipment would suffer from extended storage
Shelf Life (Consumables): No parts of the equipment would suffer from extended storage
Maintenance Costs: Maintenance cost is nominal requiring only periodic HEPA filter replacement and concentrator cleaning, depending upon environment of operation
Decontamination: The Sentry 3000 has not been specifically designed to be decontaminated after a live agent attack. During normal operation, it pulls air into the sensor module and uses external air for cooling. Hence a live agent attack would contaminate the unit inside and out. The customer could perhaps attempt decontamination using a fog, such as formaldehyde; however, GD Canada has not tested this. The philosophy behind the Sentry 3000 design is that it is intended to detect to protect. In the event that there is an actual live agent attack, the economical benefits of early warning, containment of the threat and causality minimization/prevention and far out weight the cost of a Sentry 3000 system.

SPECIAL PARAMETERS

Skills Required: No special skills are required. The system is fully autonomous providing automatic detection, alarming and sampling of biological events. Handling of the biological sample is carried out in accordance with local laws and regulations for bio-hazardous materials. The system automatically provides an audible and visual alarm when a biological event is detected, therefore the operator need notanalyze raw data.
Training Required: Less than 8 h training required
Training Available: 4WARN Sentry 3000 Operator/Maintainer Training (classroom) which results in certification. The training is offsite or onsite. Manual training is also available.
Manuals Available: Operator/Maintainer Manual
Data Storage: All raw particle data collected by the Sentry is logged by the System Management Software (SMS) on the System Management Terminal (SMT). When SMS is launched, a log file is automatically opened. A replay application is provided on the System Management Terminal, which is used replay and display the log file data at a later time.
Communications: Command Control Communications—The SMS provides for remote control of the concentrator, sampler and communications mode (RF or Ethernet). It also allows the operator to enter manual GPS coordinates in the event the internal GPS is not capable of obtaining a satellite fix. All data is monitored by and alarm information is presented at the SMT.
Computer (Control)—See above.
Computer Interface—Ethernet (RJ45) and/or wireless serial modems (RS232).
Data Transfer Capability (Interface)—All data is stored on the SMT. Data can be pulled off the SMT using standard memory devices/media (floppy, CD, USB stick).
Intelligence Standardization—Question is unclear as to what standard are we comparing.
Interoperability—Product has demonstrated interoperability with different identification technologies and command and control systems.
Commonality—Common Ethernet and Serial interfaces.
Radio Frequency (RF) Communication—902 to 928 MHz, Frequency Hopping Spread Spectrum

Conventional Radio System—The Sentry outputs a data stream over Ethernet and Serial interfaces. This should be easily be interfaced to any radio that can transmit data.

Networking Capability—Several Sentry 3000 detectors can be networked (via Ethernet or wireless modem) can all be controlled and monitored from a single SMT. Note that a network hub is not provided with the Sentry 3000 system.

Hardwire Capability—Ethernet.

Installed data processing equipment—The Sentry uses a PC-104 based processing stack for interpretation of the raw data and communications to the external SMT.

Security: The Sentry 3000 can be physically locked shut (with a padlock) to prevent unauthorized users from opening the enclosure. The SMS software requires a password for users to launch the application. In addition, there are several key parameters that can be adjusted in the software including sensitivity setting (Low, Medium, High), Threshold limit, poll time, etc. These setting are accessed through a settings panel, which is also password, protected.

Safety Requirements: The user is not authorized to remove the internal chassis from the enclosure. If it is removed with power applied, there is a risk of electrical shock. When the Sentry is used as supplied, there is no access to internal components and no risk of electrical shock.

The unit utilizes a class 3b laser that is fully enclosed and not accessible by the user. The user is warned against tampering with the laser. Tampering with the laser could result in permanent eye damage. Tampering with the unit in any way voids the manufacturers warranty. The unit has been certified to Canadian, U.S and world safety standards Canadian Standards Association CSA (C, U.S.) and CB.

Applicable Regulations: The unit is currently undergoing FCC and Industry Canada certification and approval is expected within 2 wk to 4 wk. The equipment has also been certified to Canadian, U.S. and world safety standards. Handling of the sample collected by the Sentry 3000 for laboratory analysis shall be in accordance with local and/or federal regulations pertaining to handling of bio-hazardous materials

Warranty: GD Canada warrants that the items delivered will be free from defects in materials and workmanship under normal use, service and maintenance for 1 yr from date of delivery. Shipping and handling are not covered by the warranty. The expected operational lifetime of the light source is between 3000 h to 5000 h. The unit can be refurbished with a new laser and put into service again. The unit is expected to operate several years with periodic light source replacement.

GENERAL

KT1050 HazCat Tier 4 System

Haztech Systems, Inc.
PO Box 929
Mariposa, California 95338
Dawn L. Plunkett (Operations Manager)
800–543–5487 (Tel)
209–966–8089 (Fax)
sales@hazcat.com
Information Source: http://www.hazcat.com

Status: The vendor has responded—11/21/2006
Evaluated: Yes

Technology: Optical
Portability: Mobile Laboratory Detection Equipment

Unit Cost: $38.8K plus shipping and handling
Availability: 30 d from placement of order
Description: Microscopy—H.H.A's, portable phase microscopy, qualitative analysis, field reagent chemistry
Application: Field detection and screening of unknown substances
Current Users: U.S. Army; U.S. Air Force; U.S. Coast Guard; police departments; fire departments; hazmat teams across the nation; Cleveland Health Hospital, Cleveland Ohio; FBI; and CDC.

OPERATIONAL PARAMETERS

BAs Detected: Detects Anthrax, Brucellosis, Tularemia, Meliodidosis, Salmonellosis, Cholera, Plague, E. coli, Q fever, Epidemic Typhus, Chikungunya Hemorrhagic Fever, Ebola, Cryptosporidiosis, Botulism, Bot Tox, Clostridium perfringens, toxins, ricin, and SEB
Type of Sample: Solid, liquid, air, sludge, and surface wipes
Sample Preparation: Amino acid preparation, slide/slip cover, and microscope screening
SOP Sample Preparation: Results are ready as soon as the test is perfomed, using the step-by-step instructions. The unknown substance is placed into a pre-made reagent "Amino Acid" test and heated with low flame for 5 s. Unknown is then pipetted out, and a drop placed on a glass slide. A cover slip is then applied. This slide goes under the microscope for examination.
Start-up Time: 15 min
Calibration Requirements: Instrument requires one calibration at start up, whenever it is moved, and a separate calibration with every sample.
Response Time: 15 min to 30 min
Data Analysis Time: 5 min
Alarms: No alarm, but result is visually displayed
Sensitivity: All under physical observation:
Bacteria, whole cell in CFUs (colony forming units)/mL 0.01 m x 0.01 m microscopy
Virus, particles in PFUs (plaque forming units)/mL 0.01 m x 0.1 m microscopy
Toxins, micrograms of toxin/mL, 0.01 m x 0.01 m microscopy
Confidence Interval/Sensitivity: A microscopic analysis must include at least 2 levels of magnification to include a survey by quadriant. This allows you to revisit a quadrant with higher magnification that appears suspicious, including focus through and surface focus.
Specificity: Physical observation for screening
Confidence Interval/Specificity: Nonspecific, screening tool for prePCR and growth studies. Greater than 95 % physical observation for screening.

- **False Positives**: Not specified
- **False Negatives**: Not specified

Resistance to Interferents: Minimal
Testing Information: Science paper supplied upon request

PHYSICAL PARAMETERS

Size: 1 case is 36 cm x 48 cm x 61 cm (14 in x 19 in x 24 in); 1 case is 53 cm x 41 cm x 46 cm (21 in x 16 in x 18 in); 2 cases are 51 cm x 41 cm x 20 cm (20 in x 16 in x 8 in)

Working Space: Not specified
Weight: Combined weight 61 kg (135 lb)
Total Weight: Not specified
Power Requirements: One 9 V battery for radiation monitor (WMD Kit); 2 D cell batteries for microscope; internal batteries for CommandCat or 110 V

LOGISTIC PARAMETERS

Durability: All systems are encased in rugged Pelican cases
Ease of Use: Not specified
Environmental Conditions: Above 0 ºC (32 ºF). Operates in most environments.
Support Equipment: Not specified
Consumables: Disposable test tubes, pipettes, scoops, test strips, slides, and reagents
Consumable Costs: Not specified
Maintenance: There are procedures for testing reagents every few months in the the user's manual. Routine maintenance is suggested for microscope.
Shelf Life (Equipment): Reagents—90 % can be stored indefinetely and 10 % can be stored for 1 yr to 3 yr
Shelf Life (Consumables): Some reagents are dated and will require replacing; most all reagents in the kit have an indefinite shelf life. Some hardware will need to be replaced as it is used.
Maintenance Costs: Depends upon usage
Decontamination: Not specified

SPECIAL PARAMETERS

Skills Required: No special skills, but training required
Training Required: Yes
Training Available: #S1803—4 d HazCat WMD Workshop, $750 per student. Training results in certification.
Manuals Available: User manual and MSDS manual, flow charts, and field sheet packets
Data Storage: All data and images are stored in the Technical Reference Center Computer for future use and reports
Communications: Not applicable
Security: Equipment supplied in convenient lockable, durable Pelican cases
Safety Requirements: Not specified
Applicable Regulations: Not specified
Warranty: 1 yr parts and labor

GENERAL

Biological Alarm Monitor (MAB)

Proengin USA
405 NE 8th street
Fort Lauderdale, Florida 33304
Sid Sidelbotham
954–760–9990 (Tel)
954–760–9955 (Fax)
contactusa@proengin.com
sid@proenginusa.com
Information Source: http://www.proenginusa.com
http://www.@proengin.com

Status: The vendor has responded—11/29/2006
Evaluated: Yes

Technology: Hybrid
Portability: Mobile Laboratory Detection Equipment

Unit Cost: $121K
Availability: 6 mo for a detector, consumables are stocked
Description: Flame Spectrophotometry—The MAB is a biological alarm monitor especially adapted to the rigor of a military defense (fast start-up, reliability, environment resistance, continuous running for several days)
Application: Portable early warning system/alarm device for known and unknown biological hazards
Current Users: Diagnostic Labs—France-CEB/ Sweden FOI/ German
Military—French Army

OPERATIONAL PARAMETERS

BAs Detected: This is somewhat misleading. We cannot say we do not detect the other items on this list, only that they have not been tested. Due to the operational characteristics of the detector it is likely that all agents could be detected and possibly identified. For this to happen a sample of the agent must be introduced into the detector for reference.
Bacilus anthracis, E. coli O157:H7, and Ricin
Type of Sample: Air
Sample Preparation: Due to the operational characteristics of the detector no sample preparation is required
SOP Sample Preparation: The detector continuously draws in sample air to the burner for constant almost real-time detection
Start-up Time: Item requires the mast to be inserted and the laptop that is plugged in and turned on. 5 min start-up time.
Calibration Requirements: Calibration not required at start-up
Response Time: 10 s
Data Analysis Time: 1 min
Alarms: Auto alarm, visible alarm, and audible alarm
Sensitivity: Bacteria—0.001 CFU/mL
Confidence Interval/Sensitivity: All bacteria—greater than 95 %—0.001 units
Specificity: All bacteria—greater than 80 %
Confidence Interval/Specificity: All bacteria—greater than 80 %

- **False Positives**: Not applicable
- **False Negatives**: Not applicable

Resistance to Interferents: Differentiates between viable and nonviable organisms; detects spores
Testing Information: Unclassified test reports are available

PHYSICAL PARAMETERS

Size: 30 cm x 16 cm x 80 cm (11.8 in x 6.3 in x 31.5 in)
Working Space: 2 m^2 (2.4 yd^2)
Weight: 7.3 kg (16 lb)
Total Weight: 1.8 kg (4 lb)
Power Requirements: 19 V dc to 32 V dc

LOGISTIC PARAMETERS

Durability: Able to be transported quickly without protective packaging, can be dropped from counter height without effect, can to be left in hot or cold environment without effect. Must remain stationary to use.
Ease of Use: Once turned on unit requires no further interaction unless the operator wishes to gather more indepth data from the monitoring program. If this is required operation of a keyboard is nessesary. There are no step to complete after turn on to view results/alarms.
Environmental Conditions: Operating temperature: -20 ºC to 50 ºC (-4 °F to 122 °F); storage temperature: -39 ºC to 55 ºC (-38.2 °F to 131 °F); not above 95 % rh
Support Equipment: None
Consumables: Unit runs continuously so per test requirements are not applicable. Unit requires 24 L of hydrogen per day either from a 10 d pressurized bottle or from standard Proengin hydrogen storage devices. An electrolyzer to produce hydrogen from water is in development.
Consumable Costs: 10 d bottle refill $100, hydrogen storage devices are $26 each but $20 to refill. Electolyzer will use deminralized water $1 per gal.
Unique consumables cost—$120
Maintenance: Routine maintenance cost—$2.6K per mo
24 h technical support is provided by the manufacturer or authorized agency. No loaner available but can be discussed depending on contract. System is upgradeable—new signatures can be added from other detectors. For example, should a MAB detector experience a new agent that it alarmed for as an unknown, a sample can be taken and analyzed and, if found to be dangerous, this signature (captured when the MAB alarmed) can be sent to every other MAB. Future alarms of this agent would now be identified alarms. A total of 135 signatures can be stored and identified.
Shelf Life (Equipment): 10 yr
Shelf Life (Consumables): 10 yr
Maintenance Costs: $3.8K. Contract as available on a case.-by-case basis and depend customer specifications.
Decontamination: Only the outside of the unit and the mast will be contaminated. The outside of the unit can be wiped with decon solution. The mast can be removed and immersed in solution.

SPECIAL PARAMETERS

Skills Required: Operator does not need to analyze raw data before a final result can be determined. High school diploma is sufficient education.
Training Required: Less than 8 h formal training required
Training Available: Offsite (at manufacturer site) and onsite (where equipment will be used or stored). Training does not result in certification.
Manuals Available: Operator guide, technical notes, and maintenance guide
Data Storage: Yes, with use of connected laptop
Communications: Computer (control), computer interface with RS485 MODBUS, data transfer capability (interface), and networking capability with RS485
Security: Password protected entry to software
Safety Requirements: None
Applicable Regulations: Requires the signature of a French Nontransfer certificate. Global patents apply to the technology use.
Warranty: 1 yr

GENERAL

RespondeR RCI (Model 024–1001)

Smiths Detection Danbury
21 Commerce Drive
Danbury, Connecticut 06810
203–207–9700 (Tel)
888–473–6747
203–207–9780 (Fax)
Bob Bohn
bob.bohn@smithsdetection.com
Information Source: http://www.hazmatid.com/

Status: The vendor has responded—1/12/2007
Evaluated: Yes

Technology: Screening
Portability: Mobile Laboratory Detection Equipment

Unit Cost: Not specified
Availability: 60 d
Description: Raman—RespondeR RCI is a highly specific tool that measures how much a laser beam is scattered by a chemical sample. Each chemical has its own unique Raman fingerprint, which when automatically analyzed by the onboard computer results in an identification in less than 20 s.
Application: The RespondeR RCI™ is intended to provide initial determinations and be used as an information resource in the field, and not absolute or conclusive identifications of unknown substances. The results provided by the RespondeR RCI should be verified by using other appropriate techniques. Smiths Deetction makes no recommendations nor does it assume any liability for how the information is utilized. The system can easily be carried on-scene making it an ideal tool for First Responders in an emergency situation. Smith Detection's RespondeR RCI (Raman Chemical Identifier) is the ideal complement for verifying the identity of an unknown solid or liquid when used in conjunction with the HazMatID.
Current Users: First responders. CST-WMD mobile labs can support first responders by rapidly discriminating biological from nonbiological microscopic particles as well as identifying the chemistry of the nonbiological particles.

OPERATIONAL PARAMETERS

BAs Detected: RespondeR RCI instantly compares the Raman fingerprint against an onboard database to provide the identity of the unknown. Database libraries include the following:

- WMD—nerve and blister agents
- Toxic industrial chemicals
- Forensic drugs
- White powders
- Explosives
- WMD precursors
- Common chemicals

Type of Sample: Solids and liquids
Sample Preparation: Users decide whether to analyze using the integrated sample compartment or by the optional point-and-shoot capabilities. Either way the results will be reliable, accurate and provided in <30 s.
SOP Sample Preparation: Not specified
Start-up Time: The system is operational in <2 min
Calibration Requirements: User calibration is not required
Response Time: Results in an identification in <20 s
Data Analysis Time: 30 s
Alarms: Not specified
Sensitivity: Not specified
Confidence Interval/Sensitivity: Not applicable
Specificity: 2 % to 5 % by weight of the sample
Confidence Interval/Specificity: Not applicable

- **False Positives**: Not applicable
- **False Negatives**: Not applicable

Resistance to Interferents: Not applicable
Testing Information: Not applicable

PHYSICAL PARAMETERS

Size: 22.2 cm x 19 cm 10 cm (8.75 in x 7.5 in x 4 in)
Working Space: Not specified
Weight: 2.7 kg (6 lb)
Total Weight: Not available
Power Requirements: Internal battery or mains. Battery runs for 5 h. Charge time is 5 h.

LOGISTIC PARAMETERS

Durability: Indoor and outdoor capability. The system is waterproof to allow it to pass through the decon line.
Ease of Use: RespondeR RCI was designed to be used in Level A gear
Environmental Conditions: Operational in extreme weather and temperatures ranging from -10 ºC to 50 ºC (14 °F to 122 °F). Humidity ranging from 0 % to 100 %. Operational in the hot zone and subfreezing temperatures.
Support Equipment: Not specified
Consumables: Not specified
Consumable Costs: Not specified
Maintenance: Smiths Detection has instituted a 24 h, 7 d/wk reachback capability. This will provide assistance in the identification of compounds as well as support on system operation and troubleshooting by Smith Detection spectroscopists, chemists, electrical engineers, and software engineers.
Shelf Life (Equipment): Not specified
Shelf Life (Consumables): Not specified
Maintenance Costs: Not specified
Decontamination: The system is waterproof to allow it to pass through the decon line. The system can be exposed to decontamination solution either by spraying the unit or dunking it with the cover open.

SPECIAL PARAMETERS

Skills Required: A complete identification of an unknown simply requires the user to advance each screen as it is presented
Training Required: Not specified
Training Available: Standard 1 d training course in Danbury, Connecticut or optional on-site training. Optional off-site training is available. Training results in certification
Manuals Available: User manuals and CD
Data Storage: Data is stored on a removable CompactFlash card. Data can be transferred directly from the card using an included reader, through a included USB connection or with an included flash memory device.
Communications: User interface. The RespondeR RCI software is a streamlined, touchscreen application specifically designed to be easy to use but very powerful in its capability. A complete identification of an unknown simply requires the user to advance each screen as it is presented. Network enabled.
Security: Not specified
Safety Requirements: None
Applicable Regulations: None
Warranty: The people at Smiths Detection pride themselves on being able to respond to all inquiries as quickly, and completely as possible. The support section has developeded a database of information that is literally "right at your fingertips." In the FAQ subhead we have listed the most frequently asked questions about our products and how they work. If your question is more complex check out “Tech Support” where you can find email and telephone support lines, as well as a downloadable version of our latest user manual. It is our intention to provide our customers with the most complete support possible, if you have any comments or suggestions on how we might better serve you, please do not hesitate to email our help desk.

GENERAL

BioThreat Alert™ ELISA Kits

Tetracore, Inc.
9901 Belward Campus Drive
Suite 300
Rockville, Maryland 20850
240–268–5400 (Tel)
240–268–1107 (Fax)
Customer support: service@alexeter.com
General Information: Info@alexeter.com
Sales@alexeter.com
Information Source: http://www.tetracore.com
http://www.alexeter.com
Status: The vendor has responded—1/12/2007
Evaluated: Yes

Technology: Immunochemical
Portability: Mobile Laboratory Detection Equipment (if advanced)

Unit Cost: $450—1 to 5 ELISA Kits; $400—6 to 10 ELISA Kits
Availability: Tetracore's BioThreat Alert™ ELISA Kits are available directly from Tetracore and are in stock, guaranteed to ship within 15 business days
Description: Capture ELISA—The BioThreat Alert ELISA Kit is a prepackaged capture ELISA. The kit itself comes with a positive capture antibody, a negative capture antibody (if positive/negative format is purchased), a detector antibody, a conjugate, substrate, and protein blocking buffer, as well as one or two 96-well ELISA plates. The capture antibodies (target specific) are placed in the wells first, followed by the sample and detector antibodies (target specific), creating a very sensitive and very specific antibody "sandwich" that helps to eliminate false results. When the target substance is present in the well, the conjugate and the substrate produce a blue-colored product. This color change indicates a positive result and can be detected by any ELISA plate reader, as well as the naked eye.
Application: The BioThreat Alert ELISA Kits were designed to detect biological agents in solution. While they are able to be used in the field by advanced teams, they are used more often in a laboratory setting. These kits were not intended for use on clinical samples. The BioThreat Alert ELISA Kits have better sensitivity than the BioThreat Alert Test Strips, and the ELISA format is friendly to samples from complex matrices such as food, surface swipes, unknown powders, air collected samples, air filters, etc. The optional "Positive/Negative" capture format helps to reduce matrix effects. The kits are available in either pre-coated with capture antibody format or non-coated format to allow for user flexibility.
Current Users: The BioThreat Alert ELISA Kits are currently being used by universities, commercial and private laboratories, law enforcement, military, federal, state, and local governments, and corporate security professionals, both domestic and international. The BioThreat Alert ELISA Kits are often utilized by USDA and FDA laboratories.

OPERATIONAL PARAMETERS

BAs Detected: The system tests for multiple biowarfare agents including, but not limited to, anthrax, SEB, plague, tularemia, ricin, botulism toxin, brucella, abrin, and pox
Type of Sample: The BioThreat Alert ELISA kits are capable of testing for all types of samples including powders, liquids, and solids, foods, air filter samples etc. Aerosols can be tested using additional equipment.
Sample Preparation: The sample preparation requires mixing the substance to be tested with a buffer solution. All steps follow the typical capture ELISA format.
SOP Sample Preparation: Detailed SOPs are provided by Tetracore
Start-up Time: Not applicable
Calibration Requirements: The BioThreat Alert™ test strips are factory-calibrated to ensure accuracy
Response Time: Depends on ELISA format used
Data Analysis Time: Results can be read in 7 h to 48 h depending on ELISA format used
Alarms: When the target substance is present at or above the detectable amount in the test sample the well in which it has been placed will turn a dark blue, indicating a positive result
Sensitivity: Anthrax (Bacillus anthracis)— 10^4 CFUs/mL
Plague (Yersinia pestis)— 10^4 CFUs/mL
Tularemia (F. tularensis)— 3 x 10^4 CFUs/mL
Ricin (Communis Agglutinin II)—350 pg/mL
Bot tox (Botulimun Toxin)—1.5 ng/mL

SEB (Staphylococcal Enterotoxin B)—350 pg/mL
Brucella—1.5 ng/mL
Orthopox—60 ng/mL
Abrin—20 ng/mL

Confidence Interval/Sensitivity: Not applicable

Specificity: The BioThreat Alert ELISA kit is extremely specific due to the capture nature of the assay as well as the fact that the detector antibody is monoclonal and will only attach to the target antibody

Confidence Interval/Specificity: Not applicable

- **False Positives**: As with any ELISA format false positives or "hot wells" are possible, but the BioThreat Alert ELISA Kit's positve/negative format helps to eliminate such possibilities
- **False Negatives**: As with any ELISA format false positives or "hot wells" are possible, but the BioThreat Alert ELISA Kit's positve/negative format helps to eliminate such possibilities

Resistance to Interferents: All BioThreat Alert ELISA Kits show minimal interference due to the capture nature of the assay, as well as the specificity of the antibodies used

Testing Information: Depending on the assay, independent test results are available from the company by calling 240–268–5400, X5401

PHYSICAL PARAMETERS

Size: Each kit ~18 cm x 13 cm (7 in x 5 in)

Working Space: The BioThreat Alert ELISA Kits can be operated in both field and lab settings where minimal space is required

Weight: Tetracore's BioThreat Alert ELISA Kit (1 kit) is approx. 285 g (10 oz)

Total Weight: Tetracore's BioThreat Alert ELISA Kit (1 kit) is approx. 285 g (10 oz)

Power Requirements: No power requirements

LOGISTIC PARAMETERS

Durability: Not applicable

Ease of Use: The BioThreat Alert ELISA Kits can be operated with approximately 1 d of training

Environmental Conditions: Operating range: 4 ºC to 41 ºC (40 ºF to 105 ºF)

Support Equipment: Not applicable

Consumables: The entire BioThreat Alert ELISA Kits is consumable as it is meant for a one time use

Consumable Costs: All consumables needed are provided in the kit except for phosphate buffered saline solution (PBS), and any transfer materials (pippettes/tubes) that are required by the user

Maintenance: No maintenance is required other than replacing the BioThreat Alert ELISA Kits upon expiration

Shelf Life (Equipment): • The BioThreat Alert ELISA Kits must be stored at 4 ºC (40 ºF)
• The kits must be protected from repeated freeze-thaw cycles

Shelf Life (Consumables): Stored at 4 ºC (40 ºF). Unopened BioThreat Alert ELISA Kits have a shelf life of 6 mo from manufacture.

Maintenance Costs: Upon expiration, kits can be purchased through Tetracore at $450 per kit

Decontamination: Not applicable

SPECIAL PARAMETERS

Skills Required: The BioThreat Alert ELISA Kits should only be operated by trained professionals with a working knowledge of hazardous materials as well as basic ELISA training

Training Required: Approximately 1 d by someone experienced in ELISAs

Training Available: A complete SOP is available from Tetracore upon request. Also please feel free to call with questions.

Manuals Available: A complete SOP is available from Tetracore upon request

Data Storage: Not applicable

Communications: Not applicable

Security: Not applicable

Safety Requirements: Not applicable

Applicable Regulations: Not applicable

Warranty: Not applicable

APPENDIX G—BIOLOGICAL DETECTOR DATA SHEETS (LIMITED INFORMATION)

APPENDIX G—BIOLOGICAL DETECTOR DATA SHEETS (LIMITED INFORMATION)

ID#	Name	Manufacturer	Technology	Mobility	Page G–#
1	OraQuick	Abbott Diagnostics	Immunochemical/ Colorimetric ELISA	Handheld	G–1
2	Murex SUDS	Abbott Diagnostics	Immunochemical/ Colorimetric ELISA	Handheld	G–2
3	Signify DOA	Abbott Diagnostics	Immunochemical/ Lateral Flow Immuno chromatography	Handheld	G–3
4	Assurance® EHEC EIA	BioControl Systems, Inc.	Immunochemical/ Colorimetric ELISA	Handheld	G–4
5	HHAs	DARPA	Immunochemical/ Lateral Flow Immuno chromatography	Handheld	G–5
6	Handheld Advanced Nucleic Acid Analyzer (HANAA)	LLNL	Molecular/Real Time PCR	Handheld	G–6
7	PROFILE-II	Medtox Diagnostics, Inc.	Immunochemical/ Lateral Flow Immuno chromatography	Handheld	G–7
8	Bead Array Counter (BARC)	Naval Research Laboratory	Immunochemical/ Magnetic bead based	Handheld	G–8
9	RIDASCREEN® ELISA Test Kit	R-Biopharm AG	Immunochemical/ Colorimetric ELISA	Handheld	G–9
10	Staphylococcal Enterotoxin (SET) Visual Immunoassay (VIA™)	TECRA International Pty Ltd	Immunochemical/ Colorimetric ELISA	Handheld	G–10
11	Mini VIDAS	Biomeriux	Immunochemical/ Colorimetric ELISA	Mobile Laboratory	G–11
12	CombiMatrix Biothreat Detection System	CombiMatrix	Molecular/Array-based	Mobile Laboratory	G–12

ID#	Name	Manufacturer	Technology	Mobility	Page G–#
13	Luminex 100 Analyzer System	Luminex Corporation	Immunochemical/ Multianalyte bioassay	Mobile Laboratory	G–13
14	NanoSphere's Chip Assay	Nanosphere	Molecular/DNA Microarray	Mobile Laboratory	G–14
15	Chemical-Biological Mass Spectrometer (CB-MS)	Oak Ridge National Laboratory	Hybrid/MS	Mobile Laboratory	G–15
16	Single-Particle Fluorescent Counter (SPFC)	Office of Naval Research	Optical/ Fluorescence	Mobile Laboratory	G–16
17	Richardson Technologies RTM-3	Richardson Technologies, Inc.	Optical/ Microscopy	Mobile Laboratory	G–17
18	Bio-Detector (BD)	Smith Detections	Ligand/Immuno-ligand Assay	Mobile Laboratory	G–18
19	Transport Kit Portable FT-IR	Thermo Electron Corporation	Screening	Mobile Laboratory	G–19
20	Biological Integrated Detection System (X-BIDS)	U.S. Army Soldier and Biological Chemical Command (APG)	Hybrid	Mobile Laboratory	G–20
21	VIDAS	Biomeriux	Immunochemical/ Colorimetric ELISA	Mobile Laboratory	G–21
22	Swift—FM31-LWD Field Microscope	Swift Microscopy	Optical/ Microscopy	Mobile Laboratory	G–22
23	Affymetrix GeneChip System	AFFYMETRIX, Inc.	Molecular/DNA Microarray	Fixed-Site	G–23
24	Ambri ICS™ Biosensor	AMBRI	Biosensor Based	Fixed-Site	G–24
25	API TOF Mass Spectrometer	Analytica of Branford	Hybrid/MS	Fixed-Site	G–25
26	ABI Prism® 7900HT Sequence Detection System	Applied Biosystems	Molecular/Real Time PCR	Fixed-Site	G–26
27	ABI Prism® 7000 Sequence Detection System	Applied Biosystems	Molecular/PCR—DNA Microarray (RT)	Fixed-Site	G–27
28	ABI 9700 Thermal Cyclers	Applied Biosystems	Molecular/ Standard PCR	Fixed-Site	G–28
29	Bayer Quantiplex System 340 (Automated bDNA assay)	Bayer Diagnostics	Molecular/ Branched DNA (bDNA)	Fixed-Site	G–29

ID#	Name	Manufacturer	Technology	Mobility	Page G–#
30	Label- Free Exponential Signal-Amplification System (LEXSAS) Technology	BCR Corporation	Molecular/ Branched DNA (bDNA)	Fixed-Site	G–30
31	Biocore 2000	Biacore	Ligand/Surface Plasmon Resonance (SPR)	Fixed-Site	G–31
32	Biocore 3000	Biacore	Ligand/Surface Plasmon Resonance (SPR)	Fixed-Site	G–32
33	NucliSens EasyQ System	Biomeriux	Molecular/Real Time PCR	Fixed-Site	G–33
34	iCycler iQ™	Bio-Rad Laboratories	Molecular/Real Time PCR	Fixed-Site	G–34
35	iCycler™ Thermal Cycler	Bio-Rad Laboratories	Molecular/ Standard PCR	Fixed-Site	G–35
36	Particle Size and Shape with Fluorescence (FL-ASAS)	Biral	Optical/ Fluorescence	Fixed-Site	G–36
37	MiniTOF Linear TOF Mass Spectrometer	Comstock	Hybrid/MS	Fixed-Site	G–37
38	Roto-Gene Real Time DNA Amplification System Roto-Gene 3000 4 Channel Multiplexing System	Corbett Research	Molecular/Real-Time PCR	Fixed-Site	G–38
39	BAX System	Dupont Qualicon	Molecular/ Standard PCR	Fixed-Site	G–39
40	GeneTAC Biochip System	Genomic Solutions	Molecular/Protein Array	Fixed-Site	G–40
41	Matrix-Assisted Laser Desorption Ionization-TOF Mass spectrometer (MALDI-TOF-MS)	Kratos Analytical Inc.	Hybrid/MS	Fixed-Site	G–41
42	Bio Smoke Detector	LLNL	Physical/Flow cytometry and PCR	Fixed-Site	G–42
43	MJ Research—The BaseStation®	MJ Research, Inc.	Molecular/ Sequencers and Genotypers	Fixed-Site	G–43
44	DNA Engine Opticon™ Continuous Fluorescence Detection System	MJ Research, Inc.	Molecular/Q-PCR	Fixed-Site	G–44

ID#	Name	Manufacturer	Technology	Mobility	Page G–#
45	MiniCycler Peltier Thermal Cycler	MJ Research, Inc.	Molecular/ Standard PCR	Fixed-Site	G–45
46	Peltier Thermal Cyclers PTC-100 Thermal Cycler	MJ Research, Inc.	Molecular/ Standard PCR	Fixed-Site	G–46
47	DNA Engine® Peltier Thermal Cycler (PTC-200)	MJ Research, Inc.	Molecular/ Standard PCR	Fixed-Site	G–47
48	DNA Engine Dyad Thermal Cycler and DNA Engine Tetrad Cycler	MJ Research, Inc.	Molecular/ S tandard PCR	Fixed-Site	G–48
49	On-Chip Amplification	Nanogen	Molecular/Strand Displacement Amplification (SDA)	Fixed-Site	G–49
50	NanoChip® Molecular Biology Workstation	Nanogen	Molecular/ Microarray-Workstation	Fixed-Site	G–50
51	Isothermal Sequencing and Cycling Primer	Nugen Technologies Inc.	Microarray/DNA Microarray SPIA™ Technology	Fixed-Site	G–51
52	minFlow Cytometer	Office of Naval Research	Physical/Flow Cytometry	Fixed-Site	G–52
53	HiLight Array Detection System	Qiagen	Molecular/Array-based	Fixed-Site	G–53
54	Mx4000® Multiplex Quantitative PCR System	Stratagene Inc.	Molecular/Q-PCR	Fixed-Site	G–54
55	Aerosol TOF Mass Spectrometer (ATOFMS)	TSI Incorporated	Hybrid/MS	Fixed-Site	G–56
56	Ultra Violet Aerodynamic Particle Sizer (UVAPS)	TSI Incorporated	Hybrid/MS	Fixed-Site	G–57
57	(J-Series Modulator) Non-Dispersive InfRed (NDIR)	OPTRA, Inc.	Hybrid/NDIR/ Screening	Standoff/ Remote	G–58
58	Joint Biological Point Detection System (JBPDS)	General Dynamics Armament and Technical Products Developed for U.S. Army SBCCOM	Optical/ Fluorescence	Standoff/ Remote	G–59
59	4WARN CB Systems V.2: Real Time BA Detection	General Dynamics	Optical/ Fluorescence	Standoff/ Remote	G–60

ID#	Name	Manufacturer	Technology	Mobility	Page G–#
60	4WARN CB Systems V.3: Real Time BA Detection	General Dynamics	Optical/ Fluorescence	Standoff/ Remote	G–61
61	Biological Aersol Warning (BAWS)	Lockheed Martin	Optical/ Fluorescence	Standoff/ Remote	G–62
62	Fluorescence Aerodynamic Particle Sizer (FL/APS II)	TSI Incorporated	Optical/ Fluorescence	Standoff/ Remote	G–63
63	The BioHAZ™ Kit	EAI Corporation	Immunochemical/ Sampling, Screening, Analysis	Handheld	G–64

GENERAL

OraQuick

Abbott Diagnostics
Public Affairs
Don Braakman
847–937–1237
847–937–3774 (Fax)
don.braakman@abbott.com
www.abbottdiagnostics.com

Vendor Response: No
Evaluated: No

Technology: Immunochemical/Colorimetric ELISA

Availability: Not specified
Portability: Handheld Detection Equipment
Detection Category: Colorimetric ELISA—Lateral Flow
Application: Kit list numbers:
4J77-25—OraQuick Rapid HIV-1 Antibody Test (25 test kit)
4J77-20—OraQuick Rapid HIV-1 Antibody Test (100 test kit)
4J77-10—OraQuick Rapid HIV-1 Antibody Test Kit Controls
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

Murex SUDS

Abbott Diagnostics
Public Affairs
Don Braakman
847–937–1237
847–937–3774 (Fax)
don.braakman@abbott.com
www.abbottdiagnostics.com

Vendor Response: No
Evaluated: No

Technology: Immunochemical/Colorimetric ELISA

Availability: Not specified
Portability: Handheld Detection Equipment
Detection Category: SUDS, Single Use Diagnostic System, is the only FDA licensed rapid HIV-1 assay sold in the U.S.
Application: OSHA Bloodborne Pathogens guidelines and CDC recommendations in MMWR state that any employer having employees with occupational exposure should have a written exposure Control Plan, and recommends that source blood should be tested as soon as feasible after exposure occurs. This is due to research which shows that Post Exposure Prophylaxis (PEP) initiated promptly is most effective when dealing with HIV.
In addition to accidental exposure cases, SUDS is also used in the ER, OB wards and routine screenings. It is a moderate complex assay and has been in use in the U.S. for almost 10 yr. This easy to use ELISA assay comes packaged in both 30 and 90 test kits and is used in over 2 000 facilities in the U.S.
Current Users: Not specified
BAs Detected: HIV-1

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

Signify DOA

Abbott Diagnostics
Public Affairs
Don Braakman
847–937–1237
847–937–3774 (Fax)
don.braakman@abbott.com
www.abbottdiagnostics.com

Vendor Response: No
Evaluated: No

Technology: Immunochemical/Lateral Flow Immunochromatography

Availability: Not specified
Portability: Handheld Detection Equipment
Detection Category: Signify Strep A Cassette—a lateral flow, one step immunoassay
Application: For the rapid, qualitative detection of Group A Streptococcal antigen directly from throat swabs and is intended for use as an aid in the diagnosis of Group A Streptococcal infection.
Current Users: Not specified
BAs Detected: Qualitative detection of Group A Streptococcal antigen

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

Assurance® EHEC EIA

BioControl Systems, Inc.
Worldwide Headquarters
12822 SE 32nd Street Bellevue, Washington 98005
425–603–1123 (Tel)
425–603–0070 (Fax)
800–245–0113 (Tel)
Toll-free: 800.245.0113
POC: Marotta Lp
425–603–1123 (Tel) ext. 105
425–603–0070 (Fax)
info@biocontrolsys.com
mko@biocontrolsys.com
http://www.biocontrolsys.com/products/assehec.html

Vendor Response: No
Evaluated: No

Technology: Immunochemical/Colorimetric ELISA

Availability: Not specified
Portability: Handheld Detection Equipment
Detection Category: Enzyme immunoassay (EIA)
Application: Format: Microplate with "breakapart" wells, run any number of tests at the same time with no wasted wells. Automation ready. Validation: AOAC Official Method 996.10. Highly sensitive and specific. Complex, proprietary antibody formulations overcome the challenges of differential bacterial detection. Many innovative features. Break-apart wells eliminate waste, ready-to-use liquid reagents, automation ready.
Current Users: Not specified
BAs Detected: Detects E. coli O157:H7 in food and environmental sample

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

HHAs

DARPA
3701 North Fairfax Drive
Arlington, Virginia 22203–1714
USA
General Information:
703–526–6630 (Tel)
DARPA Locator:
703–526–6624 (Tel)
Defense Science Office:
703–696–2282 (Tel)
Defense Advanced Research Program Agency (DARPA)
http://www.darpa.mil

Vendor Response: No
Evaluated: No

Technology: Immunochemical/Lateral Flow Immunochromatography
Availability: Not specified
Portability: Handheld Detection Equipment
Detection Category: HHA is designed to be used only on nonporous surface (i.e., metal, plastic, and glass).
The best results can be achieved when samples are taken from an area where the concentrations are believed to be the highest.
Cross reactivity occurs with the bacillus anthracis HHA in which the antibodies bind not only Bacillus anthracis but also other bacillus such as Bacillus thuringinsis.
** HHA's are not designed to be the sole method of identification and are not for diagnostic use.
Application: Not specified
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

Handheld Advanced Nucleic Acid Analyzer (HANAA)

LLNL
University of California
LLNL
7000 East Ave.
Livermore, California 94550–9234
P.O. Box 808
Livermore, California 94551–0808
925–422–1100 (Tel)
925–422–1370 (Fax)
925–422–2529 (Fax verification)
http://www.llnl.gov/

Vendor Response: No
Evaluated: No

Technology: Molecular/Real Time PCR

Availability: Military and commercial
Portability: Handheld Detection Equipment
Detection Category: Real Time PCR—DNA Rapid Assay Development for BW Agent Detection and Surveillance (02-ERD-045). PCR, which amplifies agent-specific DNA fragments to a detectable level. A synthesized DNA probe tagged with a fluorescent dye is introduced into the sample to amplify the DNA.
Application: HANAA, emergency responders can get answers on the scene in less than half an hour.
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

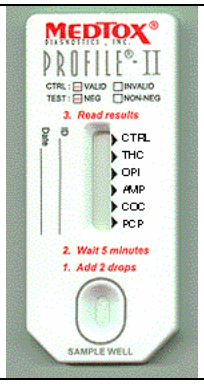
Size: Processing block: 30.5 cm x 30.5 cm x 25 cm (12 in x 12 in x 10 in)
Travel case: 61 cm x 51 cm x 65 cm (24 in x 20 in x 25.5 in)
Weight: < 1 kg (2.2 lb)
Power Requirements: 100 V ac to 240 V ac, 50 Hz to 60 Hz, 350 W

GENERAL

PROFILE-II

Medtox Diagnostics, Inc.
1238 Anthony Road
Burlington, North Carolina 27215
336–226–6311 (Tel), ext 273
336–229–4471 (Fax)
mturanchik@medtox.com
www.medtox.com

Vendor Response: No
Evaluated: No



Technology: Immunochemical/Lateral Flow Immunochromatography

Availability: Not specified
Portability: Handheld Detection Equipment
Detection Category: Lateral Flow Immunochromatography
Application: PROFILE®-II is a one-step, single strip immunochromatographic test for the rapid, qualitative detection of cannabinoids (THC), cocaine, opiates, amphetamines, and phencyclidine (PCP) in human urine.
Current Users: First responder community
BAs Detected: THC (marijuana)—50 ng/mL
COC (cocaine)—300 ng/mL
OPI (opiates)—300 ng/mL or 2000 ng/mL
AMP (amphetamine)—1000 ng/mL
PCP (phencyclidine)—25 ng/mL

PHYSICAL PARAMETERS

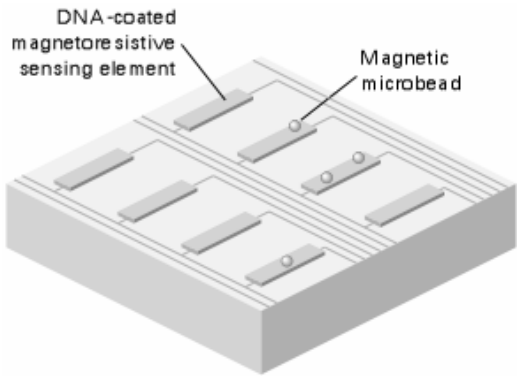
Size: Not specified
Weight: Not specified

GENERAL

Bead Array Counter (BARC)

Naval Research Laboratory
4555 Overlook Avenue, SW
Washington , DC 20375–5320
POC: Lloyd J. Whitman
Chemistry Division
202–404–8845 (Tel)
E-mail: lloyed.whitman@nrl.navy.mil
Naval Research Laboratories (with Defense Advanced Research Projects Agency (DARPA))

Vendor Response: No
Evaluated: No



Technology: Immunochemical/Magnetic bead based

Availability: Commercial
Portability: Handheld Detection Equipment
Detection Category: Magnetic bead DNA sequence
Magnetic bead counter
The pathogens will be identified by their known DNA sequence. Each pathogen will be detected using two independent pairs of DNA probes.
Application: Not specified
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

RIDASCREEN® ELISA Test Kit

R-Biopharm AG
Landwehrstrasse 54
D-64293 Darmstadt
U.S. Distributor
POC: Mr. Kurt Johnson
7950 Old US 27 South
Marshall, Michigan 49068
269–789–3033 (Tel)
269–789–3070 (Fax)
info@r-biopharm.com
http://www.r-biopharm.com/index.html
http://www.r-biopharm.com

Vendor Response: No
Evaluated: No

Technology: Immunochemical/Colorimetric ELISA

Availability: Not specified
Portability: Handheld Detection Equipment
Detection Category: The RIDASCREEN® Chloramphenicol test is an ELISA (enzyme linked immunosorbent assay), that allows detection of Chloramphenicol on a parts per trillion (ppt) level.
The quantitative evaluation of Allergy Screen is carried out using an instrument including CCD camera and the RIDA X Screen. The reaction trough with the panel strip will be inserted into the retainer of the RIDA X Screen, followed by the measurement using a reader.
Application: Not specified
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

Staphylococcal Enterotoxin (SET) Visual Immunoassay (VIA™)

TECRA International Pty Ltd
13 Rodborough Road
Frenchs Forest NSW 2086 Australia UK
POC: Nick Vale
+61 2 8977011 (Tel)
+61 2 9453 3422 (Fax)
nick.vale@tecra.net
http://www.tecra.net

Vendor Response: No
Evaluated: No

Technology: Immunochemical/Colorimetric ELISA

Availability: Assays available soon:
• Staphylococcal Enterotoxin.
• Campylobacter.
• E. coli 0157.
Portability: Handheld Detection Equipment
Detection Category: Visual immunoassay
Application: Rapid, convenient and specific identification test—Assays available soon include: Staphylococcal enterotoxin, campylobacter, and E. coli 0157.
Current Users: Not specified
BAs Detected: Specifically identify Staphylococcal enterotoxins in 4 h. Screen food and environmental samples for the presence of Enterotoxin-producing Staphylococcus spp. in as little as 22 h.

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

Mini VIDAS

Biomeriux
100 Rodolphe Street
Durham, North Carolina 27712
919–620–2000 (Tel)
800–682–2666 (Tel)
800–968–9494 (Fax)
http://www.biomerieux-usa.com

Vendor Response: No
Evaluated: No

Technology: Immunochemical/Colorimetric ELISA

Availability: Commercial
Portability: Mobile Laboratory Detection Equipment
Detection Category: ELFA technology (Enzyme Linked Fluorescent Assay)—The VIDAS and mini VIDAS are called "multiparametric" instruments. The term "multiparametric" is used to describe the functionality of the VIDAS and mini VIDAS instruments. The user is able to run compatible tests with the same protocols in the same section. For example: Salmonella, Listeria, and E. coli 0157 may be run in the same section at the same time. Tests with different protocols may also be run at the same time, but in different sections in the instrument. The mini VIDAS is a compact version of the VIDAS system with a built-in computer, keyboard, and printer. Two independent sections each accept six tests and can process up to 12 samples simultaneously. This automated immunoassay system is reliable and economical. It uses Enzyme Linked Fluorescent Assay (ELFA) technology, has no carryover risks, requires a one-point recalibration every 14 d and optimizes the cost per batch of single-sample testing. In addition, the menu of available assays is constantly growing. The mini VIDAS is a multiparametric analyzer. It allows the laboratory to run more than one compatible assay in a section at a time, and each section operates independently. The system is simple and rapid. Maintenance is minimal and most results are available in 40 min to 80 min. Teagents are ready to use in a single-dose format.
Application: The compact automated immunoassay analyzer: reliable and economical; no carryover; one-point recalibration every 14 d; optimized cost per result; multiparametric and compact; two compartments, each holding 6 tests; compatible assays may be run together in one section; each section functions independently from the other; constantly growing menu of assays; integrated computer, screen, keyboard, and printer; simple and rapid; minimal maintenance; ready-to-use, single-dose reagents (reagent strip and SPR); and results of most assays available in 30 min.
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

CombiMatrix Biothreat Detection System

CombiMatrix
6500 Harbour Heights Parkway
Suite #301 Mukilteo, Washington 98275
426–493–2000 (Tel)
426–493–2010 (Fax)
http://www.combimatrix.com/index.htm

Vendor Response: No
Evaluated: No

Technology: Molecular/Array-based

Availability: Military and commercial
Portability: Mobile Laboratory Detection Equipment
Detection Category: Amplification—Array-based
Application: Amplification—the technology is based on a lab-on-a-chip synthesis technology, array-based immunochemical assays and real time electronic signal detection technology
Current Users: Not specified
BAs Detected: Anti-botulinum toxin (A/B) (military use only) and Dengue virus 1, 2 (still under production)

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

Luminex 100 Analyzer System

Luminex Corporation
12212 Technology Blvd.
Austin, Texas 78727
512–219–8020 (Tel)
888–219–8020 (Tel)
512–219–5195 (Fax)
info@luminexcorp.com
http://www.luminexcorp.com

Vendor Response: No
Evaluated: No

Technology: Immunochemical/Multianalyte bioassay

Availability: Commercial
Portability: Mobile Laboratory Detection Equipment
Detection Category: Enhanced Immunoassay—multi-analyte bioassay detection system that can be used for immunoassays, nucleic acid research, enzymatic research, and receptor-ligand studies
Application: Description: In virtually every research laboratory environment, the revolutionary Luminex 100 System can deliver a wealth of information accurately, inexpensively, and in real-time enhancing your operational efficiency. This powerful, compact lab analysis system includes the Luminex 100, the XY Platform, and the SD. It utilizes xMAP® technology which enables you to simultaneously assay up to 100 analytes in a single well of a microtiter plate, using very small sample volumes. The system delivers fast and cost-effective bioassay results on many assay formats including nucleic acid assays, receptor-ligand assays, immunoassays, and enzymatic assays.
Current Users: Not specified
BAs Detected: Multiple analyte bioassay detection system

PHYSICAL PARAMETERS

Size: 43 cm x 51 cm x 23 cm (17 in x 20 in x 9 in)
Weight: 27 kg (60 lb)
Power Requirements: Input voltage range: 100 V to 120 V and 200 V to 240 V, 1.4 A, 47 Hz to 63 Hz
Shipping and storage: allowable shipping and storage temperature and humidity ranges, 0 °C (32 °F) to 50 °C (122 °F) and 20 % to 80 % noncondensing rt, respectively.
Luminex highly recommends using an uninterruptible power supply (UPS) to protect your system from a power outage. Choose a supply that can provide 1050 W for at least 45 min. The UPS should be UL listed, CSA certified, and CE marked when used internationally. If you do not use a UPS, as a minimum, use a surge protector. Factors to consider include electrical environment, endurance, suppressed voltage rating, and method of protection. It should have six outlets, rated at least 1500 W, and be UL listed, CSA certified, and CE marked for nondomestic use when used internationally.

GENERAL

NanoSphere's Chip Assay

Nanosphere
1818 Skoki Blvd.
Suite 200
Northbrook, Illinois 60062
847–562–8880 (Tel)
847–562–8886 (Fax)
info@nanosphere-inc.com
http://www.nanosphere-inc.com/

Vendor Response: No
Evaluated: No

Technology: Molecular/DNA Microarray

Availability: Commercial
Portability: Mobile Laboratory Detection Equipment
Detection Category: DNA Chip Assay—Nanosphere has developed gold nanoparticle probe assays to analyze DNA targets in a microarray format. A microarray is an orderly arrangement of DNA samples on a solid surface such as glass. At a microarray test site, the presence of a target DNA sequence is indicated by the binding of gold nanoparticle probes followed by a catalytic amplification of the signal. This procedure eliminates the need for target amplification processes such as PCR, saving both time and cost. The signal from the chip test site is analyzed using Nanosphere's Imaging System and data analysis software which allows the DNA present to be quantified.
Application: Mobile lab
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

Chemical-Biological Mass Spectrometer (CB-MS)

Oak Ridge National Laboratory
P.O. Box 2008
Oak Ridge, Tennessee 37831
POC: Dr. Wayne H. Griest Manager, Block II CBMS Program
Oak Ridge National Laboratory

Vendor Response: No
Evaluated: No

Technology: Hybrid/MS

Availability: Military
Portability: Mobile Laboratory Detection Equipment
Detection Category: Mass Spectrometer; Pyrolysis Mass Spectrometry
Application: The CBMS Block III is a highly reliable detector for Chemical and BW Agents. If your task is to monitor the air for BWAs or CWAs, or to reconnoitre the boundaries of a chemical contamination, the CBMS Block III is the system of choice.
Current Users: Not specified
BAs Detected: Currently, the basic Agents of Biological Origin (ABOs) are detectable BAs (bacterial spores BG) (Pyrolyzer load). 100 ng manual mode and 1 µg automated mode.

PHYSICAL PARAMETERS

Size: 53 cm x 46 cm x 22 cm (21 in x 18 in x 8.75 in)
Weight: 20 kg (44 lb) per box

GENERAL

Single-Particle Fluorescent Counter (SPFC)

Office of Naval Research
Ballston Center Tower One
800 North Quincy Street
Arlington, Virginia 22217–5660
703–696–5031 (Tel)
703–696–5940 (Fax)
Naval Research Laboratory

Vendor Response: No
Evaluated: No

Technology: Optical/Fluorescence
Availability: Military
Portability: Mobile Laboratory Detection Equipment
Detection Category: Fluorescent counter
Application: Mobile lab
Current Users: Not specified
BAs Detected: Particles of BAs

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

Richardson Technologies RTM-3

Richardson Technologies, Inc.
P.O. Box 23
Bolton, Ontario, L7E 5T1 Canada
905–951–7058 (Tel)
888–494–4541 (Tel)
905–951–7052 (Fax)
http://www.richardson-tech.com/index.htm

Vendor Response: No
Evaluated: No

Technology: Optical/Microscopy

Availability: Not specified
Portability: Mobile Laboratory Detection Equipment
Detection Category: A microscope that enables the real time study and exploration of living samples. Ground-breaking technology for the life sciences, producing unprecedented images of dynamic behaviour—in terms of colour, motion, resolution, and detection.
Application: The RTM-3 shows, with breathtaking clarity and contrast, the workings of living samples in real time, in full colour, in their normal condition, without having to use any fixation, stains, or fluorophores that may alter behaviour or structure. All ultra structural information is accessible at the instant the images are collected. By combining the best of fluorescent microscopy with a whole suite of new techniques, the RTM-3 Microscope enables unmatched speed and vision. The RTM-3 has applications in virtually all areas of the life sciences, including medicine, veterinary studies, industry and environmental studies.
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

Bio-Detector (BD)

Smith Detections
2202 Lakeside Boulevard
Edgewood, Maryland 21040
410–510–9100 (Tel)
410–510–9496 (Fax)
30 Technology Drive
Warren, New Jersey 07059
908–222–9100 (Tel)
908–222–1557 (Fax)
Info@smithsdetection.com
http://www.smithsdetection.com
Vendor Response: No
Evaluated: No

Technology: Ligand/Immuno-ligand Assay

Availability: The Bio Detector is currently in production and is a key component of P3I Biological Integrated Detection System (BIDS). Jointly developed and field-tested by Smiths Detection, Edgewood, Inc., and the U.S. Army Chemical and Biological Defense Command, the Bio Detector is an automated BA detector that simultaneously detects up to eight different agents using Immuno-ligand Assay chemistries. Additional tests can be easily incorporated to detect new and emerging biological threats.

The Bio Detector uses the principles of Immuno-ligand Assay chemistries with a light-addressable potentiometric sensor (LAPS), licensed to Smiths Detection – Edgewood, Inc., by Molecular Devices Corporation, to specifically identify BAs. The BAs are identified in three stages: Reaction, separation, and detection.

Portability: Mobile Laboratory Detection Equipment

Detection Category: Immuno-ligand Assay chemistries

The Bio Detector uses the principles of Immuno-ligand Assay chemistries with a light-addressable potentiometric sensor (LAPS), licensed to Smiths Detection – Edgewood, Inc., by Molecular Devices Corporation to specifically identify Bas. The Bio Detector is an automated BA detector that simultaneously detects up to eight different agents using Immuno-ligand Assay chemistries. Additional tests can be easily incorporated to detect new and emerging biological threats.

The Bio Detector is an on-demand, portable system that identifies specific BAs and their concentration levels. It includes sample input, fluidics system, sensor module and reagent consumables in a single, ruggedized housing, that is both portable and durable.

Application: For field missions where durability and portability are essential components of BA detection, the Bio Detector is the detector of choice for the U.S. Army.

Reaction stage: The Bio Detector draws a 1 mL liquid sample, which is segmented and specifically analyzed for eight BAs. During the reaction stage, each of the eight test samples is mixed with biotin and fluorescein-labeled antibody solutions, as well as streptavidin. The labeled antibodies attach themselves to the biological particles and act as indicators during the separation and detection stages.

Separation stage: During the separation stage, the biotin-coated biotape captures the filtered immunocomplexes at eight different locations. A solution of anti-fluorescein antibody, conjugated to the enzyme urease, filters through each spot on the tape, and tags the bound BA.

Detection stage: During the detection stage, the tape is positioned at the LAPS, where it is bathed in a solution of the substrate urea. If the tape traps the tagged BA, the urease chemically reacts with the urea solution and causes a paid change in pH. The rate of change is directly proportional to the amount of BA. The LAPS measures the pH change and transmits an electrical signal to the signal processor. A pattern-recognition algorithm in the signal processor determines the presence of BAs.

Current Users: Jointly developed and field-tested by Smiths Detection – Edgewood, Inc., and the U.S. Army Chemical and Biological Defense Command

BAs Detected: Simultaneous detection of up to eight different BAs. Detects bacterial and viral pathogens and toxins. Rapidly incorporates tests for new threats. Confidence test: operator option to conduct up to 2 tests per mission.

PHYSICAL PARAMETERS

Size: 56 cm x 61 cm x 46 cm (22 in x 24 in x 18 in)
Weight: Not specified
Power Requirements: 110 V ac (50 Hz to 60 Hz) or 28 V dc (14 h continuous operation, 40 detection requests)

GENERAL

Transport Kit Portable FT-IR

Thermo Electron Corporation
27 Forge Parkway
Franklin, Massachusetts 02038
508–520–0430 (Tel)
508–520–1460 (Fax)
508–520–1460 (Fax)
customerservice@thermoei.com
sales@thermogastech.com
http://www.thermo.com/eThermo/CDA/Products/

Vendor Response: No
Evaluated: No

Technology: Screening

Availability:
Portability: Mobile Laboratory Detection Equipment
Detection Category: FTIR—The Transport Kit is a compact and powerful portable Fourier transform IR (FTIR) spectrometer.
It is useful for analyzing samples at hazardous material sites, forensic scenes, and clandestine labs. Local, state and federal entities that require the ability to quickly identify unknown materials will find the Transport Kit a valuable tool for on-site sample analysis. It is the only portable system on the market that includes all of the sampling accessories needed in a rapidly deployable system. When the call comes in, simply grab the unit and go, confident that you have the most powerful FT-IR sampling identification tool available.
Application: For use by first responders, portable labs, HazMat teams, and on-site forensic teams. This system is designed specifically for rapid response teams and portable laboratories. Our extensive database, including white powder substances and hazardous materials, and report the identification of the sample with confidence. All of this analytical power is available in a preprogrammed procedure on an intuitive software interface. Data storage is available on the system, and extensive storage is easily accomplished through the use of CompactFlash™ memory cards. CompactFlash cards are commercially available in a variety of data capacities, giving you unlimited storage potential that does not degrade over time.
Current Users: For use by first responders, portable labs, HazMat teams, and on-site forensic teams
BAs Detected: Screening of biological samples. No specific identification of biological samples.

PHYSICAL PARAMETERS

Size: Not specified
Weight: 14.5 kg (32 lb)
Power Requirements: There are a variety of power options. Inside the carrying case, is a portable battery that offers up to 5 h of continuous operation. The battery recharges quickly to maintain the Transport Kit's operational readiness. For mobile use, a 12 V inverter plugs into a vehicle's accessory power connector for extended operation. If standard ac power is available, the power supply accepts 85 V ac to 240 V ac.

GENERAL

Biological Integrated Detection System (X-BIDS)

U.S. Army Soldier and Biological Chemical Command
(APG)
EAI Corporation, Corporate Headquarters
1308 Continental Drive Suite J
Abingdon, Maryland 21009
866–676–1449 (Tel)
410–676–1449 (Tel)
410–671–7241 (Fax)
Response Equipment Company
a subsidiary of EAI Corporation
1308 Continental Drive Suite A
Abingdon, Maryland 21009
Toll Free: 888–732–3838 (Tel)
Phone: 410–671–0056 (Tel)
Fax: 410–671–0058 (Fax)
http://www.r-e-c.com/prod_bwdetect.html

Vendor Response: No
Evaluated: No

Technology: Hybrid

Availability: The BIDS was developed and produced at the U.S. Army SBCCOM, Aberdeen Proving Ground, Maryland. The NDI BIDS was fielded during FY–96 and FY–97. The P3I BIDS fielding was completed in February 2000.
Can be mounted in either a military (e.g. HMMWV) or commercial vehicle (e.g., Ford E350 Super Cargo), or in a shelter/trailer.
Portability: Mobile Laboratory Detection Equipment
Detection Category: Customized for each customer, the system and its BA detection suite have been fully tested, proven, and fielded with U.S. military forces. The BIDS Biological Detection Suite links aerodynamic particle sizing, bioluminescence/flourescence, flow cytometry, mass spectrometry, and immunoassay technologies in a complementary, layered manner to increase detection confidence.
Application: The BIDS consists of a shelter (S-788 Lightweight Multipurpose Shelter) mounted on a dedicated vehicle [M1097 (Heavy High Mobility Multipurpose Wheeled Vehicle) HMMWV] and equipped with a biological detection suite employing complementary technologies.
Current Users: Customized for each customer, the system and its BA detection suite have been fully tested, proven, and fielded with U.S. military forces.
BAs Detected: Not specified

PHYSICAL PARAMETERS

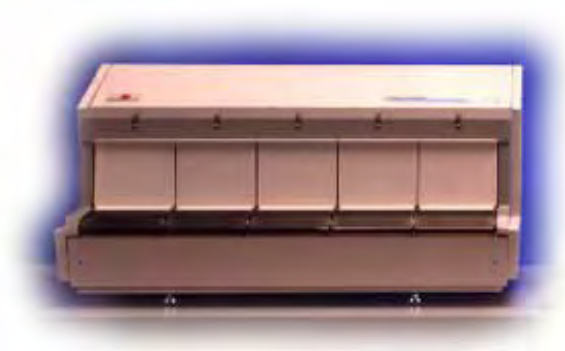
Size: Not specified
Weight: Not specified

GENERAL

VIDAS

Biomeriux
100 Rodolphe Street
Durham, North Carolina 27712
919–620–2000 (Tel)
800–682–2666 (Tel)
800–968–9494 (Fax)
http://www.biomerieux-usa.com

Vendor Response: No
Evaluated: No



Technology: Immunochemical/Colorimetric ELISA

Availability: Commercial
Portability: Mobile Laboratory Detection System
Detection Category: VIDAS is an automated, muliparametric immunoassay system.
This uniquely designed testing device stores the calibration in the analyzer's memory, thus optimizing the cost-per-test result. Plus, with its ready-to-use reagents, minimum maintenance, ease of use and uni/bi-directional interface, labor cost is also optimized. Automation and kinetic assay reactions yield rapid turnaround time.
VIDAS and mini VIDAS are called “multiparametric” instruments. The term “multiparametric” is used to describe the functionality of the VIDAS and mini VIDAS instruments. The user is able to run compatible tests with the same protocols in the same section. For example: Salmonella, Listeria, and E. coli 0157 may be run in the same section at the same time. Tests with different protocols may also be run at the same time, but in different sections in the instrument.
Application: The VIDAS system allows for a flexible work routine with a sectioned architecture, an add-on modular system, more efficient workflow, batch testing (up to 100 tests/2 h), single-sample testing, and multiparametric testing.
It is automated, has no carryover, uses fluorescence reading, is self-testing and has ready-to-use bar-code-labeled reagents.
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

Swift FM31-LWD Field Microscope

Swift Microscopy
Swift Instruments, Inc.
Scientific Instruments Division
1190 North Fourth Street
San Jose, California 95112
800–523–4544 (Tel)
408–293–2380 (Tel)
408–292–7967 (Fax)
Swift Microscopy

Vendor Response: No
Evaluated: No

Technology: Optical/Microscopy

Availability: Not specified
Portability: Mobile Laboratory Detection System
Detection Category: Field microscope
FM-31 LWD—Brighttfield; 4x, 10X LWD, 40X LWD; 10XWF 15.5 mm with case; Illuminator with bracket and case
FM-31 LWD P20—Phase Contrast; 4X, P10X LWD, P20X LWD; 10XWF 15.5mm with case; Illuminator w/bracket, phase annulus and case
FM-31 LWD P40—Phase Contrast; 4X, P10X LWD, P40X LWD; 10XWF 15.5mm with case; Illuminator w/bracket, phase annulus and case
Application: The FM31-LWD is currently the only field microscope of its type manufactured in the world! Compact, portable, reasonably priced, but with advanced capabilities. Ideal for large animal vet work, avian specialists and mobile vets. It can do just about anything that a Lab scope can do, except for 1000X. However, with optional 15X and 20X objectives and the 40X LWD objective, up to 800X magnification can be reached. Applications: urine, blood, semen (pc), parasites, etc., in field. It has darkfield and polarizing accessories, a mechanical stage, a phase annulus and objectives as well as 4X, 10, 20X, and 40X objectives. An Iris condenser, filters, etc. Powered by a Mini-Maglight!
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

Affymetrix GeneChip System

AFFYMETRIX, Inc.
3380 Central Expressway
Santa Clara, CA 95051 USA
888–DNA–CHIP (Tel)
408–731–5441 (Fax)
sales@affymetrix.com
support@affymetrix.com
http://www.affymetrix.com/support/technical/other/genechip_system_brochure.pdf

Vendor Response: No
Evaluated: No

Technology: Molecular/DNA Microarray

Availability: Not specified
Portability: Fixed-Site Detection System
Detection Category: DNA Microarray
Application: The Affymetrix instrumentation at the UCI DNA MicroArray Core Facility consists of the following: GeneChip Hybridization Oven 320 for overnight hybridization of target RNAs with the DNA oligo probes on a GeneChip array. GeneChip Fluidics Station 400 capable of processing 4 GeneChip arrays at a time for automated washing and staining protocols. Hewlett Packard Genearray Scanner for determining the amount of bound target at each probe cell site of an array and associated/dedicated computer/printer setup for controlling both the fluidics and scanner modules followed by data analysis/report generation using the Affymetrix GeneChip Analysis Suite software.
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

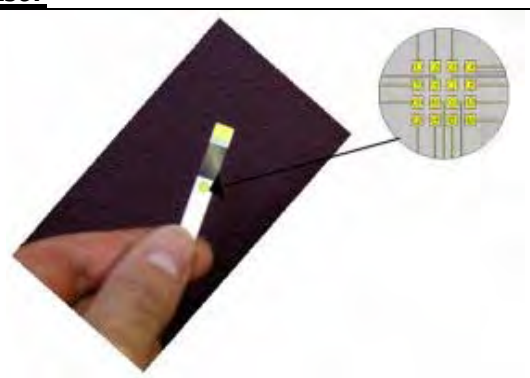
Size: Not specified
Weight: Not specified

GENERAL

Ambri ICS™ Biosensor

AMBRI
126 Greville Street
Chatswood NSW 2067
Australia
POC: Joe Shaw MD/CEO
+61 2 9422 3000 (Tel)
+61 2 9422 3013 (Fax)
http://ambri.com

Vendor Response: No
Evaluated: No



Technology: Biosensor Based

Availability: Not specified
Portability: Fixed-Site Detection System
Detection Category: Converts a biological binding event into a digital electrical signal. This enables the biosensor to employ computer technology to analyze and define this biological event. The detection mechanism operates by the binding of the target molecule to the antibody fragment, altering the population of conduction ion channels pairs within the tethered membrane. This results in a change in the membrane conduction. The following cartoon is useful in explaining the mechanism. It has been drawn to scale using single crystal structures of the component proteins. Ambri has built a biological switch: a membrane which can detect the presence of specific molecules and signal their presence by triggering an electrical current. This device, the Ambri Ion Channel Switch(ICS™) Biosensor, is a two molecular layer self assembled membrane based on the ion channel gramicidin.
Application: Ambri has received DARPA support from the U.S. Military to develop kits for bacteriological detection in cases of bio-weapons attack. Projects are continuing with the Australian military and ongoing discussions are exploring further opportunities in the U.S. Certain bacteriological tests may be transferred to applications within the human healthcare market. Ambri Limited is pioneering the integration of Biotechnology, Nanotechnology, and Electronics with a major focus in the human medical diagnostics market. Ambri has developed the Ion Chanel Switch (ICS ™) technology, a patented self assembling synthetic bio-membrane. This is one of the worlds first true 'bio,nano' devices and has a wide and varied potential range of applications in many markets. Ambri's first commercial application of the ICS ™ technology has been incorporated into the SensiDx™ System, a point-of-care diagnostic system, for the hospital critical care diagnostic market. The System has been designed to deliver accurate, quantifiable results in less than 5 min and includes an analyzer and series of test specific disposable cartridges that contain biosensors based on Ambri's patented ICS™ technology. The SensiDx™System has the potential to detect and measure drugs, hormones, viruses and bacteria in whole blood directly from a standard collection tube in less than 5 min. This provides many advantages over competitve systems. The SensiDx™ System will provide benefits to healthcare professionals by providing a faster turn around time for test results, minimal blood handling and decision making at the point-of-care. This should result in improved patient outcomes and ultimately reduce medical costs for critical care units.
Current Users: Ambri has received DARPA support from the U.S. Military to develop kits for bacteriological detection in cases of bio-weapons attack. Projects are continuing with the Australian military and ongoing discussions are exploring further opportunities in the U.S. Certain bacteriological tests may be transferred to applications within the human healthcare market.
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

API TOF Mass Spectrometer

Analytica of Branford
29 Business Park Drive
Bradford, Connecticut 06405
203–488–8899 (Tel)
203–482–0433 (Fax)
800–878–3435 (Sales Tel)
analytica@aob.com Amersham
http://www.aob.com

Vendor Response: No
Evaluated: No

Technology: Hybrid/MS

Availability: Not specified
Portability: Fixed-Site Detection System
Detection Category: Mass Spectrometry–TOF
High sensitivity detector for both flow injection MS and LC-MS
Liquid flow rates of from 50 nL/min through 2 mL/min
Application: Not specified
Current Users: Not specified
BAs Detected: Detection of fast liquid phase separations of high and low levels of species

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

ABI Prism® 7900HT Sequence Detection System

Applied Biosystems
850 Lincoln Center Drive
Foster City, California 94494
650–638–5800 (Tel)
800–327–3002 (Tel)
650–638–5884 (Fax)
andersme@appliedbiosystems.com
http://www.appliedbiosystems.com
Vendor Response: No
Evaluated: No

Technology: Molecular/Real Time PCR

Availability: Not specified
Portability: Fixed-Site Detection System
Detection Category: Peltier-based thermal cycling system with interchangeable 384- and 96-well block capability . Extended-life 488 nm argon-ion laser excitation source. Excitation light distributed to all wells via a dual-axis synchronous scanning head. Fluorescence detection via a spectrograph and cooled CCD camera. Robot compatible plate loading and unloading (Automation Accessory required to load multiple plates without user intervention). Performance—using the TaqMan® RNase P Instrument Verification Plate (384 or 96-well), the ABI Prism 7900HT Sequence Detection system can distinguish between 5 000 and 10 000 template copies with a 99.7 % confidence level. Real-time throughput: Over 5 000 sample wells/d with 384-well block configuration and standard thermal cycling protocol (requires Automation Accessory). End-point throughput: over 30 000 sample wells every 3 h with 384-well block configuration (represents a full automation accessory load with off-line thermal cycling).
Application: The ABI Prism 7900HT Sequence Detection System is a high-throughput real-time PCR system that detects and quantitates nucleic acid sequences. An Automation Accessory combined with 384-well plate capability make the 7900HT system ideally suited to meet the high-throughput requirements of today's drug discovery process. Key applications include gene expression quantitation and the detection of single nucleotide polymorphisms (SNPs) using the fluorogenic 5' nuclease assay.
• Interchangeable formats provide improved throughput and flexibility.
• Custom Automation Accessory provides 24-hr unattended operation.
• Hand-held and integrated bar code readers simplify sample tracking.
• Continuous wavelength detection from 500 nm to 660 nm allows the use of multiple fluorophores in a single reaction.
• Proven assay development guidelines save time and money.
Current Users: Peltier-based thermal cycling system with interchangeable 384- and 96-well block capability . Extended-life 488 nm argon-ion laser excitation source. Excitation light distributed to all wells via a dual-axis synchronous scanning head. Fluorescence detection via a spectrograph and cooled CCD camera
Robot compatible plate loading and unloading (Automation Accessory required to load multiple plates without user intervention). Performance—Using the TaqMan® RNase P Instrument Verification Plate (384 or 96-well), the ABI Prism 7900HT Sequence Detection system can distinguish between 5 000 and 10 000 template copies with a 99.7 % confidence level. Real-time throughput: Over 5 000 sample wells/d with 384-well block configuration and standard thermal cycling protocol (requires Automation Accessory). End-point throughput: Over 30 000 sample wells every 3 h with 384-well block configuration (represents a full automation accessory load with off-line thermal cycling).
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: 30.5 cm x 25.4 cm x 40.1 cm (12 in x 10 in x 16 in)
Width with automation accessory: 125 cm (49 in); without automation accessory: 71 cm (28 in)
Computer: 43 cm (17 in)
Height with automation accessory: 64 cm (25 in); without automation accessory: 64 cm (25 in)
Computer: 58 cm (23 in)
Depth with automation accessory: 64 cm (25 in); without automation accessory: 84 cm (33 in)
Weight: 8.6 kg (19 lb)
Power Requirements: Voltage: 200 V to 240 V

GENERAL

ABI Prism® 7000 Sequence Detection System

Applied Biosystems
850 Lincoln Center Drive
Foster City, California 94494
650–638–5800 (Tel)
800–327–3002 (Tel)
650–638–5884 (Fax)
andersme@appliedbiosystems.com
http://www.appliedbiosystems.com
Vendor Response: No
Evaluated: No

Availability: Not specified
Technology: Molecular/PCR—DNA Microarray (RT)
Portability: Fixed-Site Detection System
Detection Category: DNA Microarray (RT)—ABI Prism 7000 Sequence Detection System: Peltier-based, 96-well block thermal cycling system. Tungsten-halogen lamp excitation source. Fluorescence detection via a four-position filter wheel and CCD camera. The software runs on Windows® 2000 operating system and is used for instrument control, data collection, and data analysis. Real-time monitoring during data collection. Intuitive multiplex assay set-up and analysis. Simple dissociation curve data collection and viewing. Intuitive allelic discrimination results viewer. Automatic identification of samples containing a PCR inhibitor when performing plus/minus assays with an IPC.
Application: The ABI Prism 7000 Sequence Detection System is a complete, real-time PCR system that detects and quantitates nucleic acid sequences. In real-time PCR, cycle-by-cycle detection of accumulated PCR product is made possible by combining thermal cycling, fluorescence detection, and application-specific software in a single instrument. Quantitative results are available immediately after PCR without additional purification or analysis. Real-time, quantitative PCR applications include gene expression and pathogen detection. Post-PCR detection is also available for nonquantitative assays such as allelic discrimination (SNP detection) and plus/minus assays utilizing an internal positive control (IPC). Key features include: • Multicolor detection provides flexibility for multiplex quantitation assays, allelic discrimination assays, and plus/minus assays.
• Precision optics, combined with a sophisticated multicomponenting algorithm, provide accurate, highly-reproducible results.
• Small footprint facilitates easy placement in any laboratory.
• Peltier-based, 96-well block thermal cycling system is easy to use with standard 96-well plates or 0.2 mL tubes.
• Proven assay development guidelines save time and money.
Rapid assay development guidelines are provided to ensure success when using the fluorogenic 5' nuclease assay and SYBR® Green 1 double-stranded DNA binding dye assays.
Rapid assay development guidelines consist of the following:
• Automated primer and probe design using Primer Express® Software (included with 7000 system) .
• The use of TaqMan® Universal PCR Master Mix or SYBR® Green PCR Master Mix (provides standardized component concentrations and simplifies assay set-up).
• Universal thermal cycling parameters (enable multiple assays to be run on the same 96-well plate).
• Default primer and probe concentrations eliminate assay optimization.
Default primer and probe concentrations are valid for multicolor SNP assays using TaqMan® MGB probes and single color quantitation assays using TaqMan® probes or SYBR® Green 1 dye detection. Assay optimization is recommended for multiplex quantitation assays to minimize PCR competition.
Fluorescence Detection: All sample wells are simultaneously illuminated using a tungsten-halogen lamp. Fluorescence emission is directed sequentially through four optical filters (positioned on a filter wheel) to a cooled, charge-coupled device (CCD) camera. Emission filters are optimized for use with the following dyes: FAM™/SYBR® Green 1, VIC™/JOE, NED™/TAMRA™, and ROX™ dyes.
Current Users: Not specified
BAs Detected: Some gene and pathogen detection

PHYSICAL PARAMETERS

Size: Width: 39 cm (15.25 in), computer: 33 cm (13 in); Height: 53 cm (20.75 in), computer: 33 cm (12.25 in); Depth: 50 cm (19.75 in), computer: 28 cm (11 in)
Weight: 23 kg (50 lb)—total including backpack, laptop computer, centrifuge, and sample cuvettes
Power Requirements: Interchangeable power: 110 V to 220 V

GENERAL

ABI 9700 Thermal Cyclers

Applied Biosystems
850 Lincoln Center Drive
Foster City, California 94494
650–638–5800 (Tel)
800–327–3002 (Tel)
650–638–5884 (Fax)
AME Bioscience World Sales
Havnaasveien 21
3135 Toroed
Norway
+47 90 08 78 24 (Tel)
+47 33 40 14 44 (Fax)
USA / CANADA
312–321–6947 (Tel)
734–370–6142 (Fax)
http://www.amebioscience.com/contact.htm

Vendor Response: No
Evaluated: No

Technology: Molecular/Standard PCR

Availability: Available for immediate shipment
Portability: Fixed-Site Detection System
Detection Category: The 96-Well GeneAmp® PCR System 9700 can now be used with Gold-plated Silver and Aluminum Sample Blocks Modules. The aluminum block has been designed for routine use of PCR reactions and cycle sequencing in a conventional 8 x 12 well format. This allows the 96-well 9700 system to be used in 9600 emulation mode and standard mode. The gold-plated silver sample block has been engineered for maximum performance and durability, utilizing a rapid heat transfer design of electroformed silver to maximize heating/cooling rates and goldplating for maximum durability. This allows the gold-plated silver 96-well 9700 system to be used in MAX Mode (5 °C/s average heating/cooling of block) and 9600 emulation mode.
Application: Practice of the patented PCR process requires a license. The GeneAmp® PCR System 9700 base unit in combination with the immediately attached GeneAmp® PCR System 9700 sample block module is an Authorized Thermal Cycler for PCR and may be used with PCR licenses available from Applied Biosystems. Its use with Authorized Reagents also provides a limited PCR license in accordance with the label rights accompanying such reagents. The PCR process is covered by patents owned by Roche Molecular Systems, Inc., and F. Hoffmann-La Roche Ltd.
• Interchangeable sample block modules for greater flexibility.
• Gold-plated silver blocks for high speed -5 °C/sec average heating/cooling rate of block.
• Aluminum sample blocks designed for routine PCR and cycle sequencing.
• Gold-plated silver block provides maximum durability.
Current Users: Practice of the patented PCR process requires a license. The GeneAmp® PCR System 9700 base unit in combination with the immediately attached GeneAmp® PCR System 9700 sample block module is an Authorized Thermal Cycler for PCR and may be used with PCR licenses available from Applied Biosystems. Its use with Authorized Reagents also provides a limited PCR license in accordance with the label rights accompanying such reagents. The PCR process is covered by patents owned by Roche Molecular Systems, Inc., and F. Hoffmann-La Roche Ltd.
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

Bayer Quantiplex System 340 (Automated bDNA assay)

Bayer Diagnostics Bayer plc Bayer house Strawberry Hill Newbury Berkshire RG14 IJA United Kingdom http://www.bayer.co.uk **Vendor Response**: No **Evaluated**: No	

Technology: Molecular/Branched DNA (bDNA)

Availability: Commercial
Portability: Fixed-Site Detection System
Detection Category: The Quantiplex® 340 is the first automated platform for viral load assays. Capable of high throughput of up to 168 samples in 24 h, it meets the needs of both high and low volume laboratories. The system runs the Quantiplex® HCV RNA assay, the Quantiplex® HBV DNA assay and the ultra-sensitive Quantiplex® HIV-1 RNA 3.0 assay which has an extended dynamic range from 50 to 500 000 copies per mL.
Application: System 340 bDNA Analyzer automatically: Captures target and hybridizes amplification probes; hybridizes pre-amplifiers; hybridizes bDNA amplifiers; labels probes; and easures signal and generates report
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

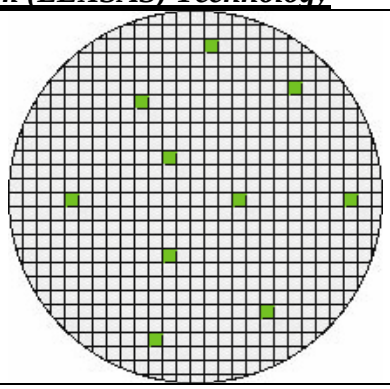
Size: Not specified
Weight: Not specified

GENERAL

Label- Free Exponential Signal-Amplification System (LEXSAS) Technology

BCR Corporation
1062 East Shore Road
Jamestown, Rhode Island 02835
410–863–1608 (Tel)
info@bcrbiotech.com

Vendor Response: No
Evaluated: No



Technology: Molecular/Branched DNA (bDNA)

Availability: Commercial
Portability: Fixed-Site Detection System
Detection Category: Amplification—Branched Chain
Application: Based on R&D at BCR laboratories, the commercial biosensor will have the following characteristics:

1. Ability to detect a single bacterium.
2. Ability to yield quantitative results in less than 5 min.
3. Minimal sample preparation.
4. No labeling reagents (such as fluorescent, radioisotopic or enzymatic reporter molecules) required.
5. Linear detection response over a wide dynamic range of 1 to 50,000 bacteria per mL.
6. Single use (disposable), low manufacturing cost.
7. Applicability to automated high-throughput operations.
8. Portability for point-of-care (POC) testing.

Current Users: Not specified
BAs Detected: Dormant spores if various Bacillus species. Escherichia coli cells.

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

Biocore 2000

Biacore, Inc.
200 Centennial Ave
Piscataway, New Jersey 08854
800–242–2599 (Tel)
732–885–5618 (Tel)
732–885–5669 (Fax)
http://www.biacore.com

Vendor Response: No
Evaluated: No

Technology: Ligand/Surface Plasmon Resonance (SPR)

Availability: Commercial
Portability: Fixed-Site Detection System
Detection Category: Allows sensitive detection of molecular interactions in real time, without the use of labels.
Biacore does not require any labels or reporter groups to detect biomolecular interactions. This saves the work of purifying and labeling material, and eliminates the risk that labels may interfere with the interaction being studied. In addition, Biacore follows every step in a multi-step analysis procedure, in contrast to label-based methods that often only report the final step. The progress of interactions is displayed directly on the computer screen in Biacore, as a plot of response (which is directly related to concentration changes at the surface) against time. Immediate feedback on the status of an interaction speeds up assay development and analysis. The results can of course be processed further after the run, for example to extract kinetic constants for the interaction.
SPR-based detection is based on measurement of light reflected from the side of the sensor surface that is not in contact with the sample. The light does not penetrate the sample so that measurements can be made on turbid or opaque samples with no interference from light absorption or scattering.
The advantages of the technology are well confirmed by independent publications from many researchers who have chosen Biacore in preference to other alternatives. Some examples are:
• Screening applications report fewer false positive results than ELISA.
• Concentration measurement with Biacore gives better reproducibiltity and less interference from nonanalyte components than ELISA.
• Determination of vitamins in foodstuffs is faster and simpler than with established HPLC or microbiological methods.
• Kinetic data are obtained with a simplicity and resolution unmatched by other techniques.
• Monitoring every stage in multiple component complex formation provides insights that other approaches cannot give.
Application: Biacore® 2000 is well suited for larger institution research facilities with multi-user applications such as structure-function studies, cell signaling, multi-molecular complexes, and all other routine applications. With full automation to handle large numbers of samples, with high sensitivity and well proven reliability, Biacore 2000 is a fully automated optical biosensor system designed for routine and accurate analysis.
Current Users: Drug discovery, food analysis, and life science research
BAs Detected: Bacteria and viruses

PHYSICAL PARAMETERS

Size: 76 cm x 36 cm x 61 cm (30 in x 14 in x 24 in)
Weight: 150 kg (110 lb)
Power Requirements: 100 V to 120 V; 220 V to 240 V, max 580 VA

GENERAL

Biocore 3000

Biacore, Inc.
200 Centennial Ave
Piscataway, New Jersey 08854
800–242–2599 (Tel)
732–885–5618 (Tel)
732–885–5669 (Fax)
http://www.biacore.com

Vendor Response: No
Evaluated: No

Technology: Ligand/Surface Plasmon Resonance (SPR)

Availability: Commercial
Portability: Fixed-Site Detection System
Detection Category: Allows sensitive detection of molecular interactions in real time, without the use of labels
Biacore does not require any labels or reporter groups to detect biomolecular interactions. This saves the work of purifying and labeling material, and eliminates the risk that labels may interfere with the interaction being studied. In addition, Biacore follows every step in a multi-step analysis procedure, in contrast to label-based methods that often only report the final step. The progress of interactions is displayed directly on the computer screen in Biacore, as a plot of response (which is directly related to concentration changes at the surface) against time. Immediate feedback on the status of an interaction speeds up assay development and analysis. The results can of course be processed further after the run, for example to extract kinetic constants for the interaction. SPR-based detection is based on measurement of light reflected from the side of the sensor surface that is not in contact with the sample. The light does not penetrate the sample so that measurements can be made on turbid or opaque samples with no interference from light absorption or scattering.
The advantages of the technology are well confirmed by independent publications from many researchers who have chosen Biacore in preference to other alternatives. Some examples are:
• Screening applications report fewer false positive results than ELISA.
• Concentration measurement with Biacore gives better reproducibility and less interference from nonanalyte components than ELISA.
• Determination of vitamins in foodstuffs is faster and simpler than with established HPLC or microbiological methods.
• Kinetic data are obtained with a simplicity and resolution unmatched by other techniques.
• Monitoring every stage in multiple component complex formation provides insights that other approaches cannot give.
Application: Biacore® 3000 is the highest performance research system available for label-free studies of biomolecular binding and an ideal system for all research laboratories, providing high quality data on the kinetic and affinity parameters for a given biomolecular interaction. Biacore® 3000 is a tool for exploring protein function and is used by therapeutic research scientists in cancer, neuroscience, immunology, and infectious disease laboratories in academic, pharmaceutical, and biotech facilities around the world. A research system providing unparalleled levels of data from a single experiment. Samples ranging from small molecules to crude extracts, lipid vesicles, viruses, bacteria and eucaryotic cells can be studied in real-time, without the use of labels and with little or no prior sample preparation. Designed for individual sample characterization where the highest resolution in kinetic analysis is essential and for automation of multi-sample analyses. New automated analyte recovery functions and integration with MS analysis includes:
• Automated wizard driven recovery functions for optimized recovery.
• Ability to deliver recovered material direct to MALDI target.
• Automated on target or in vial digestion and MALDI matrix delivery.
Biacore® 3000 is ideal for molecular recognition studies, ligand fishing, SPR-MS, and other advanced applications.
Current Users: Drug discovery, food analysis, life science research
BAs Detected: Bacteria and viruses

PHYSICAL PARAMETERS

Size: 76 cm x 36 cm x 61 cm (30 in x 14 in x 24 in)
Weight: 150 kg (110 lb)
Power Requirements: 100 V to 120 V; 220 V to 240 V, max 580 VA

GENERAL

NucliSens EasyQ System

Biomeriux
100 Rodolphe Street
Durham, North Carolina 27712
919–620–2000 (Tel)
800–682–2666 (Tel)
800–968–9494 (Fax)
POC: Lynell Grosso
919–620–2094 (Tel)
919–620–7019 (Fax)
lynell.grosso@na.biomerieus.com
http://www.biomerieux-usa.com

Vendor Response: No
Evaluated: No

Technology: Molecular/Real Time PCR

Availability: Commercial
Portability: Fixed-Site Detection System
Detection Category: The NucliSens EasyQ System is the first automated system to combine NASBA and real-time molecular beacon detection. The system is designed for ease of use and is equally suited to large- or small-volume molecular testing. The intuitive operator software and short assay hands-on and turnaround times will significantly improve the workflow of any molecular testing laboratory.
Application: Real-time NASBA amplification and detection:
• Innovative, one-tube assay eliminating amplicon contamination risks, for reliable results.
• Fast time to result with up to 48 test results in < 2 h.
• Easy-to-use, convenient assay set-up with minimal hands-on time.
• Automated data analysis and reporting with dedicated software.
NASBA (nucleic acid sequence-based amplification) technology utilizes three enzymes (AMV-RT, RNase H and T7 RNA Polymerase) and target-specific oligonucleotides. NASBA is an isothermal process that runs at 41 °C generating single-stranded RNA as the end product. Molecular beacons are a novel class of DNA hybridization probes that fluoresce upon hybridization. Molecular beacons have a stem-loop structure and contain a fluorophore and a quencher group. In its normal state the stem keeps the fluorophore and the quencher together, preventing emission or fluorescence. In the presence of a sequence, complementary to the loop sequence, the probe unfolds upon hybridization. In this state the quencher can no longer absorb photons emitted by the fluorophore, and the probe starts to fluoresce.
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: The NucliSens EasyQ Analyzer has a footprint of just 42 cm x 42 cm (16.5 in x 16.5 in). Combined with the small incubator and dedicated computer, it requires minimal workbench space.
Weight: Not specified

GENERAL

iCycler iQ™

Bio-Rad Laboratories
Headquarters
1000 Alfred Nobel Drive
Hercules, California 94547
510–724–7000 (Tel)
510–741–5817 (Fax)
POC: Hilary Srere
510–741–5811 (Tel)
510–741–5811 (Fax)
hilarysrere@bio-rad.com
http://www.bio-rad.com/icycler

Vendor Response: No
Evaluated: No

Technology: Molecular/Real Time PCR

Availability: Not specified
Portability: Fixed-Site Detection System
Detection Category: The iCycler iQ real-time PCR detection system is a sophisticated optical system that fits directly above the iCycler thermal cycler. It covers the widest range of excitation/emission wavelengths available, facilitating the greatest array of fluorescent PCR strategies. With this upgrade, the iCycler thermal cycler expands the advantages PCR brings to your research.
Practice of the patented PCR process requires a license. The iCycler iQ system includes a licensed thermal cycler and may be used with PCR licenses available from Applied Biosystems. Its use with authorized reagents also provides a limited PCR license in accordance with the label rights accompanying such reagents. Some applications may require licenses from other parties.
Application: Real-time analysis can be viewed online, during the PCR. Range of fluorophore excitation and emission from 400 nm to 700 nm. Four different fluorophores can be multiplexed per sample tube. Ninety-six samples can be tracked simultaneously, maximizing throughput. Sample data can be reanalyzed at any time. Raw data files are user accessible. Easy, intuitive software speeds setup and data presentation. Storage of hundreds of protocols. Standard PCR plate format accommodates existing protocols and minimizes costs. User interface offers easy yet powerful options for data analysis. Real-time quantitative PCR provides accurate quantitation, accelerating lead identification in drug discovery and improving viral load assessment. iCycler iQ software is designed to automate analysis options, including quantitative and melt-curve analysis; you can also choose to reanalyze raw data at any point post-run. Monitor the thermal protocol in real time, saving time and effort in your analysis. Closed-tube analysis reduces contamination concerns and speeds time to results.
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: Dimensions (including optical module): 33 cm x 36 cm x 62 cm (12.9 in x 14 in x 24.5 in)
Weight: 17.7 kg (39 lb)

GENERAL

iCycler™ Thermal Cycler

Bio-Rad Laboratories
Headquarters
1000 Alfred Nobel Drive
Hercules, California 94547
510–724–7000 (Tel)
510–741–5817 (Fax)
POC: Hilary Srere
510–741–5811 (Tel)
510–741–5811 (Fax)
hilarysrere@bio-rad.com
http://www.bio-rad.com/icycler

Vendor Response: No
Evaluated: No

Technology: Molecular/Standard PCR

Availability: Not specified
Portability: Fixed-Site Detection System
Detection Category: The iCycler thermal cycler maximizes what a thermal cycler can do for your laboratory. It features multiple sample formats, an easy graphic interface, and best of all, direct upgradability to real-time quantitative PCR. The iCycler thermal cycler will raise your expectations of what a thermal cycler can do for you.
iCycler Thermal Cycler Features:
Graphical representation of protocols, menu-driven software, and ready-made templates for ease in viewing, editing, and running
Direct modular upgrade to quantitative PCR capability
Maximum sample flexibility accommodates 0.2 mL tubes, strips and plates, and 0.5 mL tubes
Temperature monitoring and control can be specified by in-sample probe, block, or instrument algorithm
Optional security for protection of folders and protocols
Wide range of programmable personal preferences
Alphanumeric naming for maximum flexibility in storing protocols, naming folders, and identifying users
Storage of detailed validation and run reports as well as hundreds of protocols
NIST-traceable accuracy of temperature measurements
Free thermal gradient upgrade
Gradient design for maximum reagent optimization
Practice of the patented PCR process requires a license. The iCycler iQ system includes a licensed thermal cycler and may be used with PCR licenses available from Applied Biosystems. Its use with authorized reagents also provides a limited PCR license in accordance with the label rights accompanying such reagents. Some applications may require licenses from other parties.
Application: Not specified
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

Particle Size and Shape with Fluorescence (FL-ASAS)

Biral
P.O. Box 2
Poerishead
Bristol BS20 7JB
UK
POC: Steve Evans
+44 1275 847787 (Tel)
+44 1275 847303 (Fax)
Sevans@biral.com
Bristol Industrial Research Associates and Limited
http://www.biral.com

Vendor Response: No
Evaluated: No

Technology: Optical/Fluorescence

Availability: Military and commercial
Portability: Fixed-Site Detection System
Detection Category: Single particle fluorescence measurements to combine with the real-time size and shape data.
Application: To effectively identify BAs in the air it is important to characterize aerosol particles and compare this information to that of known threats. Particle size and shape have already proven themselves valuable parameters for the evaluation of this "fingerprint" and Biral's ASAS Technology is widely used in cutting-edge military biodetection equipment. Biral is further enhancing ASAS Technology for use in next-generation military and civil defence biodetection systems. These innovative devices will incorporate single particle fluorescence measurements to combine with the real-time size and shape data. Spectral analysis of fluorescence is a very powerful tool when distinguishing biological and nonbiological aerosols. This additional information will further improve software interpretation and bring more rapid identification of bacterial agents. Biral has already demonstrated a prototype device in collaboration with Dstl Porton Down (UK Ministry of Defence). Further work is now being undertaken to develop a robust commercial version.
Current Users: Not specified
BAs Detected: BAs

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

MiniTOF Linear TOF Mass Spectrometer

Comstock
1005 Alvin Weinberg Drive
Oak Ridge, Tennessee 37883
865–483–7690 (Tel)
865–481–3884 (Fax)
alesinfo@comstockinc.com
http://www.comstockinc.com

Vendor Response: No
Evaluated: No

Technology: Hybrid/MS

Availability: Military
Portability: Fixed-Site Detection System
Detection Category: Mass Spectrometry–TOF Rapid acquisition of mass spectral information (entire spectrum is acquired in under 500 µs). Has compatibility with numerous other technique (gas chromatography, molecular beams, secondary ion mass spectrometry, and MALDI).
Application: Not specified
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

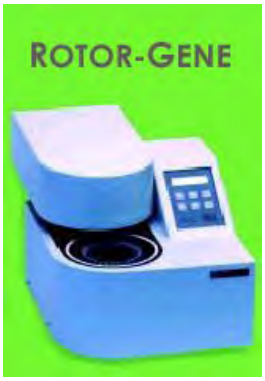
Size: Not specified
Weight: Not specified
Power Requirements: A TFP-210 power supply is used for application of the necessary voltages to the spectrometer ion optics, flight tube and detector.
LI: RPS-112 power supply. Provides pulsed or dc voltage to repeller. Pulse width, delay, and amplitude are user selectable.

GENERAL

Roto-Gene Real Time DNA Amplification System Roto-Gene 3000 4 Channel Multiplexing System

Corbett Research
1/14 Hilly Street
Mortlake, NSW 2137 Australia
011–612–973–613–20 (Tel)
011–612–973–613–64 (Fax
John@corbettresearch.com
Distribution:
Pyrosequencing Inc.
2200 West Park Drive
Suite 320
Westborough Massachusetts 01581
508–870–1109 (Tel)
508–898–3306 (Fax)
todd.deppe@pyrosequencing.com
http://www.corbettresearch.com
http://www.pyrosequencing.com

Vendor Response: No
Evaluated: No



Technology: Molecular/Real-Time PCR

Availability: Not specified
Portability: Fixed-Site Detection System
Detection Category: DNA amplification—The Corbett Research Rotor-Gene™ uses a world first centrifugal design to provide the researcher with unparalled sensitivity and precision at a fraction of the costs associated with other high end systems. The newly released Rotor-Gene™ 3000 raises the bar further with even greater sensitivity and efficiency, in addition to a new improved software interface that includes new functionality developed in conjunction with Rotor-Gene™ users.
Application: Not specified
Current Users: Not specified
BAs Detected: Excitation source: 470 nm, 530 nm, 585 nm, 625 nm; LED high power diodes
Detection filters: 510 nm, 555 nm, 610 nm band-pass; 660 nm, 585 nm, 610 nm high-pass filters
Fluorophores detected: Sybr-Green I, FAM, TET, JOE, VIC, HEX, ROX, TAMRA, CY3, CY3.5, CY5, CY5.5, Oregon Green™, CAL Red™, Red 640, and Texas Red

PHYSICAL PARAMETERS

Size: 36 cm x 48 cm x 31 cm (14 in x 19 in x 12 in)
Weight: 17 kg (38 lb)
Power Requirements: 100 V ac to 120 V ac @ 5 A; 200 V ac to 240 V ac @ 3 A (50 Hz to 60Hz)

GENERAL

BAX System

DuPont Qualicon
Bedford Bldg, 3531 Silverside Road
Wilmington, Delaware 19810
800–863–6842 (Tel)
302–695–5300 (Tel)
302–695–5301 (Fax)
Regional contact: 800–863–6842 (Tel)
http://www.qualicon.com

Vendor Response: No
Evaluated: No

Technology: Molecular/Standard PCR

Availability: Military and commercial
(Reagents are commercially available)
Portability: Fixed-Site Detection System
Detection Category: DNA-based detection
The system breaks down samples at the genetic level, using the power of the PCR to detect bacteria with certainty.
Application: With a single program for all bacteria, the automated BAX® system allows for tests of multiple targets in the same run, up to 96 samples per batch. Results are available as soon as the next day and are clearly displayed on screen with a simple positive or negative report, virtually eliminating the need for expert interpretation. Tableted reagents, which enable minimal hands-on time using standard laboratory techniques, provide long shelf life and consistency. Friendly screen prompts guide the user through the entire procedure, reducing the need for highly skilled technicians and expensive training. Electronic files allow you to print, share, and store your results for easy archiving and retrieval. The BAX® system combines the speed and accuracy of DNA-based detection, the simplicity of a load-it and leave-it operation, and the familiarity of a Microsoft® Windows® interface for smooth testing procedures at any stage in the processing pipeline..
Current Users: Not specified
BAs Detected: Screening food and environmental samples for pathogens and other organisms: Bacillus anthracis and Yesinia pestis

PHYSICAL PARAMETERS

Size: 137 cm x 66 cm x 61 cm (54 in x 26 in x 24 in)
Weight: Not specified
Power Requirements: Dedicated 100 V ac to120 V ac, 60 Hz, 15 A circuit or 220 V ac to 240 V ac , 50 Hz, 10 A circuit
Optional: uninterruptible power supply and line noise filter

GENERAL

GeneTAC Biochip System

Genomic Solutions
4355 Varsity Drive
Ann Arbor, MI 48108
Vice President, North American Sales
Jim Woynerowski
877–436–6642 (Tel) ext. 326
jim.woynerowski@genomicsolutions.com
http://www.genomicsolutions.com/

Vendor Response: No
Evaluated: No

Technology: Molecular/Protein Array

Availability: Not specified
Portability: Fixed-Site Detection System
Detection Category: DNA Biochip and Protein array
Protein arrays were produced using the company's GeneTAC G3 Library Management System configured with the microarray production tool in combination with FAST(TM) glass slides from Schleicher and Schuell.
GeneMachines UC4 and UC4x4 Microarray Scanners are compact, easy-to-use 2 or 4 color microarray scanners combining simplicity with performance. High-throughput imager/analyzer that does not compromise sensitivity.
Application: Not specified
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

Matrix-Assisted Laser Desorption Ionization-TOF Mass spectrometer (MALDI-TOF-MS)

Kratos Analytical Inc.
100 red Schoolhouse Road
Building A
Chestnut Ridge, New York 10977
845–426–6700 (Tel)
845–426–6192 (Fax)
Kratos Instruments

Vendor Response: No
Evaluated: No

Technology: Hybrid/MS

Availability: Military
Portability: Fixed-Site Detection System
Detection Category: Mass Spectrometry–TOF
MALDI TOF MS
Application: Not specified
Current Users: Not specified
BAs Detected: Intact microorganisms at genus, species and strain level

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

Bio Smoke Detector

LLNL
7000 East Ave.
Livermore, California 94550–9234
P.O. Box 808
Livermore, California 94551–0808
925–422–1100 (Tel)
925–422–1370 (Fax)
925–422–2529 (Fax verification)
http://www.llnl.gov/
http://www.zhdanov.ru/classified-catalogue/k-companies/kratos_analytical.htm

Vendor Response: No
Evaluated: No

Technology: Physical/Flow cytometry and PCR
Availability: Not specified
Portability: Fixed-Site Detection System
Detection Category: Autonomous Pathogen Detection System (APDS)-II uses capture beads coated with antibodies specific to the target pathogen. It consists of an aerosol collector, a sample preparation subsystem, and two subsystems for detecting and analyzing the samples: one based on PCR and the other based on flow Cytometry, which uses antibodies to identify pathogens.
Application: Air sampler—gathers an air sample every 30 min. Autonomous and continuous testing with no human direction, the system will perform on its own, monitoring 24 h/d, 7 d/wk.
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

MJ Research—The BaseStation®

MJ Research, Inc.
5350 Capital Court, #102
Reno, Nevada 89502
888–735–8437 (Tel)
617–972–8180 (Tel)
POC: John Hansen
617–972–8157 (Tel)
617–923–8080 (Fax)
http://www.mjr.com/html/instruments/index.html

Vendor Response: No
Evaluated: No

Technology: Molecular/Sequencers and Genotypers

Availability: Not specified
Portability: Fixed-Site Detection System
Detection Category: The BaseStation® platform offers benefits that matter most: great data quality, versatility and low cost. The instrument centers around the performance of horizontal ultra-thin gels, which separate DNA fragments with the speed of capillaries, but with the consistency and robustness of cross-linked gels.
For higher-throughput environments, the BaseStation analyzer is equipped with an internal automated gel loader. The gel loader transfers samples from 96- or 384-well microplates directly onto a 100-lane gel. For medium throughput users, the economical BaseStation51™ analyzer exploits all of the same performance characteristics in a 51-lane format.
Application: A 4-color capability accommodates a variety of applications utilizing standard sequencing chemistries and visible-range dyes. Sensitive optical detection delivers high signal-to-noise ratio, wide dynamic range, and a low detection limit.
Fast run times resolve 500 bases in as little as 1 h. Long reads averaging 1100 bases, with reads out to 1300 bases, make this the longest reading 4-color instrument available. Cartographer™ analysis software supports a wide range of applications, including sequencing (using the Phred basecaller), microsatellite genotyping, SNP analysis and detection, AFLP®, and SSCP. Low running costs are made possible by the instrument's sensitivity, which allows reagents and standards to be diluted without loss in data quality.
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

DNA Engine Opticon™ Continuous Fluorescence Detection System

MJ Research, Inc.
5350 Capital Court, #102
Reno, Nevada 89502
888–735–8437 (Tel)
617–972–8180 (Tel)
POC: John Hansen
617–972–8157 (Tel)
617–923–8080 (Fax)
http://www.mjr.com/html/instruments/index.html

Vendor Response: No
Evaluated: No

Technology: Molecular/Q-PCR

Availability: Not specified
Portability: Fixed-Site Detection System
Detection Category: Multicolor capability allows detection of SYBR® Green I or FAM in the first channel, and a range of fluorophores in the second channel—including TET, HEX, VIC, and TAMRA—for a multitude of applications such as RT-qPCR, and allelic discrimination
DNA Engine® thermal cycler offers precision thermal control and a temperature gradient feature permits simultaneous incubation at 12 different temperatures to optimize reactions in a single run.
Real-time results allow for plotting of signal intensity vs. cycle number and graphically monitoring the thermal profile during the run.
Extraordinary sensitivity permits reliable detection of one initial template copy, while delivering a linear range of up to 10 orders of magnitude in starting copy number (with appropriate chemistry).
Researcher-oriented software allows quantification of samples and generation of melting curves to verify product identity.
Innovative optical system incorporates an array of 96 LEDs for excitation and a pair of sensitive PMTs for detection in a robust, no-moving-part design.
High sample capacity accommodates up to 96 samples in standard, low-profile microplates or strip tubes making specialized disposables unnecessary.
Application: Not specified
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: A compact footprint 34 cm x 47 cm x 60 cm (13 in x 19 in x 24 in) ensures the Opticon system comfortably fits on any lab bench
Weight: Not specified

GENERAL

MiniCycler Peltier Thermal Cycler

MJ Research, Inc.
5350 Capital Court, #102
Reno, Nevada 89502
888–735–8437 (Tel)
617–972–8180 (Tel)
POC: John Hansen
617–972–8157 (Tel)
617–923–8080 (Fax)
http://www.mjr.com/html/instruments/index.html

Vendor Response: No
Evaluated: No

Technology: Molecular/Standard PCR

Availability: Not specified
Portability: Fixed-Site Detection System
Detection Category: MiniCycler instruments offer just what researchers want: speedy ramping, multiple formats, extraordinary uniformity, heated lid, and low price. These trusty tools have long set the standard for "personal cyclers" by which other brands of machines are judged.
Application: New Hot Bonnet™ heated lid
Sophisticated Peltier
Thermal accuracy: average temperature between 89.7 °C to 90.3 °C (193 °F to 194.5 °F) of programmed value 90 °C (194 °F), NIST-traceable
Thermal range: -23 °C to 41 °C (-9 °F to 105 °F)
Display: 32-character LCD
Programs: 80 typical programs
Ports: (1) Parallel printer port available for non-HB units (optional)
Available block formats: (i) 16—0.5 mL tubes, (ii)25—0.2 mL tubes or V-bottom 25-well plate
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: 22 cm x 28 cm x 11 cm (8.7 in x 11 in x 4.31 in)
Weight: 3 kg (6.6 lb)
Power Requirements: 100 V ac to 240 V ac, 50 Hz to 60 Hz, 225 W maximum

GENERAL

Peltier Thermal Cyclers PTC-100 Thermal Cycler

MJ Research, Inc. 5350 Capital Court, #102 Reno, Nevada 89502 888–735–8437 (Tel) 617–972–8180 (Tel) POC: John Hansen 617–972–8157 (Tel) 617–923–8080 (Fax) http://www.mjr.com/html/instruments/index.html **Vendor Response**: No **Evaluated**: No	

Technology: Molecular/Standard PCR

Availability: Not specified
Portability: Fixed-Site Detection System
Detection Category: PTC-100 cyclers use advanced Peltier technology to deliver accuracy, economy, and ease-of-use. Six standard models offer a range of configurations, accommodating tubes, plates, or in situ slides. Six standard models that can hold a wide variety of vessels, including 0.5 mL and 0.2 mL tubes, 96-well plates and glass slides.
Features and specifications:
• Hot Bonnet™ heated lid incorporates a thumbwheel to adjust height and pressure. This feature assures tight sealing of reaction vessels, even microplates, during oil-free thermal cycling (extra-cost option).
• Precise Peltier-effect heat pumps are robustly designed for repeated cycling and deliver the full temperature range of 0 C° to 100 °C electronically.
• Optional Slide Griddle™ adapters allow many models to cycle up to four glass slides with speed and precision.
• Speedy ramping rates of up to 1 °C/s in models that hold 0.5 mL tubes; up to 1.4 °C/s in models that hold 0.2 mL tubes or V-well plates; up to 2.5°/s in models with the silver-gold block.
• Unparalleled temperature homogeneity: ±0.4 °C within 30 s of arrival @ 60 °C for all standard models.
• Elephantine memory stores approximately 320 programs, and cycler comes with 14 preprogrammed protocols. Any sequence of temperatures can be cycled up to 10 000 times; ramping rates less than maximum may be specified.
• Extremely accurate incubations, with NIST-traceable calibration. Any temperature including below-ambient temperatures may be held indefinitely. This feature allows refrigeration after an unattended run.
• Power-failure protection will resume program after power interruptions of up to 12 hr.
• Two-year parts and labor warranty with optional extended warranties.
Application: Thermal uniformity: 59.6 °C to 60.4 °C (139 °F to 141 °F) within 30 s of arrival at 60 °C (140 °F)
Ramping Speed: 60: up to 1 °C/s , 96: up to 1.4 °C/s , 96 AgV: up to 2.5 °C/s, 16 MS: up to 0.5 °C/s
Thermal accuracy: Average temperature within ±15.6 °C (±0.5 °F) of programmed value at 60 °C, NIST-traceable
Thermal Range: 0 °C to 100 °C (32 °F to 212 °F)
Available block formats: (i) 60—0.5 mL tubes, (ii) 96—0.2 mL tubes or one 96-well plate, (iii) 16 glass slides and 24 x 0.2 mL tubes
Note: Specifications subject to change without notice.
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: 24 cm x 28 cm x 27 cm (9.4 in x 11.2 in x 10.6 in)
Weight: 7 kg (15.4 lb)
Power Requirements: 100 V ac to 240 V ac, 50 Hz to 60 Hz, 350 W maximum

GENERAL

DNA Engine® Peltier Thermal Cycler (PTC-200)

MJ Research, Inc.
5350 Capital Court, #102
Reno, Nevada 89502
888–735–8437 (Tel)
617–972–8180 (Tel)
POC: John Hansen
617–972–8157 (Tel)
617–923–8080 (Fax)
http://www.mjr.com/html/instruments/index.html

Vendor Response: No
Evaluated: No

Technology: Molecular/Standard PCR

Availability: Not specified
Portability: Fixed-Site Detection System
Detection Category: The DNA Engine instrument is the cycler that revolutionized thermal cycling. Unprecedented thermal uniformity and swappable blocks ensure consistent results, experiment-to-experiment and block-to-block. This rugged machine is more than just a cycler, it's a platform for new features and upgrades as research needs evolve.
DNA Engine featuring Dual Alpha™ unit with 96-well and Power Bonnet™ Alphas alongside.
Application: Features of the DNA Engine thermal cycler include a single-bay cycler accommodates over 10 different Alpha™ sample blocks, including independently controlled dual blocks; temperature gradient capability employs dynamic ramping, guaranteeing consistent hold times across all sample wells; and upgradable to real-time fluorescence detection with the Opticon™ or Opticon 2 retrofit.
Advantages of all DNA Engine® systems include swappable Alpha unit sample blocks are designed for frequent change, they can be swapped in seconds; they seat many types of reaction vessels; independently controlled dual blocks are available for running two different protocols simultaneously; gradient capability is standard on all DNA Engine systems when fitted with 96-well Alpha units.
Unique Peltier heat pumps are built by MJ Research specifically for cycling. Years of experience and proprietary technologies make MJ modules last longer than any other. Multi-zone feedback control utilizes multiple sensors combined with four "zones" for heating and/or cooling to optimize thermal profiles every 50 millisecond. Extraordinary temperature uniformity of 89.6 °C to 90.4 °C (193 °F to195 °F) within 30 s of arrival at 90 °C (194 °F)—(well-to-well) average, all Alphas). Superb thermal accuracy of blocks within 89.7 °C to 90.3 °C (193 °F to195 °F) of NIST standard at 90 °C (194 °F)—average across block, all Alphas.
Thermal range of -5 °C to 105 °C (23 °F to 221 °F). Rapid ramp rates of up to 3.0 °C/s. Two thermal control options block control or calculated control. Choice of two heated-lid designs accommodates many vessel types and various sealing options, allowing maximum flexibility in experimental designs. Heated lid temperatures can be set with any DNA Engine instrument. Manual Hot Bonnet® heated lid with a unique thumbwheel for adjusting height and pressure.
Power Alpha™ units can be remotely commanded to open, close, and adjust height and pressure. Alternatively it may be opened and closed with the touch of a button. Thermal uniformity: 89.6 °C to 90.4 °C (193 °F to195 °F) within 30 s of arrival at 90 °C (194 °F). Ramping speed: Up to 3 °C/s, varies with block. Thermal Accuracy: Average temperature within 89.7 °C to 90.3 °C (193 °F to195 °F) of programmed value at 90 °C (194 °F), NIST-traceable. Thermal Range: -5 °C to 105 °C (23 °F to 221 °F). Eleven available block formats.
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: Base only: 24 cm x 33 cm x 24 cm (9.5 in x 13 in x 9.54 in)
Weight: 9 kg (19.8 lb) chassis and Alpha™ unit
Power Requirements: 100 V ac to 240 V ac, 50 Hz to 60 Hz, 850 W maximum, 11.5 A maximum

GENERAL

DNA Engine Dyad Thermal Cycler and DNA Engine Tetrad Cycler

MJ Research, Inc.
5350 Capital Court, #102
Reno, Nevada 89502
888–735–8437 (Tel)
617–972–8180 (Tel)
POC: John Hansen
617–972–8157 (Tel)
617–923–8080 (Fax)
http://www.mjr.com/html/instruments/index.html

Vendor Response: No
Evaluated: No

Technology: Molecular/Standard PCR

Availability: Not specified
Portability: Fixed-Site Detection System
Detection Category: The DNA Engine Dyad instrument is the most advanced thermal cycler ever made. Featuring MJ's world-class thermal performance, the Dyad™ also boasts graphical programming and color display, as well as point-and-click navigation via touch pad or mouse. The Dyad can be easily and economically expanded to a four-bay system with the addition of a Dyad Disciple™ thermal cycler.
Application: Features of the DNA Engine Dyad thermal cycler include dual-bay cycler accommodates any combination of more than 10 different Alpha sample blocks, with an incredibly small footprint. The internal power supply requires between 200 V and 240 V.
Ethernet capability allows instant updating of new software features. Expandable with a Dyad Disciple cycler to a 4-bay system under full control of the Dyad user software, capable of running up to 8 independently controlled blocks (when equipped with 4 Dual Alpha blocks).
Advantages of all DNA Engine® systems include swappable Alpha unit sample blocks are designed for frequent change; they can be swapped in seconds; they seat many types of reaction vessels. Independently controlled dual blocks are available for running two different protocols simultaneously. Gradient capability is standard on all DNA Engine systems when fitted with 96-well Alpha units. Unique Peltier heat pumps are built by MJ Research specifically for cycling. Years of experience and proprietary technologies make MJ modules last longer than any other. Multi-zone feedback control utilizes multiple sensors combined with 4 “zones” for heating and/or cooling to optimize thermal profiles every 50 milliseconds. Extraordinary temperature uniformity of 89.6 °C to 90.4 °C (193 °F to195 °F) within 30 s of arrival at 90 °C (194 °F)—(well-to-well) average, all Alphas). Superb thermal accuracy of blocks within 89.7 °C to 90.3 °C (193 °F to195 °F) of NIST standard at 90 °C (194 °F)—(average across block, all Alphas). Thermal range of -5 °C to 105 °C (23 °F to 221 °F). Rapid ramp rates of up to 3.0 °C/s
Two thermal control options, block control or calculated control. Choice of 2 heated-lid designs accommodate many vessel types and various sealing options, allowing maximum flexibility in experimental designs. Heated lid temperatures can be set with any DNA Engine instrument. Manual Hot Bonnet® heated lid with a unique thumbwheel for adjusting height and pressure. Power Alpha™ units can be remotely commanded to open, close, and adjust height and pressure. Alternatively it may be opened and closed with the touch of a button. Thermal Uniformity: ±0.4 °C within 30 s of arrival at 90 °C. Thermal Accuracy: Average temperature within ±0.3 °C of programmed value at 90 °C, NIST-traceable. Speed of Ramping: Up to 3 °C/s. Thermal Range: 0 °C to 105 °C (32 °F to 221 °F). Available block formats: 11. Gradient Specifications (96-well Alpha block only). Temperature gradient accuracy: ±0.3 °C of target at end columns within 30 s of arrival at programmed target, NIST-traceable. Thermal column uniformity: ±0.4 °C, in column, well-to-well, within 30 s of target attainment. Calculator accuracy: ±0.4 °C of actual column temperature, NIST-traceable. Lowest temperature for gradient: 30 °C (86 °F). Highest temperature for gradient: 105 °C (221 °F). Temperature differential range: 1 °C to 24 °C (33.8 °F to 75 °F).
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

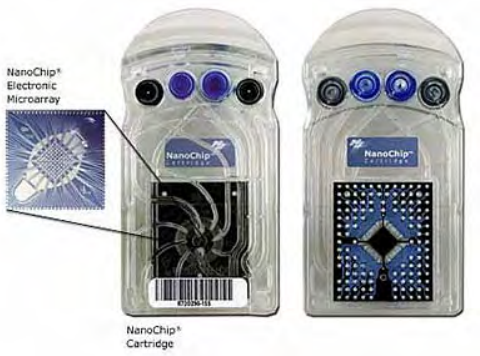
Size: Base only: 48 cm x 29 cm x 15 cm (18.9 in x 11.4 in x 5.9 in)
Weight: 17 kg (37.5 lb) chassis and two Alpha™ units
Power Requirements: 200 V ac to 240 V ac, 47 Hz to 63 Hz, 1600 W maximum, 8 A maximum, Nema L6/p20 plug

GENERAL

On-Chip Amplification

Nanogen
10398 Pacific Center Ct.
San Diego, California 92121
877–NANOGEN (Tel)
(8:00 am to 5:00 pm, PST)
858–410–4952 (Fax)
techsupport@nanogen.com
http://www.nanogen.com/

Vendor Response: No
Evaluated: No



Technology: Molecular/Strand Displacement Amplification (SDA)

Availability: Not specified
Portability: Fixed-Site Detection System
Detection Category: Nanogen has a license to Strand Displacement Amplification (SDA) for clinical applications through our relationship with Becton, Dickinson, and Company. SDA enables rapid, exponential amplification of DNA in an isothermal reaction, simplifying detection of low levels of diagnostic targets. The speed and specificity of SDA are ideally suited for use with Nanogen's technology.
SDA can be performed directly on the NanoChip® Cartridge. SDA oligonucleotide primers are electronically addressed and anchored to discrete test sites on the electronic microarray. Rapid (2 min to3 min) hybridization of target DNA to the SDA primers is facilitated by electronic concentration of genomic DNA to those sites.
After hybridization, a DNA polymerase extends the anchored SDA primers, using the hybridized target as template. The combined action of the polymerase and a restriction endonuclease are utilized to exponentially amplify the target sequence. The products of the amplification reaction are double-stranded target sequences with one strand anchored to the test site.
For genotyping the amplified SNP or STR locus, the unanchored strand is removed and the anchored strand is probed with a fluorescent reporter oligonucleotide. Several methods of genotype discrimination have been developed, including the oligonucleotide stabilizer procedure.
Application: Not specified
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

NanoChip® Molecular Biology Workstation

Nanogen
10398 Pacific Center Ct.
San Diego, California 92121
877–NANOGEN (Tel)
(8:00 am to 5:00 pm, PST)
858–410–4952 (Fax)
techsupport@nanogen.com
http://www.nanogen.com/

Vendor Response: No
Evaluated: No

Technology: Molecular/Microarray-Workstation

Availability: Not specified
Portability: Fixed-Site Detection System
Detection Category: The heart of our technology, the NanoChip® Electronic Microarray, is a tiny silicon chip. Tiny but powerful. For this little chip holds the power of electricity.
Application: Current applications performed on the NanoChip® array include single nucleotide polymorphisms (SNPs), short tandem repeats (STRs), insertions, deletions, and other mutation analyses. Each of these is a genetic marker used in cutting-edge clinical research and clinical diagnostics. In addition, we are continuously expanding our capabilities and have under development on-chip non-PCR amplification. On-chip amplification simplifies testing by amplifying genetic material on the microarray, making variations easier to detect with greater reliability and speed. Using electricity, this new generation of microarray is more accurate, faster, and more flexible than other available technologies.
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: Chip size: 0.7 sq cm
Array dimensions: 2 sq mm
Test site size: 80 µ
Distance between site centers: 200 µ
Number of test sites: 100
Weight: Not specified

GENERAL

Isothermal Sequencing and Cycling Primer

Nugen Technologies Inc.
821 Industrial Road, Unit A
San Carlos, California 94070
650–590–3600 (Tel)
650–590–3630 (Fax)
Product Information
sales@nugeni.com
Order placement and customer service:
custserv@nugeninc.com
http://www.nugeninc.com/technology/other.shtml

Vendor Response: No
Evaluated: No

Technology: Microarray/DNA Microarray SPIA™ Technology

Availability: Not specified
Portability: Fixed-Site Detection System
Detection Category: Isothermal Sequencing and Cycling Primer Methods:
In addition to SPIA™ technolology, NuGEN has developed a patented nucleic acid sequence detection method called Isothermal Sequencing, and a novel SNP genotyping method called Cycling Primer (patent pending). Both methods integrate signal amplification and signal generation in one rapid step. These approaches enable homogeneous detection of specific nucleic acid sequences, i.e., one-step genotyping, as well as signal generation for future research and clinical applications such as proteomics and immunoassays. Isothermal Sequencing and Cycling Primer technologies are exceedingly simple, fast, and cost-effective methods that will be ideally suited for integration into miniaturized devices.
eXponential Single Primer Isothermal Amplification:
NuGEN has also developed a proprietary exponential isothermal amplification method called X-SPIA™ (eXponential Single Primer Isothermal Amplification; patent pending) for applications requiring very high amplification efficiency (e.g., detecting very low levels of pathogenic agents). Both SPIA™ and X-SPIA™ methods produce single-stranded copies of the target sequence, and are readily amenable to integration with microarrays or microfluidic chips.
Application: Not specified
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

minFlow Cytometer

Office of Naval Research
Ballston Center Tower One
800 North Quincy Street
Arlington, Virginia 22217–5660
703–696–5031 (Tel)
703–696–5940 (Fax)
Naval Research Laboratory

Vendor Response: No
Evaluated: No

Technology: Physical/Flow Cytometry
Availability: Military
Portability: Fixed-Site Detection System
Detection Category: Flow Cytometry
Application: Analytical
Current Users: Not specified
BAs Detected: Multiple analyte bioassay detection system

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

HiLight Array Detection System

Qiagen
28159 Avenue Stanford
Valencia, California 91355
800–426–8157 (Tel)
800–718–2056 (Fax)
http://www.qiagen.com/

Vendor Response: No
Evaluated: No

Technology: Molecular/Array-based

Availability: Commercial
Portability: Fixed-Site Detection System
Detection Category: DNA Array
Application: Not specified
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

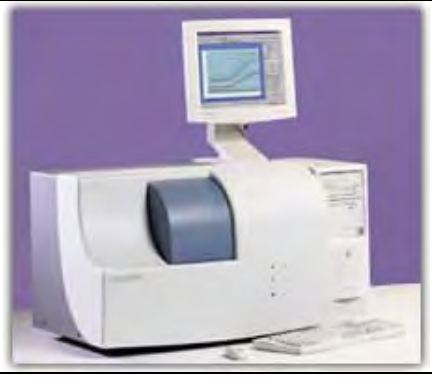
Size: Not specified
Weight: Not specified

GENERAL

Mx4000® Multiplex Quantitative PCR System

Stratagene Inc.
11011 N. Torrey Pines Road
La Jolla, California 92037
POC: Mike Metzler
800–894–1304 (Tel)
858–535–0034 (Fax)
tech_services@stratogene.com
http://www.stratagene.com/contact.htm

Vendor Response: No
Evaluated: No



Technology: Molecular/Q-PCR

Availability: Not specified
Portability: Fixed-Site Detection System
Detection Category: New System for Advanced Q-PCR

Stratagene delivers a new standard in Q-PCR with the Mx4000™ multiplex quantitative PCR system. This new system offers superior performance, more flexibility, and reasonable pricing.

• Exceptional Reliability and Reproducibility.
• Real-time plots while your PCR progresses.
• Superior dye discrimination.
• Better temperature uniformity.

Real-time quantitative PCR (Q-PCR) allows researchers to quickly and easily quantify nucleic acids for studying gene expression, mutational analysis, disease state, and gene dosage. Q-PCR measures PCR product accumulation during the exponential phase of the reaction and before amplification becomes vulnerable to limiting reagents and cycling variability. Fluorescent Q-PCR data provides accurate information on initial starting copy number.

Using Q-PCR, amplification and detection are combined in a single step and in a single closed tube. This eliminates the need for numerous post-PCR manual steps, and reduces the possibility of introducing variability or laboratory contamination.

Application: The Mx4000 system detects multiple fluorescent PCR chemistries and combines the capabilities of a microplate fluorescence reader with a PCR thermal cycler into a single real-time detection system. The Mx analyzer integrates precision thermal control with a multi-wavelength detection system. Applications include allelic discrimination, plate reads, melting curves, and quantification of single or multiplexed targets. The Mx4000 multiplex quantitative PCR system provides a detection range of 350 nm to 830 nm, allowing greater flexibility of fluorophore choice, providing high sensitivity and excellent signal-to-noise ratio. The Mx4000 system's light source generates an extended excitation range from 350 nm to 750 nm. This allows choosing of fluorophores with little or no spectral overlap, producing clean, delineated signals for superior multiplexing. Each of the four scanning fiber-optic heads independently excites and detects dyes, reading up to 4 different dyes in a single tube.

Optimized filters: Optimized interference filters precisely match the excitation and emission wavelengths for each fluorophore to block out unwanted cross-talk from spectrally adjacent fluorophores. Researchers can choose from FAM, TET, HEX/JOE/VIC, TAMRA, Texas Red/ROX, Cy5, and Cy3 filter sets. Custom filter sets are also available for other fluorophores.

Intuitive, easy-to-use software: Your options are increased with new features such as real-time amplification plots that can be viewed as your PCR progresses. It makes many applications easier than ever before, such as real-time and plate-read allelic discrimination, real-time Q-PCR, qualitative detection, and melting curve profiles.

View Real-Time Plots while PCR Progresses: Many features are included, including real-time amplification plots as the run progresses. This allows you to determine at a glance how an experiment is running at any time during thermal cycling, rather than waiting until the end of the run. You can choose to abort a run if a problem develops in a reaction, or stop the experiment and save the data as soon as the desired information is generated.

The ability to make allelic discrimination calls by endpoint fluorescence values, as well as by threshold cycle is also featured. Data can be viewed in many forms including amplification plots, scatter plots, sample value screens for the entire plate for all dyes, fluorescence intensity screen, final call results, melting curves, annealing range, and text reports. A time-saving protocol allows you to select a subset of the 96 wells for independent analysis, allowing you to perform multiple sub-experiments on a single plate.

Better temperature uniformity for more precise PCR: The thermal system delivers unsurpassed temperature control to the sample, using patent-pending solid-state heating and cooling technology. Superior thermal ramp rates, unparalleled thermal

accuracy, and the best temperature uniformity in a 96-well plate format are performance benefits of this advanced system. The extremely low thermal mass of the sample thermal control block promotes rapid changes in temperature, so your experiments are completed in less time. A typical 96-sample quantitative PCR thermal profile of 40 cycles can be completed in less than 90 min.

Better communication between instrument and PC: The software establishes robust communication between the instrument and the attached personal computer. Even in the event of a power loss to the PC or communications error, data collection continues. When communication is restored, the data from the run is transferred from the instrument's embedded software to the software on the PC, ensuring that the experiment will be completed and your data successfully saved.

Current Users: Not specified

BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: 76 cm x 46 cm x 51 cm (30 in x 18 in x 20 in)

Weight: 50 kg (110 lb)

Power Requirements: Electrical power

GENERAL

Aerosol TOF Mass Spectrometer (ATOFMS)

TSI, Inc.
500 Cardigan Road
Shoreview, Minnesota 55126-3996
651–483–0900 (Tel)
651–490–2748 (Fax)
tsiinfo@tsi.com
http://www.tsi.com

Vendor Response: No
Evaluated: No

Technology: Hybrid/MS

Availability: Military and commercial
Portability: Fixed-Site Detection System
Detection Category: Mass Spectrometer
Application: Mass Spectrometry–TOF
Determines size and chemical composition of individual aerosol particles in near real-time
Current Users: Not specified
BAs Detected: BAs

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

Ultra Violet Aerodynamic Particle Sizer (UVAPS)

TSI Incorporated
500 Cardigan Road
Shoreview, Minnesota 55126-3996
651–483–0900 (Tel)
651–490–2748 (Fax)
tsiinfo@tsi.com
http://www.tsi.com

Vendor Response: No
Evaluated: No

Technology: Hybrid/MS

Availability: Military
Portability: Fixed-Site Detection System
Detection Category: Mass Spectrometry
Quantification capabilities: Fluorescence plus aerodynamics size and scattered-light intensity.
Measures fluorescence characteristics of individual particles in real-time, allowing for identification of airborne biological particles.
Application: Not specified
Current Users: Not specified
BAs Detected: Particles of BAs

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

(J-Series Modulator) Non-Dispersive InfRed (NDIR)

OPTRA, Inc.
461 Boston Street
Topsfield, Massachusetts 01983
978–887–6600 (Tel)
978–887–0022 (Fax)
sales@optra.com
http://www.optra.com

Vendor Response: No
Evaluated: No

Technology: Hybrid/NDIR/Screening

Availability: Not specified
Portability: Standoff
Detection Category: IR spectrometry
Nondispersive IR (NDIR)
Application: Standoff
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

Joint Biological Point Detection System (JBPDS)

Developed for U.S. Army SBCCOM General Dynamics Armament and Technical Products Four LakePointe Plaza 2118 Water Ridge Parkway Charlotte, North Carolina 28217 Subcontractor: Battelle, Columbus, Ohio 703–414–1800 (Tel) 703–414–1823 (Fax) GDBusDev@gdatp.com **Vendor Response**: No **Evaluated**: No	

Technology: Optical/Fluorescence

Availability: Full rate production of Block I is expected to begin in FY 2004 for an objective of full operation capability wiith 152 systems in FY 2007, afterwhich Block II production may begin.
Portability: Standoff/Remote/Monitoring
Detection Category: Laser-induced fluorescence
The Joint Biological Point Detection System (JBPDS) is a robust bio-detection instrument suite that is fully functional in any operational environment the user may encounter in their operations.
It provedes automatic detection and identification of airborne biological agents at very low levels, triggers local and remote warning systems, and communicates threat information over standard communication systems.
Using laser-induced fluorescence, the trigger/detector continuously evaluates the atmospheric background for traces of potential biological agents. When the system detects something of a suspicious nature, the collector/concentrator is initiated to sample hundreds of liters of air per minute, providing a small amount of liquid containing the collected aerosol sample.
This sample is then evaluated for specific biological agents using immunoassays (similar to a litmus strip) with an automated reader assembly. If the assay shows signs of biological agents, an alarm is sounded and a portion of the collected sample is provided for later analysis at a certified laboratory. The entire operation is automated.
Application: Target Applications: HMMWV-mounted shelters (M31E2 BIDS); Light Armored Vehicles (LAV, Stryker, NBCRV, and JSLNBCRS); and shipboard, shore, and port facilities
Current Users: Not specified
BAs Detected: Not specified

PHYSICAL PARAMETERS

Size: BBSU: 76.2 cm x 91 cm x 51 cm (30 in x 36 in x 20 in)
Ship and shelter power packs: 23 cm x 53 cm x 46 cm (9 in x 21 in x 18 in)
MP/TR/fixed power packs: 25 cm x 91 cm x 64 cm (10 in x 36 in x 25 in)
MP/TR/fixed only: 76.2 cm x 51 cm x 33 cm (30 in x 20 in x 13 in)
Weight: BBSU 125 kg (275 lb)
Ship and shelter power packs 29.5 kg (65 lb)
MP/TR/fixed power packs 91 kg (200 lb)
MP/TR/fixed only 45 kg (100 lb)

GENERAL

4WARN CB Systems V.2: Real Time BA Detection

General Dynamics
3785 Richmond Road
Ottawa, Ontario, Canada
K2H 5B7
613–596–7000 (Tel)
613–820–5081 (Fax)
E-mail: wwwinfo@gdcanada.com
1020 - 68th Avenue N.E
Calgary, Alberta, Canada
T2E 8P2
403–295–6700 (Tel)
403–295–6790 (Fax)
http://www.gdcanada.com/

Vendor Response: No
Evaluated: No

Technology: Optical/Fluorescence

Availability: Military and commercial
Portability: Standoff/Remote/Monitoring
Detection Category: Generic detection: Fluorescence Particle Detection, Biological Real Time Sensor (BARTS).
Identification: Antibody assay strips and automated reader. Self contained automated multi-assay reader (SCAMAR).
Concentrators: Particle impingers. 4WARN V.2 MicroVic Concentrator, which is integral with BARTS, 28 L/min.
Sample collectors: Triggered by fluorescence particle detector.
400 L/min MicroVic with impingement module.
Dry samples for verification sample.
Application: 4WARN V.2 is a fully-automated third generation biological agent detection and identification system based on field-proven fluorescence particle detection for real-time detection of biological agents and anti-body based assays for identification of specific agents.
Current Users: Not specified
BAs Detected: Generic detection of all BAs. Identification of all bio agents for which assay strips can be procured from JPO Bio Defense. Identification of 11 agents simultaneously by combined assay strips.

PHYSICAL PARAMETERS

Size: 2 boxes each 30.5 cm x 40.6 cm x 55.9 cm (12 in x 16 in x 22 in)*
Bio Sentry and Bio Ident (includes SCAMAR)
*Not including concentrator
Weight: 45 kg (100 lb) per box
Power Requirements: 400 W normal, 115/22 V, 12/24 V, battery capable

GENERAL

4WARN CB Systems V.3: Real Time BA Detection

General Dynamics
3785 Richmond Road
Ottawa, Ontario, Canada
K2H 5B7
613–596–7000 (Tel)
613–820–5081 (Fax)
wwwinfo@gdcanada.com
1020 - 68th Avenue N.E
Calgary, Alberta, Canada
T2E 8P2
403–295–6700 (Tel)
403–295–6790 (Fax)
http://www.gdcanada.com/

Vendor Response: No
Evaluated: No

Technology: Optical/Fluorescence

Availability: Military and commercial
Portability: Standoff/Remote/Monitoring
Detection Category: Fluorescence, immunoassay, and combines sampling
Application: General Dynamics Canada's involvement in Biochemical agent detection and identification stems from its work in response to the Canadian Forces' program for a CIBADS. As the lead in an Integrated Product Team, General Dynamics Canada has worked with the Canadian Defense Research Establishment Suffield (DRES), the University of Alberta, the Canadian Forces, SIL, Dycor, and TSI to produce the CIBADS Advanced Development Model. CIBADS forms the basis for the 4WARN family of real-time biochemical agent detection and identification systems. CIBADS is a broad-spectrum, real-time CB detection and identification system, which responds to critical requirements including:
Detect biological and chemical agents in time to warn and protect personnel in real time (seconds rather than minutes); identify biological and chemical agents in time to treat casualties (chemical agents under 1 min, BAs in under 1 min to 5 min); collect samples for off-site verification and absolute proof of agent use; and monitor levels of contamination.
Current Users: Not specified
BAs Detected: All BAs

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

Biological Aersol Warning (BAWS)

Lockheed Martin
Naval Electronics and Surveillance Systems,
NBC Defense Systems, Manassas
9500 Godwin Drive
Manassas, Virginia 20110
703–367–1546 (Tel)
703–367–5576 (Fax)
http://www.lmco.com/manassas

Vendor Response: No
Evaluated: No

Technology: Optical/Fluorescence

Availability: Military and commercial
Portability: Standoff/Remote/Monitoring
Detection Category: The Biological Aerosol Warning System (BAWS) is UV-fluorescence-based bioaerosol detection system. BAWS is an array of point biological aerosol detectors networked to detect BAs. The system is intended for a remote, early detection capability for biological attack and for perimeter monitoring of key areas and high-value assets. Comprised of a network of Remote Detection Stations, a Base Control Station, and a PC Analysis Workstation, BAWS provides an overall picture of a developing biological attack with detection, wind-speed and direction, and location data. Remote stations transfer information to the base station where it is collated to help determine appropriate alarm conditions and generate necessary NBC reports. The PC Analysis Workstation allows the operator to monitor the status of the deployed network and, when necessary, to check the status of each sensor individually. When linked with a chemical sensor (e.g., M8A1, M90, M22 ACADA, etc.) BAWS becomes CBAWS (Chemical Biological Warning System). In addition, the BAWS is configured to allow easy integration with other types of sensors (i.e., motion detectors, IR sensors, etc.) in order to create a customized overall perimeter monitoring system.
Application: This equipment can be used for the following purposes: chemical sensor; Airborne Particle Counter (APC); electronic compass; GPS; communications controller; air mass sensor; network radio; discrete alert systems connectivity. Target applications include airfields, naval bases/port facilities, support areas, special forces, key public venues, and sensitive facilities.
Current Users: Not specified
BAs Detected: CBAs

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

Fluorescence Aerodynamic Particle Sizer (FL/APS II)

TSI, Inc.
500 Cardigan Road
Shoreview, Minnesota
55126–3996
651–483–0900 (Tel)
651–490–2748 (Fax)
tsiinfo@tsi.com
http://www.tsi.com

Vendor Response: No
Evaluated: No

Technology: Optical/Fluorescence

Availability: Not specified
Portability: Standoff/Remote/Monitoring
Detection Category: FL/APS II is the first APS which can measure the intrinsic fluorescence of particles counting living organisms.
Application: It is able to distinguish, in real time, those particles in air which contain living organisms from all other background particles.
Current Users: Not specified
BAs Detected: Detects low concentration of man-made aerosols such as BAs clouds

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified

GENERAL

The BioHAZ™ Kit

EAI Corporation
1308 Continental Drive Suite J
Abingdon, Maryland 21009
888–676–1449 (Tel)
410–676–1449 (Tel)
410–671–7241 (Fax)
marketing@eaicorp.com
http://www.eaicorp.com/

Vendor Response: No
Evaluated: No

Technology: Immunochemical/Sampling, Screening, Analysis

Availability: Not specified
Portability: Handheld Detection Equipment
Detection Category: Lateral Flow Immunochromatography/Screening
Liquid and solid sampler and screening device
Sample screening is conducted through fluorometry, luminescence, colorimetry, and sample specific analyses are performed through the use of sensitive membrane antigen rapid tests.
Application: Target applications: HAZMAT trained technicians and environmental technicians and hygienists. The BioHAZ™ is a portable field system designed for use by emergency response personnel at incidents where biological materials may be present, and sample collection and analysis are necessary. The system contains all materials necessary to collect liquid and solid samples and collection of air sampling media for on-site biological analysis. The system prescribes detailed instructions to ensure sample integrity, resulting in legally defensible data. The BioHAZ™ is designed to allow the user to select the proper sampling package which includes items found in kit component list on back. Step-by-step instructions from preparation for entry into the hot zone through sample splits, analysis, and transfer to law enforcement are included. The system is packaged in rugged, portable, water-tight containers with each sample collection kit and sample processing kit marked for easy locating and use. All sampling/processing kits and other individual components are designed to be disposable and replaceable.
• Designed for HAZMAT personnel working in Level A, B, and C PPE.
• Environmental technicians and hygienists.
• Medical and forensic evidence collection teams.
• Based on proven technology for collection, screening and analysis of biological warfare agents.
• Employs current best practices for evidentiary process control methodology to maintain sample integrity.
• Meets GMP cleanliness standards.
• Flowcharts illustrate step-by-step use instructions.
• New emerging technology for specific biological analysis is also available upon request.
Current Users: Not specified
BAs Detected: New emerging technology for specific biological analysis is available upon request

PHYSICAL PARAMETERS

Size: Small, size of slides
Weight: Not specified
Power Requirements: Not applicable

APPENDIX H—BIOLOGICAL SAMPLING EQUIPMENT

APPENDIX H—BIOLOGICAL SAMPLING EQUIPMENT

Name	Manufacturer	Detection System Used	ID#	Page H–#
Biotest RCS Plus Handheld Microbial Air Sampler	Biotest Diagnostics Corporation	Air sampler–impaction principle	1	H–1
air IDEAL	Biomeriux	Air sampler–impaction principle	2	H–2
Surface-Air System (SAS) Super 100 Air Sampler	Bioscience International	Air Sampler	3	H–3
Intelligent Cyclone Air Sampler (ICAS)	Biotrace International	Air sampler—wetted-wall cyclone	4	H–4
Cyclone sampler for airborne particles	Burkard Manufacturing Co. Limited	Air sampler—reverse-flow cyclone	5	H–5
BIO SAS	Bioscience International	Bioaerosol sampler	6	H–6
Dry Filter Unit (DFU)	Joint Program Office for Biological Defense (JPO-BD)	Air sampling—dry filter unit	7	H–7
BioCapture® BT-550 Air Sampler	MesoSystems Technology, Inc.	Air sampler	8	H–8
BioCapture® 650	MesoSystems Technology, Inc.	Air sampler	9	H–9
MicroVIC® Aerosol Concentrator	MesoSystems Technology, Inc.	Air sampler—impaction principle	10	H–10
CyClex Deluxe Kit (120160)	EMS Environmental Monitoring Systems	Air sampler—impaction principle	11	H–11
SASS 2100 Wetted-Wall Cyclone Air Sampler	Research International	Air sampler—wetted-wall cyclone	12	H–12
SASS 2000 Plus™ Smart Air Sampler System	Research International	Air sampler—wetted-wall cyclone	13	H–13
SASS 3000 Dry Air Sampler	Research International	Air sampler—collection by novel, dry filter media	14	H–14
SpinCon® Advanced Air Sampler	Sceptor Industries, Inc.	Air sampler—wet concentrator	15	H–15
The SKC BioSampler®	SKC, Inc.	Air sampler—impinger	16	H–16
Staplex® Microbial (Viable Particle) Air Samplers	The Staplex® Company	Air sampler	17	H–17
Cascade Impactors	Thermo Electron Corporation	Air sampler—non-viable impactor	18	H–18
Portable Single-Stage Bioaerosol Sampler	Thermo Hybaid	Air sampler	19	H–19
DIO-SIBCA, Sampling and Identification Kit NATO Stock # 6665-27-012-2714	DIOMED Defense Systems Technologies	Liquid sampler	20	H–20
Incident Response Sample Collection Kit	EAI Corporation	Air, liquid, and solid sampling	21	H–21
CarpetChek System	Aerotech Laboratories, Inc.	Surface sampling—vacuuming	22	H–22

Name	Manufacturer	Detection System Used	ID#	Page H–#
BiSKit Kit QS Kit (FACTM)	QuickSilver Analytics, Inc.	Surface sampling	23	H–23
Chemical-Biological Sampling Kit, FAC™ Model 102	QuickSilver Analytics, Inc.	Surface sampling	24	H–24
S3 Bio Sampling Kits	QuickSilver Analytics, Inc.	Surface sampling	25	H–25
Chemical and Biological Individual Sampler (CBIS)	CyTerra Corporation	Sampler	26	H–26

GENERAL

Biotest RCS Plus Handheld Microbial Air Sampler

Biotest Diagnostics Corporation
HYCON® Division
66 Ford Road, Suite 220
Denville, New Jersey 07834
973–625–1300 (Tel)
800–522–0090 (Tel)
973–625–9454 (Fax)
www.biotestusa.com/industrial/industrial.htm

Unit Cost: Not specified

Technology Area: Air sampler–impaction principle

Mobility: Handheld
Current Users: Not specified
Application: Airborne microorganisms impact onto agar media strip by centrifugal force.
Use the Biotest RCS PLUS air sampler to evaluate the microbiological quality of ambient air, the functionality of air treatment equipment and systems, and the effectiveness of decontamination measures. Just fit an agar media strip around the rotor, turn on the sampler, and send the strip to a laboratory of your choice for analysis.
The RCS Plus and RCS Plus explosion proof air samplers are high precision instruments for detecting the microbial content of air. They can sample volumes of up to 1 cu m. Included in the package is an infrared remote control, 2 Ni/Cad batteries, an opener for the battery compartment, and a carrying case.
The samplers work on the impaction principle through centrifugal force. Impaction of airborne microbes onto the agar strip by centrifugal force provides a gentle and efficient collection mechanism. Even damaged airborne microbes can be detected. This has been documented in papers with high values of physical and biological sampling efficiency. This bio efficiency can only be achieved with a complete system with the Biotest Agar Strips being uniquely designed for this air sampler.
The air samplers sample at a flow rate of 50 L/min and can provide quantitative and reproducible results for sample volumes of 10 L to 1000 L. The instruments are lightweight, portable and battery operated, and have autoclavable rotors and protection caps, which makes sterilisation much easier.

PHYSICAL PARAMETERS

Size: Not specified
Weight: 1.36 kg (3.3 lb)
Power Requirements: Rapid-charge NiCad batteries, 1 h operation

GENERAL

air IDEAL

Biomeriux
100 Rodolphe Street
Durham, North Carolina 27712
919–620–2000 (Tel)
800–682–2666 (Tel)
800–968–9494 (Fax)
POC: Lynell Grosso
919–620–2094 (Tel)
919–620–7019 (Fax)
lynell.grosso@na.biomerieus.com
BioMerieux
http://www.biomerieux-usa.com

Unit Cost: Not specified

Technology Area: Air sampler–impaction principle

Mobility: Handheld
Current Users: Not specified
Application: For active air sampling, air IDEAL meets the latest ISO standards while remaining economical to operate. At just 1.2 kg, it is one of the lightest portable air samplers available. The air IDEAL's ergonomic design is user-friendly, easy to operate and programmable for volume, time to collect and start time delay. The air IDEAL is suited to meet the needs of various applications for the detection of viable organisms through active air sampling. It uses standard prepared media, such as contact plates or 100 mm plates. The air IDEAL is available exclusively from bioMerieux.

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified
Power Requirements: Not specified

GENERAL

Surface-Air System (SAS) Super 100 Air Sampler

Bioscience International
Rockville, Maryland 20852–4365
301–230–0072 (Tel)
301–230–1418 (Fax)
11607 Magruder Lane
Electronic mail
BioInfo@Biosci-Intl.com
Bioscience International

Unit Cost: Not specified

Technology Area: Air Sampler

Mobility: Handheld
Current Users: Not specified
Application: Portable sampler working on rechargeable batteries giving about 7 h of operation (about 40000 L of air sampled on 1 charge).
•100 L or 180 L per min calibrated flow with real-time electronic control of actual air flow.
•8 preset and 8 user-set volumes of air saved to memory.
•Programmable intervals between samplings to extend each sampling from few minutes to several hours without operator's supervision.
•Delayed start option.
•Active status confirmed by extra-bright warning light.
•Optional IR remote control.
•Autoclavable head made of chrome-plated aluminium or stainless steel identified by engraved serial No. and ID certificate (as per EN45001 specifications).
•Polyurethane resin case, easily cleaned and disinfected—large soft-touch control panel and lighted alphanumeric display for set sampling volume and actual aspirated volume in real-time.
•Multiple language option—RS232 serial port for data transfer to PC.
•Microbiological validation.
•Software for sampling data input according to EN45001 specifications.
•Uses 55 mm^3 contact plates - ergonomic grip.
"SAS Super 180" Air Sampler is recommended for all applications in which large volumes of air need to be sampled in a short time.
Microbiological validation—NIST traceable validation system.

PHYSICAL PARAMETERS

Size: 30.5 cm x 7.6 cm x 11.2 cm (12 in x 3 in x 4.4 in)
Weight: 1.75 kg
Power Requirements: Rechargeable batteries giving about 7 h of operation; 8.4 V, 1.2 A/h

GENERAL

Intelligent Cyclone Air Sampler (ICAS)

Biotrace International
The Science Park
Bridgend
CF31 #NA
United Kingdom
+44 1656 641 400 (Tel)
+44 1656 768 835 (Fax)
E-mail: sales@biotrace.co.uk
support@biotrace.co.uk
BioProducts Inc
PO Box 0746
Bothell, Washington 98041
425–398–7993 (Tel)
425–398–7973 (Fax)
Email: sales@biotrace.com
Web: www.intlbioproducts.com

Unit Cost: Not specified

Technology Area: Air sampler—wetted-wall cyclone

Mobility: Mobile
Current Users: Foreign Government Defence Agencies
Prime Defence Contractors
UK MoD/Dstl
Application: The Biotrace Intelligent Cyclone Air Sampler is a high efficiency environmental air sampler. The system automatically compensates for changes in temperature and humidity to provide a continuous flow of liquid sample. The air and sample flow rates are user adjustable.
The ICAS has high sample collection efficiency, with a user adjustable flow rate of up to 750 L/min. It can be used in conjunction with the Continuous Flow ATP Detector (CFAD) to provide a generic, biological detection monitoring system providing continuous data output.
For those applications not requiring continuous data, samples collected with the ICAS can be tested using Biotrace rapid water test Aqua-Trace®.
The ICAS can also be used as a high efficiency sampler providing a liquid for other detection/monitoring technologies, be it conventional microbiology or specific detection systems – these are not currently supplied by Biotrace International.

PHYSICAL PARAMETERS

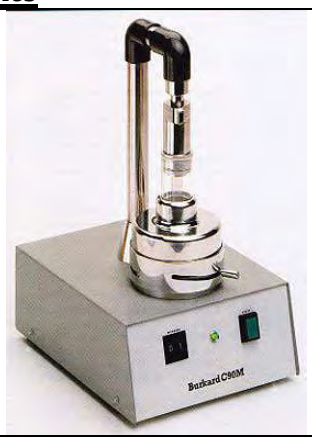
Size: Not specified
Weight: Not specified
Power Requirements: Not specified

GENERAL

Cyclone sampler for airborne particles

Burkard Manufacturing Co., Ltd.
Woodcock Hill Industrial Estate
Rickmansworth
Hertfordshire
WD3 1PJ
England
(44) (0)1923 773134/5 (Tel)
(44) (0)1923 774790 (Fax)
Telex: 932620 (Telex)
Burkard Manufacturing Co.

Unit Cost: Not specified



Technology Area: Air sampler—reverse-flow cyclone

Mobility: Handheld
Current Users: Not specified
Application: A new technique developed for the collection of airborne particles using a small reverse-flow cyclone. High efficiency over a wide range of captured particles. Ninety percent for particles in the 1 µm range. No danger of overloading with catch. Particles are collected into a 1.5 mL eppendorf vial through a smooth vortex air flow of 16.6 L/min. Gentle capture of sample and capable of sterile handling. Small flow resistance within the sampler so that low power and a very quiet built-in suction pump make it possible for long-term operation. Further advantages include more flexible and less laborious sampling well suited to new technologies including immunological methods for quantitative assessment and highly specific recognition. The sampler utilizes a standard 0.35 mm x 0.12 mm (0.01 in x 0.005 in) vertical orifice and is recommended for use in slow moving air or directed into light winds of constant direction. The Cyclone sampler will give valuable information on many indoor situations, for which its mains/battery operation and almost silent turbine fan make it very acceptable.

PHYSICAL PARAMETERS

Size: 17 cm x 22 cm (6.7 in x 8.7 in)
Weight: 4.5 kg (10 lb)
Power Requirements: A self-contained instrument with built-in mains charger and mains voltage selector available for 120 V or 240 V ac. The power unit is fitted with NiCad batteries maintaining an air throughput up to 20 L per min. The pre-set timer on the front panel will allow 99 min of running time and an audible alarm will sound when the sampling time is complete. A neon indicator shows when the system is functioning.

GENERAL

BIO SAS

International pbi S.p.A.
Via Novara, 89
20153 Milano, Italy
Tel: +39-2-48.779.1
Fax: +39-2-400.900.10
Bioscience International

Unit Cost: Not specified

Technology Area: Bioaerosol sampler

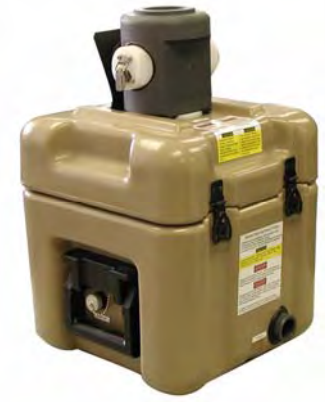
Mobility: Handheld
Current Users: Not specified
Application: Compact and light weight for easy use:
• Ergonomic configuration.
• Aspirating cycle from 10 L to 9999 L of air.
• Air flow rate 100 L/min.
• The unit stands on a flat surface as well as on tripod.
• Shock proof case.
• Single certified aspirating head.
• Complies with USP < 1116 >.
• Referenced worldwide in numerous official compendial methods.
• Intuitive programming.
7 h sampling on 1 battery charge.
Over 42 L of air per battery charge.
Stainless steel or aluminium sampling head with discrete serial number.
SOP Guide line documentation.
Applications: Clean room and sterile areas, Agro-food production premises, dairy production premises, operating theatre, infectious disease wards, vaccine production premises, microbiological laboratories, sewage and solid waste recycling plants, public environments (cinemas, restaurants, etc.), heating ventilation air conditioning, and indoor air quality.

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified
Power Requirements: Not specified

GENERAL

Dry Filter Unit (DFU)

Joint Program Office for Biological Defense (JPO-BD) Developed by the military dcfp@navsea.navy.mil Joint Program Office for Biological Defense (JPO-BD) **Unit Cost**: $1.2K	

Technology Area: Air sampling—dry filter unit

Mobility: Mobile
One person portable
Current Users: Not specified
Application: The Dry Filter Unit (DFU) is a biological sample collection system developed by the Joint Program Office for Biological Defense (JPO-BD) and available for the emergency first responder community. The unit consists of a high flow air sampling pump that collects airborne spores on 47-mm polyester filters (PEF-1 filters). The DFU 1000's purpose is to collect bio-particulates from ambient air for analysis using hand held assays (HHAs), polymerase chain reaction (PCR), and other microbiological confirmatory techniques.
After collection, each filter may be transferred into a 50 mL conical tube or may be left in the sample filter holder and transferred into a 50 mL conical tube in the laboratory. In the laboratory, the sample is prepared in a manner that will yield a suspension. Aliquots of the suspension may be assayed by different microbiological techniques depending on the sensitivity needed.
Airflow with 1-micron polyester felt filter: 1000 L/min with two installed, 700 L/min with one installed
• The DFU units can sample for hours and even days.
• Allows for a sample preparation step (e.g., heat shock) that is selective for the spores and will eliminate many competitive bacteria.

PHYSICAL PARAMETERS

Size: 33 cm x 33 cm 38 cm (13 in x 13 in x 15 in)
Weight: Approximately 19.1 kg (42 lb)
Power Requirements: 5.6 A at@ 120 V ac (17 A starting)
The DFU 1000 comes with two separate cables enabling power supply from 120 V to 240 V (50 Hz to 60 Hz) commercial power supply. An optional auxiliary power pack for 24 V dc can also be purchased.

GENERAL

BioCapture® BT-550 Air Sampler

MesoSystems Technology, Inc.
1001 Menaul Blvd., NE, Suite A
Albuquerque, NM 87107
505–314–8100 (Tel)
505–314–8101 (Fax)
email: info@mesosystems.com
POC: Patrick Call, BioAerosol Product Manager
pcall@mesosystems.com
415 N. Quay, Bldg A, Suite 3
Kennewick, WA 99336
509–222–2000 (Tel)
509–222–2027
http://www.mesosystems.com/
Customer Support Center:
877–692–2120 (Tel)
sales@mesosystems.com

Unit Cost: $9.6K for BioCapture®, accessories, and onsite training

Technology Area: Air sampler

Mobility: Handheld
Current Users: Emergency responders—average customer has 2 units in operation for the past 3 yr
Civil support teams—average customer has 2 units in operation for the past 3 yr
Military—average customer has 1 unit in operation for the past 2 yr
Commercial—average customer has 2 units in operation for the past 2 yr
Application: The BioCapture® is a hand-held, battery operated, portable, bio-collection air sampler for field or lab detection. A tool for "first responders" to effectively identify the presence of a known biological threat, the BioCapture® is compatible with all types of field and laboratory analysis techniques. It pulls an air sample through a solution that can be run through a PCR-type instrument or can be used with colorimetric test strips and spectrophotometric readers. Captured particles are automatically deposited into a small volume of liquid. Tetracore's hand-held assays, the Bio-Threat-Alert™ Test Strips, can be inserted into a port on the back of the device. With the push of a button, the correct amount of fluid is automatically deposited onto the strip. The BioCapture™ is also compatible with other detection methodologies such as PCR, GC, MS, and traditional microbiological culturing. BioCapture® has been validated by several outside groups including SBCCOM, Dugway, and CBIRF.

PHYSICAL PARAMETERS

Size: 32 cm x 18.4 cm x 14 cm (12.5 in x 7.25 in x 5.5 in)
Weight: 6.1 kg (13.5 lb)
Power Requirements: One 12 V rechargeable battery

GENERAL

BioCapture® 650

MesoSystems Technology, Inc.
1001 Menaul Blvd., NE, Suite A
Albuquerque, New Mexico 87107
505–314–8100 (Tel)
505–314–8101 (Fax)
email: info@mesosystems.com
POC: Patrick Call, BioAerosol Product Manager
pcall@mesosystems.com
415 N. Quay, Bldg A, Suite 3
Kennewick, Washington 99336
509–222–2000 (Tel)
509–222–2027
http://www.mesosystems.com/
Customer Support Center:
877–692–2120 (Tel)
sales@mesosystems.com

Unit Cost: $8.4K (includes 2 test cartridges, pelican, waterproof carrying case, two lithium ion rechargeable batteries, and a battery recharger)

Technology Area: Air sampler

Mobility: Handheld
Current Users: Military and commercial use
Nearly 500 units in 250 cities worldwide are using the BioCapture® for a period of nearly 4 yr. Customers include the WMD Civil Support Teams (central order from National Guard Bureau), Municipal Fire and Police Departments, FEMA, Urban Search and Rescue, State Highway Patrol Teams, County Response Teams, DOE National Lab installations, and Mail Sorting facilities.
Application: Bio-warfare agent concentrations and monitoring of BAs such as airborne anthrax, plague, smallpox, and tularemia.
Reports and applications note provided upon request.

PHYSICAL PARAMETERS

Size: 17.8 cm x 15.2 cm x 35.6 cm (7 in x 6 in x 14 in)
Weight: 3.4 kg (7.5 lb)
Power Requirements: Commercial Lithium ion cell (includes spare battery)
75 W-h

GENERAL

MicroVIC® Aerosol Concentrator
MVA-33A

MesoSystems Technology, Inc.
1001 Menaul Blvd., NE, Suite A
Albuquerque, New Mexico 87107
505–314–8100 (Tel)
505–314–8101 (Fax)
email: info@mesosystems.com
POC: Patrick Call, BioAerosol Product Manager
pcall@mesosystems.com
415 N. Quay, Bldg A, Suite 3
Kennewick, Washington 99336
509–222–2000 (Tel)
509–222–2027
http://www.mesosystems.com/
Customer Support Center:
877–692–2120 (Tel)
sales@mesosystems.com

Unit Cost: $4K/unit

Technology Area: Air sampler—impaction principle

Mobility: Handheld
Current Users: Military use: Yes
Commercial use: 3 yr
Laboratories—4 yr
Application: MicroVIC® Particle Concentrators are designed with systems integrators and applications developers in mind. The MicroVIC® is a virtual impactor that has been developed and optimized using computational fluid dynamics. Virtual impactors may be combined in series to enhance the concentration of desired particles. For example, two-stage models concentrate 400 lpm inlet flow to 3 lpm minor flow.
Applications: Particle concentration and large particle pre-filtering.
Features: Low power, lightweight, flow-rate scalable , amenable to high-volume, and low-cost manufacturing.

PHYSICAL PARAMETERS

Size: 1.9 cm x 5.1 cm x 7.95 cm (0.75 in x 2 in x 3.13 in) without fan
27.3 cm x 25.4 cm x 12.7 cm (10.75 in x 10 in x 5 in) with fan
Weight: 86 g (3.03 oz)—Ertalyte (PET)
349 gm (12.3 oz)—aluminum
Power Requirements: Power requirements: 7.51 V, 1.46 A
Fan: 12 V dc at 2A

GENERAL

CyClex Deluxe Kit (120160)

EMS Environmental Monitoring Systems Corporate address: 164 Ashley Avenue Charleston, South Carolina 29403 Billing Address: P.O. Box 767 Mt. Pleasant, South Carolina 29465–0767 800–293–3003 (Tel) 866–724–5702 (Fax) info@emssales.net www.emssales.net **Unit Cost**: Not specified	

Technology Area: Air sampler–impaction principle

Mobility: Fixed-site
Current Users: Not specified
Application: The CyClex utilizes a unique 360° aluminum impaction chamber designed to enhance performance and efficiency associated with Bioaerosol sampling. The CyClex has the ability to evenly and qualitatively collect aeroallergens such as pollens, mold and fungal spores, fibers, dander, insect components, and other air-borne contaminants. In addition, the CyClex has a feature for collecting "inner" wall samples.
(1) CyClex Impactor
(1) EMS MegaLite pump with mounted 3-30LPM Rotameter
(1) Multi-accessory Adapter Cap
(25 each) Wall Probes with Debris Cap
(1) 30.5 m (100 ft) of Vinyl Tubing (enough for 25 samples)
(1) Stud Sensor
(1) Hand Drill with 0.64 cm (1/4 in) Drill Bit
(1) Debris Cap Removal Rod
(25 ea) Prepared Slides, with 25 Slide Mailers
(20 ea) Vacuum Dust Sampling Cassettes
(20 ea) Vacuum Templates
(20 ea) Vacuum Zip Bags
(1) IAQStand
(1) Heavy Duty Case

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified
Power Requirements: Not specified

GENERAL

SASS 2100 Wetted-Wall Cyclone Air Sampler

Research International
18706 142nd Avenue, NE.
Woodinville, Washington 98072
425–486–7831 (Tel)
425–485–9137 (Fax)
E-mail: info@resrchintl.com
East Coast Office
Jonathan Tobelmann, Director of Marketing
703–803–8380 (Tel)
jtobelmann@cs.com
Research International

Unit Cost: $15K

Technology Area: Air sampler–wetted-wall cyclone

Mobility: Mobile
Current Users: Not specified
Application: The NEW SASS 2100™ is a highly efficient, multiple-effect, wetted-wall cyclone collector that extracts and transfers pathogens from sampled air to a small fixed water volume for subsequent user-defined wet analysis. A unique and patented feature is its ability to perform this function continuously for an extended time period without fluid sample loss: Fluid sample volume is maintained constant regardless of air temperature or relative humidity using a proprietary liquid inventory sensor and onboard make-up water. This feature is particularly valuable for continuous long-term monitoring and provides useful amplification of low-level airborne concentrations.
The SASS 2000 model is ideal for fixed installations where monitoring may take place over an extended time period and the sampler will be integrated with other equipment. The new 2100 model provides 2000 series features as well as a washable inlet filter box. Both series allow grab-samples to be taken for use with lateral flow bioassay tickets- features of particular interest to first responders.

PHYSICAL PARAMETERS

Size: 18.3 cm x 21.3 cm x 34.3 (7.2 in x 8.4 in x 13.5 in)
Weight: 2.9 kg (6.3 lb) without battery, 3.8 kg (8.3 lb) with battery
Power Requirements: Primary battery: 82 V to 265 V (47 Hz to 63 Hz) ac lump-in-cord and internal BA-5590/U primary battery or optional BA-5390/U extended life primary battery.
Rechargeable battery: 100 V to 240 V (50 Hz to 60 Hz) ac lump-in-cord/charger with internal rechargeable battery.
Power consumption 0.7 A @ 12 V, 8.4 W

GENERAL

SASS 2000 Plus™ Smart Air Sampler System

Research International
18706 142nd Avenue, NE
Woodinville, Washington 98072
425–486–7831 (Tel)
425–485–9137 (Fax)
E-mail: info@resrchintl.com
East Coast Office
Jonathan Tobelmann, Director of Marketing
703–803–8380 (Tel)
jtobelmann@cs.com
www.baesystems.com

Unit Cost: Not specified

Technology Area: Air sampler—wetted-wall cyclone

Mobility: Handheld
Current Users: Not specified
Application: The SASS 2000 Plus™ extracts chemical and particulate-based threat agents from surrounding air and transfers them to a liquid phase for detection and analysis. Distilled water is typically the liquid of choice, no additives or surfactants are required for maximum efficiency. It is microcontroller-based and can function as a stand-alone unit or can be slaved to other sampling, detection or communication systems. It is designed to continuously recycle sample fluid within the cyclone for an arbitrary time period to maximize target analyte concentration. A low-power built-in microcontroller-operated peristaltic pump is used to transfer samples to any user-defined detector. Electric power consumption is minimized by operating the unit's blower at peak electric-to-hydraulic efficiency conditions and by using natural airflow through the cyclone structure to drive water recirculation.
The SASS 2000™ Plus has been field-tested at a number of independent international facilities where it performed above and beyond the capabilities of competitors. Weight and power consumption are far below other comparable biowarfare agent collection systems.

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified
Power Requirements: Not specified

GENERAL

SASS 3000 Dry Air Sampler

Research International
18706 142nd Avenue, NE
Woodinville, Washington 98072
425–486–7831 (Tel)
425–485–9137 (Fax)
E-mail: info@resrchintl.com
East Coast Office
Jonathan Tobelmann, Director of Marketing
703–803–8380 (Tel)
jtobelmann@cs.com
www.baesystems.com

Unit Cost: $15K

Technology Area: Air sampler—collection by novel, dry filter media

Mobility: Handheld
Current Users: Not specified
Application: The SASS 3000™ is an advanced high performance dry air sampler weighing less than 2 kg (4.4 lb) that integrates a new high efficiency collection media with electronic tagging technology and satellite communications. Key components are a disposable snap-on filter element and a computer-controlled miniature blower. The capture element is a 10.2 cm (1.85 in) diameter micro-fibrous filter mounted in a circular holder. The fibrous media is up to 50X more efficient than a conventional glass or cellulosic material because each fiber incorporates a built-in electric field that captures particles using electrostatic dust precipitator principles, but at a microscopic level. This "electret" media is virtually inert, is stable up to 70 °C (158 °F), and has high holding capacity due to a large internal surface-to-volume ratio.
The filter holder incorporates an embedded read/write RF data chip that allows each filter to be individually date-stamped, and electronics internal to the unit communicates with the chip when the filter is mounted onto it or when an air sample is taken. The electronics also monitors GPS position, temperature and humidity, all of which can be recorded on the data chip. An optional add-on card allows the unit to be remotely controlled and interrogated via satellite.

PHYSICAL PARAMETERS

Size: Filter media: 4.8 cm (1.9 in) diameter filter [active area 4.6 cm (1.8 in)] mounted in 6.1 cm (2.4 in) diameter injection-molded holder.
Blower unit: 17.8 cm x 19.1 cm x 11.9 cm (7 in x 7.5 in x 4.7 in)
Weight: 1.93 kg (4.25 lb)
Power Requirements: Built-in rechargeable battery; 100 V to 240 V ac/50 Hz to 60 Hz lump-in-cord

GENERAL

SpinCon® Advanced Air Sampler

Sceptor Industries, Inc.
4950 Cherry
Kansas City, Missouri 64110
816–753–7600 x1892 (Tel)
816–931–2451 (Fax)
Erika Rich
CAO
e-mail: erich@sceptorindustries.com
Sceptor

Unit Cost: Not specified

Technology Area: Air sampler—wet concentrator

Mobility: Mobile
Current Users: SpinCon is currently used in several military applications, mailrooms and offices, a major urban biodetection system, laboratories, clean rooms, and event monitoring. It has shown superior performance and reliability in multiple environments. It is the machine of choice for both of the prime contractors competing for the biodetection system for the U.S. Postal Service.
Application: The SpinCon® is a portable and energy-efficient wet concentrator air sampler. Tested and proven in usersponsored tests, it is ideally suited for the collection of bioaerosols, particulate matter, and soluble vapors, including submicron-sized particles, airborne molecular contamination, biological particulates, and volatile and semivolatile chemical compounds. The SpinCon samples air at a rate of 450 L/min and can be operated in either single sample or continuous monitoring mode. The SpinCon can sample any level of target in the air and achieve sample concentrations that can be analyzed, making it suitable for virtually any airsampling task. This capacity is made possible by combining a high sampling rate with the ability to concentrate the analyte in a small volume of liquid, aided by high collection efficiency and the ability to vary sampling time.
The system has been developed to address a broad range of advanced air sampling requirements and is rapidly becoming the gold standard for collecting large quantities of airborne pathogens, including anthrax, foot and mouth, citrus canker, avian influenza, mold, and many others. SpinCon performance has been verified at Dugway Proving Grounds, Plum Island, Aberdeen Proving Grounds, Battelle Labs, Lawrence Livermore Labs, Midwest Research Institute, and several major universities.

PHYSICAL PARAMETERS

Size: 45.7 cm x 38 cm x 20.3 cm (18 in x 15 in x 8 in)
Weight: 20.1 kg (46 lb)
Power Requirements: 120 V ac or 12/24 V dc

GENERAL

The SKC BioSampler®

SKC, Inc.
863 Valley View Road
Eighty Four, Pennsylvania 15330
724–941–9701 (Tel)
800–752–8472 (Tel)
skcinc@skcinc.com
www.skcinc.com

Unit Cost: Not specified

Technology Area: Air sampler—impinger

Mobility: Handheld
Current Users: Not specified
Application: The patented BioSampler bioaerosol glass collection device externally resembles an all-glass impinger such as the AGI-30*.
Inside, it contains specific design features that overcome some of the sampling problems evidenced while using impingers for bioaerosol collection. The BioSampler's inlet design limits the collection of airborne particles to those that would pass through the human nose. The sampler is normally used with a liquid that swirls upward on the sampler's inner wall and removes collected particles. This gentle swirling motion generates very few bubbles minimizing re-aerosolization of collected particles. The BioSampler's design also reduces particle bounce off the inner wall helping to ensure bioaerosol viability.
The BioSampler can be used with collection liquids that have a viscosity much higher than water such as ViaTrap®, a special mineral oil for sampling bioaerosols. When used with ViaTrap, the BioSampler's collection efficiency stays constant over an 8 h sampling period. The BioSampler is highly effective at collecting viable samples. Allows use of nonevaporating collection liquids. Significantly reduces particle bounce and re-aerosolization. Preserves microorganism integrity and viability.
Reusable—can be autoclaved. Provides greater sampling efficiency over longer sampling time. Allows sampling times over a workshift of 8 h.

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified
Power Requirements: Not specified

GENERAL

Staplex® Microbial (Viable Particle) Air Samplers

The Staplex® Company
777 Fifth Avenue
Brooklyn, New York 11232-1695
USA
800–221–0822 (Tel)
718–768–3333 (Tel) in NYC and outside USA
718–965–0750 (Fax)
E-mail: info@staplex.com
E-mail: info@staplex.com

Unit Cost: Not specified

Technology Area: Air sampler

Mobility: Mobile
Current Users: Not specified
Application: Staplex® Model MAS-1 and MAS-1A Single Stage Microbial Air Samplers are designed to meet the specifications of the latest A.C.G.I.H. Bioaerosol Committee concerning sampling protocol and analytical procedures. The single stage design and verifiable low sampling flow rate minimize microorganism damage and allow efficient sampling and sterilizing. Spring retainers allow more samples to be taken in less time, with less culture damage.
Designed for in-house microbial sampling, the MAS-1 viable sampler collects and enumerates all airborne microorganisms. Model MAS-1 (single stage) includes 115 V ac air sample. The MAS-1 is comprised of an aluminum inert core, sampling stage and a base plate held together by three spring clamps and sealed with O-ring gaskets. The sampling stage had 400 precision-machined orifices.
The collection and assessment of aerosol samples is very simple. A petri dish containing an agar medium appropriate for the microorganisms that may be encountered is placed in the instrument and a sample of air is drawn. The petri dish is then removed, inverted in its cover, incubated and counted by an accepted method. (Petri dishes/agar not included.)
It is used for indoor air quality studies, food processing areas, medical treatment and office environments, sterile manufacturing, filter and clean room efficiency studies, pharmaceutical production, hospital environments, brewery fermentation, animal care laboratories, sewage treatment plants, cosmetic manufacturing, grain processing, and transportation.

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified
Power Requirements: 115 V ac air sampler

GENERAL

Cascade Impactors

Thermo Electron Corporation
450 Fortune Blvd.
Milford, Massachusetts 01757
866–984–3766 (Tel)
508–634–2199 (Fax)
customerservice@thermoei.com
www.anderseninstruments.com
http://www.thermo.com/com/cda/newsevents/home

Unit Cost: Not spevified

Technology Area: Air sampler—non-viable impactor

Mobility: Fixed-site
Current Users: Not specified
Application: The Eight Stage Non-Viable Impactor is designed to measure the size distribution and mass concentration levels of liquid and solid particulate matter. Samples wet or dry particulates. Gravimetric analysis allows reference method precision. Particle bounce and wall losses virtually eliminated. High mass collection and high flow rate. Gravimetric or chemical sample analysis.
The Thermo Electron (formerly Andersen) design cascade impactors are made up of classification stages consisting of a series of jets and impaction surfaces. At each stage, an aerosol stream passes through the jets and impacts upon the surface. Particles in the aerosol stream with significant inertia will settle upon the impaction plate. Smaller particles pass as aerosols on to the next jet stage. By designing the following consecutive stages with higher aerosol jet velocities, smaller dia particles are collected at each sunsequent stage giving the cascade affect of separation.
The particle size range collected at each of the eight stages depends on the jet orifice velocity of the specific stage, the distance between the orifices, and the collection surface, and the collection characteristics of the preceding stage.

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified
Power Requirements: Not specified

GENERAL

Portable Single-Stage Bioaerosol Sampler

Thermo Electron Corporation
450 Fortune Blvd.
Milford, Massachusetts 01757
Dr. Miles Schofield
866–984–3766 (Tel)
508–634–2199 (Fax)
customerservice@thermoei.com
Thermo Hybaid

Unit Cost: Not specified

Technology Area: Air sampler

Mobility: Handheld
Current Users: Not specified
Application: This rugged, easily portable system samples air in order to test for hazardous bacteria, viruses, fungi or particles. Disposable, pre-filled 100 mm x 15 mm (4 in x 0.6 in) agar-filled petri dishes are used as a collection medium. NIOSH-developed, the N6 renders lowest cutpoint (0.6 µm) and highest efficiency of all samplers based on government evaluation. The unit is extremely quiet, and can be set up for remote, unattended operation. A built-in microprocessor directs continuous monitoring and automatic control of the reference 28, 3 L-per-min flow rate, and also manages sample data collection, power management and serial communication of test data. Menu-driven, Windows-type software and an easy-to-read LCD display let you easily configure sample volume, delayed start times, data transmission, and calibration. Power is supplied by 2 lithium ion batteries, which quickly recover 90 % of their charge within 1 h. System can operate from 120 V ac power.

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified
Power Requirements: Not specified

GENERAL

DIO-SIBCA, Sampling and Identification Kit
NATO Stock #
6665-27-012-2714

DIOMED Defense Systems Technologies
Sanayi Cad. No:19 Dudullu 81260
İstanbul - Turkey
90 (216) 420 03 73 (4 line) (Tel)
90 (0216) 466 63 01 (Fax)
info@diomed.com.tr
DIOMED Defense Systems Technologies

Unit Cost: Not specified

Technology Area: Liquid sampler

Mobility: Handheld
Current Users: Not specified
Application: Liquid sampler

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified
Power Requirements: Not specified

GENERAL

Incident Response Sample Collection Kit

EAI Corporation
1308 Continental Drive Suite J
Abingdon, Maryland 21009
888–676–1449 (Tel)
410–676–1449 (Tel)
410–671–7241 (Fax)
marketing@eaicorp.com
http://www.eaicorp.com/

Unit Cost: Not specified

Technology Area: Air, liquid, and solid samples

Mobility: Handheld
Current Users: Designed for HAZMAT technicians, medical and forensic evidence collection teams, and decontamination teams
Application: Designed for HAZMAT technicians, medical and forensic evidence collection teams, and decontamination teams, EAI's sample collection kit contains all materials needed to collect air, liquid, and solid samples for determining whether and which hazardous materials may be present.
Packaged in water-tight cases, the kit includes equipment for collecting materials for chemical and biological analysis, with each sampling component marked for ease of use. Ruggedized for field use, the kit also includes detailed instructions to ensure sample integrity required for legally defensible data.

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified
Power Requirements: Not specified

GENERAL

CarpetChek System

Aerotech Laboratories, Inc.
1501 West Knudsen Drive
Phoenix, Arizona 85027
623–780–4800 (Tel)
800–651–4802 (Tel)
623–780–7695 (Fax)
www.aerotechlabs.com

Unit Cost: Not specified

Technology Area: Surface sampling—vacuuming

Mobility: Handheld
Current Users: Not specified
Application: Sampling for the CarpetChek System™ includes collecting carpet dust by vacuuming relatively large areas of carpet 0.36 m x 2.8 m (1 ft 2 in x 9 ft 2 in), based on amount of dust present, with a high-volume pump and a dust cassette. Any 3-piece cassette fitted with a 0.8 µ polycarbonate filter is sufficient. The area of carpet sampled is inconsequential as the fungi are analyzed on a per gram basis. The sampling technique, however, should be consistent, working the inlet tube as deep as possible into the carpet to collect a representative sample. Approximately 1 g of dust should be collected. One significant facet of many Indoor Air Quality (IAQ) microbial investigations is the assessment of the carpeting in an occupied building. Carpet is listed as one of the nine potential sources of BAs in an occupied space by the American Conference of Governmental Industrial Hygienists (Bioaerosols—Assessment and Control, ACGIH 1999). The difficulties in assessing carpet contamination arise from the porous nature of the material, lack of standardized sampling methods, and obscurity of data interpretation.

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified
Power Requirements: Not specified

GENERAL

BiSKit Kit
QS Kit (FACTM)

QuickSilver Analytics, Inc.
1309 Continental Drive, Suite N
Attn: Ms. Patti Riggs
Abingdon, Maryland 21009–2335
410–676–4300 (Tel)
410–676–4004 (Fax)
patti.riggs@qckslvr.com
QuickSilver Analytics, Inc.

Unit Cost: $30

Technology Area: Surface sampling

Mobility: Handheld
Current Users: Not specified
Application: Kit designed and patented by ECBC, licensed to QS and is used to sample large surface areas (1 M2) for BAs. The kit has been extensively tested by ECBC for sampling efficiency and for PCR and Immunoassay interferences for the common BA analyses.
The Chemical/Biological Sampling Kits (QuickSilver Analytics, Inc.) was developed by the U.S. Army Soldier Biological Chemical Command (SBCCOM) Forensic Analysis Center's Rapid Prototyping Team as a field adaptable sampling collection kit. The device was designed, developed, fabricated, and utilized so that environmental samples, including potentially toxic samples and forensic evidence samples could be collected by kits. These kits are provided to government and commercial clients by QuickSilver, under a Cooperative Research and Development Agreement with SBCCOM.

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified
Power Requirements: Not specified

GENERAL

Chemical-Biological Sampling Kit, FAC™ Model 102

QuickSilver Analytics, Inc.
1309 Continental Drive, Suite N
Attn: Ms. Patti Riggs
Abingdon, Maryland 21009-2335
410–676–4300 (Tel)
410–676–4004 (Fax)
patti.riggs@qckslvr.com
QuickSilver Analytics, Inc. is part of a Cooperative Research and Development Agreement with SBCCOM

Unit Cost: $209

Technology Area: Surface sampling

Mobility: Handheld
Current Users: Not specified
Application: A simple, yet highly efficient and adaptable field sampling collection kit has been designed, developed, fabricated and utilized to collect environmental samples, including potentially toxic samples and forensic evidence samples by the U.S. Army Soldier and Biological Chemical Command Army (SBCCOM) Forensic Analytical Center's Rapid prototyping Team. Kits are provided to Government and Commercial clients.
This module is used to sample surfaces for biological agents. The FAC Model 102 Kit contains all required components in one handy "backpack" configuration designed to take up to six (6) wipe, solid, liquid, and/or biological samples.

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified
Power Requirements: Not specified

GENERAL

S3 Bio Sampling Kits

QuickSilver Analytics, Inc.
1309 Continental Drive, Suite N
Attn: Ms. Patti Riggs
Abingdon, Maryland 21009–2335
410–676–4300 (Tel)
410–676–4004 (Fax)
patti.riggs@qckslvr.com
QuickSilver Analytics, Inc. is part of a Cooperative Research and Development Agreement with SBCCOM

Unit Cost: $22.50

Technology Area: Surface sampling

Mobility: Handheld
Current Users: Not specified
Application: Kit designed by ECBC is used to sample surfaces for BAs. This kit is produced under a CRADA with ECBC.

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified
Power Requirements: Not specified

GENERAL

Chemical and Biological Individual Sampler (CBIS)

CyTerra Corporation
85 First Avenue
Waltham, Massachusetts 02451
781–697–2500 (Tel)
http://www.cyterracorp.com/cychemicalsensing.htm

Unit Cost: Not specified

Technology Area: Sampler

Mobility: Handheld
Current Users: Not specified
Application: CyTerra Corporation developed the CBIS and Reader System for the U.S. Marine Corps to address immediate requirements for chemical and biological warfare agent detection. CBIS stands for a Chemical and Biological Individual Sampler. It is a small device, about the size of a silver dollar that is worn by a soldier; it is designed to passively sample the surrounding air. The Reader System is a high-speed analyzer that uses thermal desorption, fast gas chromatography, and mass spectroscopy to analyze or "read" the CBIS. The CBIS can be worn for up to 7 d and the Reader System completes the analysis in 2 min. Together, the CBIS and Reader System can provide early warning for sub-clinical levels of Chemical or Biological Threats. Other volatile organic materials can also be determined with the CBIS and Reader System. This technology provides a basic approach to meet the needs of deployed military personnel and, in light of recent attacks on U.S. soil, can be used to address detection requirements in the civilian, industrial, and government sectors as well.

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified
Power Requirements: Not specified

APPENDIX I—BIOLOGICAL REAGENT KITS

APPENDIX I—BIOLOGICAL REAGENT KITS

ID#	Name	Manufacturer	Detection System Used	Page I–#
1	PCR Core System I—200 Reactions (M7660)	Promega North	Kit/Molecular—PCR	I–1
2	PCR Core System II (M7665) 200 Reactions	Promega North	Kit/Molecular—PCR	I–3
3	The Access RT PCR Introductory System (A1260) 20 Reactions	Promega North	Kit/Molecular—PCR Reverse transcription	I–5
4	The Access RT PCR System (A1250) 100 Reactions	Promega North	Kit/Molecular—PCR Reverse transcription	I–7
5	The Access RT PCR system (A1280) 500 Reactions	Promega North	Kit/Molecular—PCR Reverse transcription	I–9
6	PCR Amplification Kit SuperScript™ III Platinum® One or Two-Step qRT-PCR Kits	Panvera	Kit/Molecular—qRT-PCR amplification	I–11
7	Invader Assays	Third Wave Technologies, Inc.	Kit/Molecular—Invader Assays	I–12
8	Single Primer Isothermal Amplification (SPIA)	Nugen Technologies Inc.	Kit/Molecular—Isothermal PCR	I–13
9	BV Tests	BioVeris Corporation	Kit/Immunochemistry—Magnetic bead	I–14
10	Gen-Probe Amplified AccuProbe Culture Identification Reagent Kit	Gen-Probe	Kit/Immunochemistry—Magnetic bead	I–16

GENERAL

PCR Core System I—200 Reactions (M7660)

Promega North
2800 Woods Hollow Road
Madison, Wisconsin 53711
608–274–4330 (Tel)
800–356–9526 (Tel)
608–277–2601 (Fax)
800–356–9526 (Tech Tel)
E-mail address: custserv@promega.com
E-mail Address: techserv@promega.com
Web Address: www.promega.com
Saiki, R. et al. (1985) Science 230, 1350.

Vendor Response: Yes

Type: Kit/Molecular

Unit Cost: $91
Portability: Mobile Laboratory Detection
Availability: Overnight
Detection Category: PCR
Application: General kit that needs primers
Current Users: Scientific research labs, diagnostic labs, and hospitals

OPERATIONAL PARAMETERS

BAs Detected: This system can be used to identify DNA from, essentially, any organism if the appropriate analyte-specific reagent is used in conjunction.
Sample Preparation: Preparation of DNA is a required first step; product may be detected by numerous methods. Time required for either varies greatly.
SOP Sample Preparation: None
Sample Type: DNA, typically purified to some extent
Calibration Requirements: Users will determine necessity for assay controls
Sensitivity: Varies with specific assay performed
Specificity: Varies with specific assay performed
Confidence Interval/Specificity: Varies with specific assay performed
Testing Information: Quality Control—All components of the PCR Core System I are tested for performance in the polymerase chain reaction. All solutions are tested for the absence of contaminating nucleases using radioactive susbstrates. Magnesium concentrations in the appropriate reaction buffers are verified using a spectrophotometric, dye-binding method.

PHYSICAL PARAMETERS

Size: 8.3 cm x 8.3 cm x 2.54 cm (3.25 in x 3.25 in x 2.37 ft)
Weight: Not specified
Total Weight: This item IS the consumable. Otherwise, varies with specific assay performed.
Power Requirements: Varies with specific assay performed

LOGISTIC PARAMETERS

Durability: Good if stored properly
Environmental Conditions: Varies with specific assay performed
Support Equipment: 1—250 µ Taq DNA polymerase, Storage Buffer
1—1.2 mL Thermophilic DNA Polymerase 10x Reaction Buffer, Mg Free
1—1.2 mL Magnesium Chloride
1—200 µL PCR Nucleotide Mix
1—1 mL Taq DNA Polymerase 10x Buffer with 15 mM Magnesium Chloride
1—200 µL PCR Nucleotide Mix
Consumables: This item is the consumable

Maintenance: Storage at -20 ºC (-4 ºF)
Shelf Life (Equipment): Storage at -20 ºC (-4 ºF)
Shelf Life (Consumables): Store all components at -20 ºC (-4 ºF)
Maintenance Costs: Whatever it costs to store at -20 ºC (-4 ºF)

SPECIAL PARAMETERS

Skills Required: Varies with specific assay performed
Training: Varies with specific assay performed
Manuals Available: Technical Bulletin TB254 provided; various manuals available upon request.
Data Storage: Varies with specific assay performed
Safety Requirements: Varies with specific assay performed
Warranty: Expiration date is on label. Approximately 2 yr expiration

GENERAL

PCR Core System II (M7665) 200 Reactions

Promega North
2800 Woods Hollow Road
Madison, Wisconsin 53711
608–274–4330 (Tel)
800–356–9526 (Tel)
608–277–2601 (Fax)
800–356–9526 (Tech Tel)
E-mail address: custserv@promega.com
E-mail Address: techserv@promega.com
Web Address: www.promega.com
Saiki, R. et al. (1985) Science 230, 1350.

Vendor Response: Yes

Type: Kit/Molecular

Unit Cost: $101
Portability: Mobile Laboratory Detection
Availability: Overnight delivery
Detection Category: PCR
Application: General kit that needs primers
Current Users: Scientific research labs, diagnostic labs, and hospitals

OPERATIONAL PARAMETERS

BAs Detected: This system can be used to identify DNA from, essentially, any organism if the appropriate analyte-specific reagent is used in conjunction.
Sample Preparation: Preparation of DNA is a required first step; product may be detected by numerous methods. Time required for either varies greatly.
SOP Sample Preparation: None
Sample Type: DNA, typically purified to some extent
Calibration Requirements: Users will determine necessity for assay controls
Sensitivity: Varies with specific assay performed
Specificity: Varies with specific assay performed
Confidence Interval/Specificity: Varies with specific assay performed
Testing Information: Quality Control—All components of the PCR Core System II are tested for performance in the polymerase chain reaction. All solutions are tested for the absence of contaminating nucleases using radioactive susbstrates. Magnesium concentrations in the appropriate reaction buffers are verified using a spectrophotometric, dye-binding method.

PHYSICAL PARAMETERS

Size: 8.3 cm x 8.3 cm x 2.54 cm (3.25 in x 3.25 in x 2.37 ft)
Weight: Not specified
Total Weight: This item IS the consumable. Otherwise, varies with specific assay performed.
Power Requirements: Varies with specific assay performed

LOGISTIC PARAMETERS

Durability: Good if stored properly
Environmental Conditions: Varies with specific assay performed
Support Equipment: 1 x 250 µ Taq DNA polymerase, Storage Buffer
1 x 1.2 mL Thermophilic DNA Polymerase 10x Reaction Buffer, Mg Free
1—1.2 mL Magnesium Chloride
1—200 µL PCR Nucleotide Mix
1—1 mL Taq DNA Polymerase 10x Buffer with 15mM Magnesium Chloride
1—200 µL PCR Nucleotide Mix
1—100 µL Positive Control Plasmid DNA

1—100 µL Upstream Control Primer
1—100 µL Downstream Control Primer
Consumables: This item is the consumable
Maintenance: Storage at -20 ºC (-4 ºF)
Shelf Life (Equipment): Storage at -20 ºC (-4 ºF)
Shelf Life (Consumables): Store all components at -20 ºC (-4 ºF)
Maintenance Costs: Whatever it costs to store at -20 ºC (-4 ºF)

SPECIAL PARAMETERS

Skills Required: Varies with specific assay performed
Training: Varies with specific assay performed
Manuals Available: Technical Bulletin TB254 provided; various manuals available upon request.
Data Storage: Varies with specific assay performed
Safety Requirements: Varies with specific assay performed
Warranty: Expiration date is on label. Approximately 2 yr expiration.

GENERAL

Access RT PCR Introductory System (A1260) 20 Reactions

Promega North
2800 Woods Hollow Road
Madison, Wisconsin 53711
608–274–4330 (Tel)
800–356–9526 (Tel)
608–277–2601 (Fax)
800–356–9526 (Tech Tel)
E-mail address: custserv@promega.com
E-mail Address: techserv@promega.com
Web address: www.promega.com

Vendor Response: Yes

Type: Kit/Molecular

Unit Cost: $106
Portability: Mobile Laboratory Detection
Availability: Commercially available; overnight delivery
Detection Category: PCR—Reverse transcription followed by Polymerase Chain Reaction
Application: General kit that needs primers
Current Users: Scientific research labs, diagnostic labs, and hospitals

OPERATIONAL PARAMETERS

BAs Detected: This system can be used to identify RNA from, essentially, any organism if the appropriate analyte-specific reagent is used in conjunction.
Sample Preparation: Preparation of RNA is a required first step; product may be detected by numerous methods. Time required for either varies greatly.
SOP Sample Preparation: None
Sample Type: RNA, typically purified to some extent
Calibration Requirements: Users will determine necessity for assay controls
Sensitivity: 1 pg of total RNA or mRNA. Varies with specific assay performed.
Specificity: Varies with specific assay performed
Confidence Interval/Specificity: Varies with specific assay performed
Testing Information: Quality Control—RT-PCR: 2.5 zeptomoles (approximately 1000 copies) of template, Promega's 1.2 kb Kanamycin Positive Control RNA, can be replicated and amplified into a clear, discrete 323 base pair DNA product when visualized in an agarose gel by ethidium bromide staining using conditions described in Technical Manual 220.

PHYSICAL PARAMETERS

Size: 15.9 cm x 8.3 cm x 2.54 cm (6.25 in x 3.25 in x 2.37 in)
Weight: Varies with specific assay performed
Total Weight: Varies with specific assay performed
Power Requirements: Varies with specific assay performed

LOGISTIC PARAMETERS

Durability: Good if stored properly
Environmental Conditions: Storage at -68 ºF
Varies with specific assay performed
Support Equipment: 1—100 µ AMV Reverse Transcriptase
1—100 µ Tfl DNA Polymerase
1—1 mL AmV/Tfl 5X Reaction Buffer
1—1250 µL Magnesium Sulfate
1—20 µL dNTP Mix
1—50 µL Positive Control RNA with Carrier
1—100 µL Upstream Control Primer

1—100 µL Downstream Control Primer
1—13 mL Nuclease-Free Water
Consumables: This item is the consumable
Maintenance: Storage at -20 ºC (-4 ºF)
Shelf Life (Equipment): Storage at -20 ºC (-4 ºF)
Shelf Life (Consumables): Store all system components at -20 ºC (-4 ºF). For long-term storage, the positive control RNA with carrier must be stored at -70 °C (-94 °F).
Maintenance Costs: Whatever it costs to store at -20 ºC (-4 ºF)

SPECIAL PARAMETERS

Skills Required: Not specified
Training: Varies with specific assay performed
Manuals Available: Technical Bulletin TB220. Various manuals available upon request.
Data Storage: Varies with specific assay performed
Safety Requirements: Varies with specific assay performed
Warranty: Expiration date is on label. Approximately 1 yr expiration.

GENERAL

Access RT PCR System (A1250) 100 Reactions

Promega North
2800 Woods Hollow Road
Madison, Wisconsin 53711
608–274–4330 (Tel)
800–356–9526 (Tel)
608–277–2601 (Fax)
800–356–9526 (Tech Tel)
E-mail address: custserv@promega.com
E-mail Address: techserv@promega.com
Web address: www.promega.com

Vendor Response: Yes

Type: Kit/Molecular

Unit Cost: $377
Portability: Mobile Laboratory Detection
Availability: Commercially available; overnight delivery
Detection Category: PCR—Reverse transcription followed by Polymerase Chain Reaction
Application: General kit that needs primers
Current Users: Scientific research labs, diagnostic labs, and hospitals

OPERATIONAL PARAMETERS

BAs Detected: This system can be used to identify RNA from, essentially, any organism if the appropriate analyte-specific reagent is used in conjunction.
Sample Preparation: Preparation of RNA is a required first step; product may be detected by numerous methods. Time required for either varies greatly.
SOP Sample Preparation: None
Sample Type: RNA, typically purified to some extent
Calibration Requirements: Users will determine necessity for assay controls
Sensitivity: 1 pg of total RNA or mRNA. Varies with specific assay performed.
Specificity: Varies with specific assay performed
Confidence Interval/Specificity: Varies with specific assay performed
Testing Information: Quality Control—RT-PCR: 2.5 zeptomoles (approximately 1000 copies) of template, Promega's 1.2 kb Kanamycin Positive Control RNA, can be replicated and amplified into a clear, discrete 323 base pair DNA product when visualized in an agarose gel by ethidium bromide staining using conditions described in Technical Manual 220.

PHYSICAL PARAMETERS

Size: 15.9 cm x 8.3 cm x 2.54 cm (6.25 in x 3.25 in x 2.37 in)
Weight: Varies with specific assay performed
Total Weight: Varies with specific assay performed
Power Requirements: Varies with specific assay performed

LOGISTIC PARAMETERS

Durability: Good if stored properly
Environmental Conditions: Storage at -68 ºF
Varies with specific assay performed
Support Equipment: 1—500 µ AMV Reverse Transcriptase
1—500 µ Tfl DNA Polymerase
1—1 mL AmV/Tfl 5X Reaction Buffer
1—125 µL Magnesium Sulfate
2—50 µL dNTP Mix
1—50 µL Positive Control RNA with Carrier
1—100 µL Upstream Control Primer

1—100 µL Downstream Control Primer
1—13 mL Nuclease-Free Water
Consumables: This item is the consumable
Maintenance: Storage at -20 ºC (-4 ºF)
Shelf Life (Equipment): Storage at -20 ºC (-4 ºF)
Shelf Life (Consumables): Store all system components at -20 ºC (-4 ºF). For long-term storage, the positive control RNA with carrier must be stored at -70 °C (-94 °F).
Maintenance Costs: Whatever it costs to store at -20 ºC (-4 ºF)

SPECIAL PARAMETERS

Skills Required: Not specified
Training: Varies with specific assay performed
Manuals Available: Technical Bulletin TB220. Various manuals available upon request.
Data Storage: Varies with specific assay performed
Safety Requirements: Varies with specific assay performed
Warranty: Expiration date is on label. Approximately 1 yr expiration.

GENERAL

Access RT PCR system (A1280) 500 Reactions

Promega North
2800 Woods Hollow Road
Madison, Wisconsin 53711
608–274–4330 (Tel)
800–356–9526 (Tel)
608–277–2601 (Fax)
800–356–9526 (Tech Tel)
E-mail address: custserv@promega.com
E-mail Address: techserv@promega.com
Web address: www.promega.com

Vendor Response: Yes

Type: Kit/Molecular

Unit Cost: $1.5K
Portability: Mobile Laboratory Detection
Availability: Commercially available; overnight delivery
Detection Category: PCR—Reverse transcription followed by Polymerase Chain Reaction
Application: General kit that needs primers
Current Users: Scientific research labs, diagnostic, and hospitals

OPERATIONAL PARAMETERS

BAs Detected: This system can be used to identify RNA from, essentially, any organism if the appropriate analyte-specific reagent is used in conjunction.
Sample Preparation: Preparation of RNA is a required first step; product may be detected by numerous methods. Time required for either varies greatly.
SOP Sample Preparation: None
Sample Type: RNA, typically purified to some extent
Calibration Requirements: Users will determine necessity for assay controls
Sensitivity: 1 pg of total RNA or mRNA. Varies with specific assay performed.
Specificity: Varies with specific assay performed
Confidence Interval/Specificity: Varies with specific assay performed
Testing Information: Quality Control—RT-PCR: 2.5 zeptomoles (approximately 1000 copies) of template, Promega's 1.2 kb Kanamycin Positive Control RNA, can be replicated and amplified into a clear, discrete 323 base pair DNA product when visualized in an agarose gel by ethidium bromide staining using conditions described in Technical Manual 220.

PHYSICAL PARAMETERS

Size: 2 boxes—15.9 cm x 8.3 cm x 2.54 cm (6.25 in x 3.25 in x 2.37 in)
Weight: 0.9 kg (2 lb)—varies with specific assay performed
Total Weight: 1.13 kg (2.5 lb) belt carried battery pouch
4.98 kg (11 lb) belt carried battery pouch
Power Requirements: Operates for 1.4 h from 1.13 kg (2.5 lb) belt carried battery pouch
Operate for 5.5 h from an 4.98 kg (11 lb) battery pouch.

LOGISTIC PARAMETERS

Durability: Good if stored properly
Environmental Conditions: Storage at -68 ºF
Varies with specific assay performed
Support Equipment: 1—500 µ AMV Reverse Transcriptase
1—500 µ Tfl DNA Polymerase
1—1 mL AmV/Tfl 5X Reaction Buffer
1—1250 µL Magnesium Sulfate
2—50 µL dNTP Mix

1—50 µL Positive Control RNA with Carrier
1—100 µL Upstream Control Primer
1—100 µL Downstream Control Primer
1—13 mL Nuclease-Free Water
1—100 reactions Access RT-PCR System
4—1 each Access RT -PCR Core Reagents
Consumables: This item is the consumable
Maintenance: Storage at -20 ºC (-4 ºF)
Shelf Life (Equipment): Storage at -20 ºC (-4 ºF)
Shelf Life (Consumables): Store all system components at -20 ºC (-4 ºF). For long-term storage, the positive control RNA with carrier must be stored at -70 °C (-94 °F).
Maintenance Costs: Whatever it costs to store at -20 ºC (-4 ºF)

SPECIAL PARAMETERS

Skills Required: Not specified
Training: Varies with specific assay performed
Manuals Available: Technical Bulletin TB220. Various manuals available upon request.
Data Storage: Varies with specific assay performed
Safety Requirements: Varies with specific assay performed
Warranty: Expiration date is on label. Approximately 1 yr expiration.

GENERAL

PCR Amplification Kit
SuperScript™ III Platinum® One or Two-Step qRT-PCR Kits

Panvera
Discovery Center
501 Charmany Drive
Madison, Wisconsin 53719
800–791–1400 (Tel)
608–204– 5000 (Tel)
608–204–5300 (Fax)
608–204–5200 (Fax, order)
http://www.panvera.com
E-mail: techsupport@panvera.com

Vendor Response: No

Type: Kit/Molecular
Unit Cost: Not specified
Portability: Mobile Laboratory Detection
Availability: Commercially available
Detection Category: qRT-PCR amplification
Application: PCR Amplification (FTC labeled)
Current Users: Not specified

OPERATIONAL PARAMETERS

BAs Detected: Kit designed to perform PCR on all DNA templates
Sample Preparation: Not specified
Sample Type: Not specified
Sensitivity: Not specified
Confidence Interval/Specificity: Not specified
SOP Sample Preparation: Not specified
Calibration Requirements: Not specified
Specificity: Not specified
Testing Information: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Total Weight: Not specified
Weight: Not specified
Power Requirements: Not specified

LOGISTIC PARAMETERS

Durability: Not specified
Consumables: Not specified
Shelf Life (Equipment): Not specified
Maintenance Costs: Not specified
Environmental Conditions: Not specified
Maintenance: Not specified
Shelf Life (Consumables): Not specified

Support Equipment: Kit Components:

Taq DNA polymerase (5 U/µL) 250U	Control Primer 1 (20 pmol/µL) 50 mL
dNTP Mixture (2.5 mM each) 1.28	Control Primer 2 (20 pmol/µL) 50 µL
10x PCR Buffer (without Mg2+) 1 mL	Control Primer 3 (20 pmol/µL) 50 µL
Magnesium Chloride (25 mM) 1 mL	pHY Size Maker (100 ng/µL) 20 µL
Control Tenokate (1 µg/mL lambda DNA)100 µL	Taq Dilution Buffer 1 mL

SPECIAL PARAMETERS

Skills Required: Not specified
Manuals Available: Not specified
Safety Requirements: Not specified
Training: Not specified
Data Storage: Not specified
Warranty: Not specified

GENERAL

Invader Assays

Third Wave Technologies, Inc.
502 South Rosa Rd.
Madison, Wisconsin 53719–1256

888–898–2357 (Tel)
608–273–8933 (Tel)
608–273–8618 (Fax)
E-mail: techserv@twt.com
E-mail: techserv@twt.com

Vendor Response: No

Type: Kit/Molecular

Unit Cost: Not specified
Portability: Mobile Laboratory Detection
Availability: Commercially available
Detection Category: Invader Assays
Application: Third Wave Technology has developed several clinical assays that incorporate Invader technology. The technology relies on Cleavase®, Third Wave's proprietary family of enzymes that recognize specific DNA and RNA structures. The assays are formatted to operate with equipment found in most research and clinical labs. No detection items were identified that use the invader assay technology. The Invader platform is transforming both how and where genetic analysis can be performed. Traditional methods generally require time-consuming, specialized labor and dedicated, expensive equipment in a tightly controlled setting. The Invader platform, conversely, is a simpler, scalable, and extremely accurate solution that allows any size CLIA-high-complexity laboratory to provide patient results more quickly, increase throughput, and lower costs. The Invader platform is uniquely capable of enabling the clinical laboratory to realize the growth in molecular diagnostics and to revolutionize the delivery of health care. Our most frequently requested products include:
Connexin 26—ApoE
Cystic Fibrosis—PAI-1
Factor V Leiden—Factor VII
Factor II—Tay-Sachs
MTHFR—PL A1/A2

OPERATIONAL PARAMETERS

BAs Detected: Not specified
SOP Sample Preparation: Not specified
Calibration Requirements: Not specified
Sensitivity/specificity: Not specified
Sample Preparation: Not specified
Sample Type: Not specified
Testing Information: Not specified
Confidence Interval/Specificity: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Power Requirements: Not specified
Weight: Not specified
Total Weight: Not specified

LOGISTIC PARAMETERS

Durability: Not specified
Support Equipment: Not specified
Maintenance: Not specified
Shelf Life (Consumables): Not specified
Environmental Conditions: Not specified
Consumables: Not specified
Shelf Life (Equipment): Not specified
Maintenance Costs: Not specified

SPECIAL PARAMETERS

Skills Required: Not specified
Manuals Available: Not specified
Safety Requirements: Not specified
Training: Not specified
Data Storage: Not specified
Warranty: Not specified

GENERAL

Single Primer Isothermal Amplification (SPIA)

Nugen Technologies Inc.
821 Industrial Road, Unit A
San Carlos, California 94070
650–590–3600 (Tel)
650–590–3630 (Fax)
Product Information
sales@nugeni.com
Order Placement and Customer Service
custserv@nugeninc.com
http://www.nugentechnologies.com/

Vendor Response: No

Type: Kit/Molecular

Unit Cost: Not specified
Portability: Mobile Laboratory Detection
Availability: Commercially available
Detection Category: Isothermal PCR
Application: Isothermal Amplification (SPIA)
Current Users: Not specified

OPERATIONAL PARAMETERS

BAs Detected: Anthrax
Sample Preparation: Not specified
SOP Sample Preparation: Not specified
Sample Type: Not specified
Calibration Requirements: Not specified
Sensitivity: <20 ng total RNA
Specificity: Not specified
Confidence Interval/Specificity: Not specified
Testing Information: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Weight: Not specified
Total Weight: Not specified
Power Requirements: Not specified

LOGISTIC PARAMETERS

Durability: Not specified
Support Equipment: Not specified
Maintenance: Not specified
Shelf Life (Consumables): Not specified
Environmental Conditions: Not specified
Consumables: Not specified
Shelf Life (Equipment): Not specified
Maintenance Costs: Not specified

SPECIAL PARAMETERS

Skills Required: Not specified
Manuals Available: Not specified
Safety Requirements: Not specified
Training: Not specified
Data Storage: Not specified
Warranty: Not specified

GENERAL

BV Tests

BioVeris Corporation
16020 Industrial Drive
Gaithersburg, Maryland 20877
800–336–4436, ext. 2183
301–230–0158 (Fax)

bvcorp@bioveris.com
bv@igen.com

Vendor Response: No

Type: Immunochemical/Magnetic Bead

Unit Cost: Not specified
Portability: Mobile Laboratory Detection
Availability: Commercially available
Detection Category: BV Tests use a sandwich immunoassay format. One antibody, specific for the pathogen to be measured, is immobilized on micro particles. The other antibody is labeled with BioVeris' BV-TAG™ label. The sample is mixed with these reagents. When the specific pathogen to be measured is present in the sample, both antibodies bind to it, effectively linking together the micro particles, the organism and BV-TAG label. The reaction mixture is then transported with an assay buffer to a flow cell with an electrode which stimulates the bound BV-TAG label to emit light.
The bead-based format has been proven to provide robust performance from many different applications, even when challenged with the most demanding and complex food matrices. Only BV Tests provide unprecedented levels of sensitivity and accuracy.
Application: BV Test Kits: BioVeris offers several test kits for the detection of BAs. Each product has been developed for our BV technology, and is compatible with the BV detection systems and M-SERIES M1 instrumentation. BV Test Kits are available for the detection of Botulinum Neurotoxins A, B, E and F, Staphylococcal Enterotoxin A and B, Ricin, and Anthrax spores. BioVeris' Biodefense Initiatives: BioVeris Corporation is presently involved in a series of U.S. Government programs and initiatives intended to meet the increasing demands for detection technologies and systems for homeland security and military defense. The Automated BA Testing System (ABATS) is designed to screen 300 samples a day with a staff of only 1 to 2 people. In its basic configuration, it targets 6 threat agents but has the capacity to target greater than 20. It can be loaded with a variety of reagent packs and performs everything from sample extraction, setup, and analysis in an automated fashion.
Current Users: Products based on the company's proprietary BVTM technology are being used by the DoD ABATS at the ECBC for the development of automated biological weapons detection systems. ECBC, in conjunction with BioVeris and Beckman Coulter, has integrated the M-SERIES® Analyzer with Beckman Coulter's SAGIAN™ and Biomek® FX lab automation systems to automate sample preparation and plate handling for BV immunoassays.
BioVeris has entered into a cooperative research and development agreement (CRADA) with the U.S. Army Medical Research Institute of Infectious Diseases for the development of tests based on the Company's proprietary BV technology, for food-, water- and environmentally borne toxins. Products based on the Company's proprietary BV technology are being used by the DoD U.S. Army Space and Missile Defense Command to produce and deliver labeled reagents for the detection of specific BAs important to the DoD. BioVeris is expanding its efforts to participate in a growing number of federal, state and local agency programs designed and intended to advance biodefense and homeland security initiatives. Biodefense and industrial markets for the detection of bacteria, viruses, and toxins that may pose a military or public health threat and industrial testing for the detection of foodborne and waterborne disease causing pathogens.

OPERATIONAL PARAMETERS

BAs Detected: The BV Tests are intended for the detection of BAs, including Botulinum neurotoxins A, B, E and F, Staphylococcal Enterotoxin A and B, Ricin, and Anthrax spores. Test kits are also available for the detection and presumptive identification of E.coli O157, Salmonella, Listeria, and Campylobacter in food and environmental samples. The E.coli O157 test is AOAC Performance Tested Method No. 010301. The Salmonella test is in review. The revolutionary tests utilize the proprietary BioVeris (BV) TM technology to establish a rapid and highly sensitive test for the specific pathogen. The tests are

utilized by food processors, contract laboratories, U.S. Government, DOD, poultry and ground beef producers, and research laboratories.

Sample Preparation: Not specified
Sample Type: Not specified
Sensitivity: Not specified
Testing Information: Not specified
SOP Sample Preparation: Not specified
Calibration Requirements: Not specified
Specificity: Not specified
Confidence Interval/Specificity: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Power Requirements: Not specified
Weight: Not specified
Total Weight: Not specified

LOGISTIC PARAMETERS

Durability: Not specified
Support Equipment: Not specified
Maintenance: Not specified
Shelf Life (Consumables): Not specified
Environmental Conditions: Not specified
Consumables: Not specified
Shelf Life (Equipment): Not specified
Maintenance Costs: Not specified

SPECIAL PARAMETERS

Skills Required: Not specified
Manuals Available: Not specified
Safety Requirements: Not specified
Training: Not specified
Data Storage: Not specified
Warranty: Not specified

GENERAL

Gen-Probe Amplified AccuProbe Culture Identification Reagent Kit

Gen-Probe
10210 Genetic Center Drive
San Diego, California
92121–4362
858–410–8000 (Tel)
800–523–5001 (Tel)
cindyi@gen-probe.com
http://www.gen-probe.com

Vendor Response: No

Type: Molecular

Unit Cost: Not specified
Portability: Fixed-Site Detection System
Availability: Not yet available (waiting approval from the FDA)
Commercial use: Yes
Detection Category: Rolling Circle Amplification/rRNA
Application: Not specified
Current Users: Not specified

OPERATIONAL PARAMETERS

BAs Detected: Not specified
SOP Sample Preparation: Not specified
Calibration Requirements: Not specified
Sensitivity: Not specified
Testing Information: Not specified
Sample Preparation: Not specified
Sample Type: Not specified
Specificity: Not specified
Confidence Interval/Specificity: Not specified

PHYSICAL PARAMETERS

Size: Not specified
Power Requirements: Not specified
Weight: Not specified
Total Weight: Not specified

LOGISTIC PARAMETERS

Durability: Not specified
Consumables: Not specified
Environmental Conditions: Not specified
Maintenance: Not specified
Support Equipment: Reagents and materials provided include the following:
Reagent 1 (Lysis reagent)—one 10 mL
Reagent 2 (Hybridization buffer)—one 10 mL
Reagent 3 (Selection reagent)—one 60 mL
(Reagents provided for 200 bacterial determinations per kit)
Gen probe luminometers (for reading the results)
Shelf Life (Equipment): 2 ºC to 25 ºC (35.6 ºF to 77 ºF)
Do not freeze these reagents
Stable until the experimentation date
Shelf Life (Consumables): Convenient packaging provides extended shelf life
Maintenance Costs: Not specified

SPECIAL PARAMETERS

Skills Required: Not specified
Manuals Available: Not specified
Warranty: Not specified
Training: Relatively inexperienced lab personnel
Data Storage: Not specified
Safety Requirements: The kit has sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. Upon disposal of the reagents, always dilute the material with a large column of water to prevent azide build-up in plumbing.

APPENDIX J—BIOLOGICAL DETECTOR UPDATES

Appendix J—Biological Detector Updates

Appendix J includes the changes made to the draft *Guide for the Selection of Biological Agent Detection Equipment for Emergency First Responders b*ased on vendor information following the final vendor contact in December 2006. Most of the changes were made to appendix F [Biological Detection Equipment data sheets (vendor supplied)] and appendix G [Biological Detection Equipment data sheets (limited information)]. In the following table, R (rated) represents the equipment included in appendix E, and NR (not rated) represents the equipment included in appendix G.

Biological Detector Updates (October 2005)

Current					Draft					Action
ID #	Name	Manufacturer	Vendor Response (2006)	Evaluated	ID #	Name	Manufacturer	Vendor Response (2005)	Evaluated	
1	BADD™ BioWarfare Agent Detection Devices	ADVNT Biotechnologies	Yes	Yes	**1**	BADD™ BioWarfare Agent Detection Devices	ADVNT Biotechnologies	Yes	Yes	Vendor updated information
2	Rapid Response Hand Held Assay (RRHHA)	ANP Technologies, Inc.	Yes	Yes	**2**	Rapid Response Hand Held Assay (RRHHA)	ANP Technologies, Inc.	Yes	Yes	Vendor updated information
3	Prime Alert™ Biodetection/Threat Verification System (Model PAE002)	GenPrime, Inc.	Yes	Yes	**3**	Prime Alert™ Biodetection/Threat Verification System, Model PAE001	GenPrime, Inc.	Yes	Yes	Vendor updated information. Removed Prime Alert™ Biodetection/Threat Verification System, Model PAE001 (per vendor) and replaced with updated R # 36
4	SMART II (Biothreat Detection Diagnostic Kits)	New Horizons Diagnostics Corporation	Yes	Yes	**4**	Biothreat Detection Diagnostic Kits	New Horizons Diagnostics Corporation	No	Yes	Vendor updated information
5	Bio-seeq™ Handheld PCR Detector (Model 2430999)	Smiths Detection	Yes	Yes	**5**	Bio-seeq™ Hand-held PCR Detector	Smiths Detection	No	Yes	Vendor updated information
6	R.A.P.I.D.® System (7200)	Idaho Technology, Inc.	Yes	Yes	**6**	Ruggedized Advanced Pathogen Identification Device System (R.A.P.I.D.)	Idaho Technology, Inc.	Yes	Yes	Vendor updated information
7	RAMP	Response Biomedical Corp.	Yes	Yes	**7**	RAMP Biowarfare Detection	Response Biomedical Corp.	Yes	Yes	Vendor updated information

Current					Draft					Action
ID #	Name	Manufacturer	Vendor Response (2006)	Evaluated	ID #	Name	Manufacturer	Vendor Response (2005)	Evaluated	
8	Guardian Reader System (P–102)	Alexeter Technologies	Yes	Yes	**8**	The Guardian Reader System™ for Tetracore's BioThreat Alert™ Tests	Alexeter Technologies	Yes	Yes	Vendor updated information
9	BioThreat Alert Bio Threat Test Strips	Tetracore, Inc.	Yes	Yes	**9**	BioThreat Alert Bio Threat Test Strips with Alexeter Reader	Tetracore, Inc.	Yes	Yes	Vendor updated information and name change
10	MICROCYTE® Field Family MICROCYTE® Field and MICROCYTE® Aqua	BioDETECT AS	Yes	Yes	**10**	MICROCYTE® Field family MICROCYTE® Field MICROCYTE® Lab MICROCYTE® Aqua	BioDETECT AS	Yes	Yes	Vendor updated information and name change
11	Analyte 2000 Biowarfare Detection (Analyte 2000 Fiber Optic Fluorometer)	Research International	Yes	Yes	**11**	Analyte 2000 Biowarfare Detection (Analyte 2000 Fiber Optic Fluorometer)	Research International, Inc.	Yes	Yes	Vendor updated information
12	RAPTOR Plus	Research International	Yes	Yes	**12**	RAPTOR Rapid, Automatic Portable Fluorometric Assay System	Research International, Inc.	Yes	Yes	Vendor updated information and name change
13	Smart Cycler II TD System (SC2000N2–1)	Cepheid	Yes	Yes	**13**	Smart Cycler II System	Cepheid	Yes	No	Updated information, name change, and rated
14	GeneXpert® System (GX1000N4–1)	Cepheid	Yes	Yes	**14**	Smart Cycler II TD System	Cepheid	Yes	No	Replaced Smart Cycler with GeneXpert and Vendor updated information

Current					Draft					Action
ID #	Name	Manufacturer	Vendor Response (2006)	Evaluated	ID #	Name	Manufacturer	Vendor Response (2005)	Evaluated	
15	LightCycler™ (Model 1.2)	Roche Applied Science	No	Yes	**15**	LightCycler™ Model 1.2	Roche Applied Science	Yes	No	No vendor response, evaluated
16	Gen-Probe Amplified AccuProbe Culture Identification Reagent Kit	Gen-Probe	No	No	**16**	Gen-Probe Amplified AccuProbe Culture Identification Reagent Kit	Gen-Probe	Yes	No	Vendor updated information
17	Gen-Probe Leader 450i	Gen-Probe	No	No	**17**	Gen-Probe Leader 450i	Gen-Probe	Yes	No	Vendor updated information
18	M-SERIES® M1M Analyzer	BioVeris Corporation	Yes	Yes	**18**	M-Series M1	Igen	Yes	No	Vendor updated information, manufacturer and name change, and evaluated
—	—	—	—	—	**19**	ORIGEN 1.5 Analyzer	Igen	Yes	No	Removed old #19 (ORIGEN 1.5 Analyzer) per vendor
19	M-SERIES® 384 Analyzer	BioVeris Corporation	Yes	No	**20**	M-Series M8	Igen	Yes	No	Vendor updated information, manufacturer and name change, and ID change
20	FACSCaliber	BD Biosciences Immunocytometry Systems	No	No	**21**	FACSCaliber	BD Biosciences Immunocytometry Systems	Yes	No	ID change only
21	BD FACSCount (337858)	BD Biosciences Immunocytometry Systems	Yes	No	**22**	Cytometer FACSCount	BD Biosciences Immunocytometry Systems	Yes	No	Vendor updated information, name change and ID change
22	Agilent 2100 Bioanalyzer	Agilent Technologies	No	No	**23**	Agilent 2100 Bioanalyzer	Agilent Technologies	Yes	No	ID change only

Current					Draft					Action
ID #	Name	Manufacturer	Vendor Response (2006)	Evaluated	ID #	Name	Manufacturer	Vendor Response (2005)	Evaluated	
23	HPLC Diode Array Detector 20/20	GROTON Biosystems	No	No	**24**	HPLC Diode Array Detector 20/20	GROTON Biosystems	Yes	No	ID change only
24	Agilent 6850	Agilent Technologies	No	No	**25**	Agilent 6850	Agilent Technologies	Yes	No	ID change only
25	Capillary Electrophoresis System (GPA100)	GROTON Biosystems	No	No	**26**	Capillary Electrophoresis System GPA100	GROTON Biosystems	Yes	No	ID change only
26	HPLC Fluorescence Detector (FD500)	GROTON Biosystems	No	Yes	**27**	HPLC Fluorescence Detector—FD500	GROTON Biosystems	Yes	No	ID change only
27	BioCheck™ Powder Screening Test Kit (GB 1001)	20/20 GeneSystems Inc.	Yes	Yes	**28**	BioCheck™ Powder Screening Test Kit	20/20 GeneSystems Inc.	Yes	No	Vendor updated informtion, ID change, and evaluated
28	KT1030 HazCat Anthrax Screening Test Kit	Haztech Systems, Inc.	Yes	Yes	**29**	HazCat Anthrax Screening Test Kit	Haztech Systems, Inc.	No	Yes	Vendor updated information and ID change
29	KT1035 HazCat® WMD Kit	Haztech Systems, Inc.	Yes	Yes	**30**	KT1035 HazCat® WMD Kit	Haztech Systems, Inc.	No	Yes	Vendor updated information and ID change
30	KT1040 HazCat® MicroCat/WMD	Haztech Systems, Inc.	Yes	Yes	**31**	HazCat® MicroCat/WMD Model KT1040 HazCat® KT1040 MicroCat Kit	Haztech Systems, Inc.	No	Yes	Vendor updated information, name changd, and ID change
—	—	—	—	—	**32**	TravelIR	Smiths Detection Danbury	No	Yes	Removed #32 TravelIR, no longer available
31	HazMatID (023–1001)	Smiths Detection Danbury	Yes	Yes	**33**	HAZMATID	Smiths Detection Danbury	Yes	Yes	Vendor updated information and ID change

Current					Draft					Action
ID #	Name	Manufacturer	Vendor Response (2006)	Evaluated	ID #	Name	Manufacturer	Vendor Response (2005)	Evaluated	
32	IlluminatIR ML Package (006–2019)	Smiths Detection Danbury	Yes	Yes	**34**	IlluminatIR ML Package 006–2019	Smiths Detection Danbury	Yes	Yes	Vendor updated information and ID change
33	HMB Portable Biohazard Detector (HMB V–PS)	BioTech International, Inc.	Yes	Yes	**35**	HMB Portable Biohazard Detector HMB V–PS	BioTech International, Inc.	Yes	Yes	Vendor updated information and ID change
—	—	—	—	—	**36**	Prime Alert™ Biodetection/Threat Verification System, Model PAE002	GenPrime, Inc.	Yes	Yes	#36 Prime Alert™ Biodetection/Threat Verification System, Model PAE002 replaced #3 Model PAE001
34	PROFILE® 1 (Model 3560)	New Horizons Diagnostics Corporation	Yes	Yes	—	—	Alexeter Technologies	Yes	Yes	Moved NR #71 (Profile I, Model 3560, New Horizon) to R #34
35	Defender TSR (Test Strip Reader) System (P–502)	Alexeter Technologies	Yes	Yes	—	—	—	—	—	New—vendor updated information
36	MPD-based BW Detector (P-chip/MPD/2004)	BioTraces, Inc.	Yes	Yes	—	—	BioTraces, Inc.	Yes	Yes	#16 from not rated table, vendor updated information
37	QTL Biosensor (2000)	QTL Biodefense	Yes	Yes	—	—	QTL Biodefense	—	—	#10 from not rated table, vendor updated information
38	Prime Alert® Biodetection System (096–3130)	GenPrime, Inc.	Yes	Yes	—	—	GenPrime, Inc. (Manufacturer)	—	—	New—vendor updated information

Current					Draft					Action
ID #	Name	Manufacturer	Vendor Response (2006)	Evaluated	ID #	Name	Manufacturer	Vendor Response (2005)	Evaluated	
39	RAZOR® System (RAZR-ASY-0010)	Idaho Technology, Inc.	Yes	Yes	—	—	Idaho Technology, Inc.	—	—	New—vendor updated information
40	Uni-Lite NG	Biotrace International, Ltd.	Yes	Yes	—	—	Biotrace International, Ltd.	—	—	New—vendor updated information
41	Autotrack (Continuous Flow ATP Detector)	Biotrace International, Ltd.	Yes	Yes	—	—	Biotrace International, Ltd.	—	—	#41 from not rated table, vendor updated information
42	VeroTect	Biral	Yes	Yes	—	—	Biral	—	—	New
43	4 WARN Sentry 3000 (Model 718866–901)	General Dynamics Canada	Yes	Yes	—	—	General Dynamics Canada	—	—	#68 from not rated table, vendor updated information
44	KT1050 HazCat Tier 4 System	Haztech Systems, Inc.	Yes	Yes	—	—	Haztech Systems, Inc.	—	—	New—vendor updated information
45	Biological Alarm Monitor (MAB)	Proengin USA	Yes	Yes	—	—	Proengin USA	—	—	#9 from not rated table, vendor updated information
46	RespondeR RCI (024-1001)	Smiths Detection Danbury	Yes	Yes	—	—	Smiths Detection Danbury	—	—	New—vendor updated information

Biological Detector Updates (Post November 2006)

Current				
ID #	**Name**	**Manufacturer**	**Vendor Response (2006)**	**Evaluated**
1	BADD™ BioWarfare Agent Detection Devices	ADVNT Biotechnologies	11-17-06	Yes
2	Rapid Response Hand Held Assay (RRHHA)	ANP Technologies, Inc.	No	Yes
3	Prime Alert™ Biodetection/Threat Verification System (Model PAE002)	GenPrime, Inc.	11-27-06	Yes
4	SMART II (Biothreat Detection Diagnostic Kits)	New Horizons Diagnostics Corporation	11-29-06	Yes
5	Bio-seeq™ Handheld PCR Detector (Model 2430999)	Smiths Detection	11-17-06	Yes
6	R.A.P.I.D.® System (7200)	Idaho Technology, Inc.	11-28-06	Yes
7	RAMP	Response Biomedical Corp.	11-17-06	Yes
8	Guardian Reader System (P–102)	Alexeter Technologies	11-21-06	Yes
9	BioThreat Alert Bio Threat Test Strips	Tetracore, Inc.	11-22-06	Yes
10	MICROCYTE® Field Family MICROCYTE® Field and MICROCYTE® Aqua	BioDETECT AS	11-17-06	Yes
11	Analyte 2000 Biowarfare Detection (Analyte 2000 Fiber Optic Fluorometer)	Research International	No	Yes
12	RAPTOR Plus	Research International	No	Yes
13*	Smart Cycler II TD System (SC2000N2–1)	Cepheid	11-17-06	Removed
14	GeneXpert® System (GX1000N4–1)	Cepheid	11-17-06	Yes
15	LightCycler™ (Model 1.2)	Roche Applied Science	No	Yes
16*	Gen-Probe Amplified AccuProbe Culture Identification Reagent Kit	Gen-Probe	No	Moved from appendix F to Kits (appendix I)
17	Gen-Probe Leader 450i	Gen-Probe	No	No
18	M-SERIES® M1M Analyzer	BioVeris Corporation	No	Yes
19	M-SERIES® 384 Analyzer	BioVeris Corporation	No	No
20	FACSCaliber	BD Biosciences Immunocytometry Systems	No	No
21	BD FACSCount (337858)	BD Biosciences Immunocytometry Systems	No	No
22	Agilent 2100 Bioanalyzer	Agilent Technologies	11-6-06	No
23	HPLC Diode Array Detector 20/20	GROTON Biosystems	No	No

Current				
ID #	**Name**	**Manufacturer**	**Vendor Response (2006)**	**Evaluated**
24	Agilent 6850	Agilent Technologies	11-6-06	No
25	Capillary Electrophoresis System (GPA100)	GROTON Biosystems	No	No
26	HPLC Fluorescence Detector (FD500)	GROTON Biosystems	No	Yes
27	BioCheck™ Powder Screening Test Kit (GB 1001)	20/20 GeneSystems Inc.	No	Yes
28	KT1030 HazCat Anthrax Screening Test Kit	Haztech Systems, Inc.	11-21-06	Yes
29	KT1035 HazCat® WMD Kit	Haztech Systems, Inc.	11-21-06	Yes
30	KT1040 HazCat® MicroCat/WMD	Haztech Systems, Inc.	11-21-06	Yes
31	HazMatID (023–1001)	Smiths Detection Danbury	1-12-07	Yes
32	IlluminatIR ML Package (006–2019)	Smiths Detection Danbury	1-12-07	Yes
33	HMB Portable Biohazard Detector (HMB V–PS)	BioTech International, Inc.	11-22-06	Yes
34	PROFILE® 1 (Model 3560)	New Horizons Diagnostics Corporation	11-29-06	Yes
35	Defender TSR (Test Strip Reader) System (P–502)	Alexeter Technologies	11-21-06	Yes
36	MPD-based BW Detector (P-chip/MPD/2004)	BioTraces, Inc.	11-21-06	Yes
37	QTL Biosensor (2000)	QTL Biodefense	12-4-06	Yes
38	Prime Alert® Biodetection System (096–3130)	GenPrime, Inc.	11-27-06	Yes
39	RAZOR® System (RAZR-ASY-0010)	Idaho Technology, Inc.	11-29-06	Yes
40	Uni-Lite NG	Biotrace International, Ltd.	No	Yes
41	Autotrack (Continuous Flow ATP Detector)	Biotrace International, Ltd.	No	Yes
42	VeroTect	Biral	11-29-06	Yes
43	4 WARN Sentry 3000 (Model 718866–901)	General Dynamics Canada	No	Yes
45	Biological Alarm Monitor (MAB)	Proengin USA	11-29-06	Yes
46	RespondeR RCI (024-1001)	Smiths Detection Danbury	1-15-07	Yes
47	BioThreat Alert™ ELISA Kits	Tetracore, Inc.	1-12-07	Yes (New item)