SUMMARY OF SAFETY AND EFFECTIVENESS

Chembio HIV 1/2 STAT-PAK™ Assay

I. General Information

Device Generic Name: Rapid HIV 1/2 Assay Antibody Test

Device Trade Name: Chembio HIV 1/2 STAT-PAK™ Assay

Applicants Name and Address: Chembio Diagnostic Systems, Inc.
3661 Horseblock Road,
Medford, NY 11763

Tel: 1-631-924-1135
Tel: 1-800-327-3635
Fax:1-631-924-6033
Email: info@chembio.com

Premarket Approval Application (PMA) Number: BP050010

Date of Notice of Approval to Applicant: May 25, 2006

II. Name And Intended Use

The Chembio HIV 1/2 STAT-PAK™ Assay is a single-use immunochromatographic test for the detection of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in fingerstick whole blood, venous whole blood, serum or plasma specimens. The Chembio HIV 1/2 STAT-PAK™ assay is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2. This test is suitable for use in multi-test algorithms designed for the statistical validation of rapid HIV test results. When multiple rapid HIV tests are available, this test should be used in appropriate multi-test algorithms.

III. Device Description

The Chembio HIV 1/2 STAT-PAK™ Assay employs a unique combination of a specific antibody binding protein which is conjugated to colloidal gold dye particles and HIV-1/2 antigens which are bound to the solid phase membrane. The venous or capillary (fingerstick) whole blood, serum or plasma is applied to the SAMPLE (S) well of test device followed by the addition of Running Buffer. The Buffer facilitates the lateral flow of the specimen and test reagents and promotes the binding of the antibodies to the antigen. The specimen/buffer mixture migrates along the test strip by capillary action, reconstituting the conjugate. If present, the antibodies bind to the colloidal gold conjugated antibody binding protein. In a reactive sample, the dye conjugated-immune complex migrates on the nitrocellulose membrane and is captured by the antigens immobilized in the TEST (T) area producing a pink/purple line. In the absence of HIV-1 and HIV-2 antibodies, there is no pink/purple line in the TEST (T) area. The sample continues to migrate along the membrane and produces a pink/purple line in the CONTROL (C) area containing immunoglobulin G antigens. This procedural control serves to demonstrate that specimen and reagents have been properly applied and have migrated through the device.

IV. RESTRICTIONS

1. Sale of the Chembio HIV 1/2 STAT-PAK™ Assay is restricted to clinical laboratories that have an adequate quality assurance program, including planned systematic activities that provide adequate confidence that requirements for quality will be met and where there is assurance that operators will receive and use the instructional materials.
2. The Chembio HIV 1/2 STAT-PAK™ Assay is approved for use only by an agent of a clinical laboratory.
3. Test subjects must receive the “Subject Information Notice” prior to specimen collection and appropriate information when test results are provided.
4. The Chembio HIV 1/2 STAT-PAK™ Assay is not approved for use to screen blood, plasma, cell or tissue donors.

V. Warnings

For *IN VITRO* diagnostic use

a. Read the Product Insert completely before using this assay. Follow the instructions carefully as not doing so may result in inaccurate Test Results.
b. Users of this test should follow the CDC Universal Precautions for prevention of transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other bloodborne pathogens. [1]
c. Use of this test Kit with specimen types other than those specifically approved for use with this device may result in inaccurate test results.
d. This test should be performed at 18 to 30°C (64 to 86°F). If stored refrigerated, ensure that the pouch is brought to operating temperature before performing testing.
e. If the test Kit is stored at temperatures outside the storage temperature 8 to 30°C (46 to 86°F), or used outside the operating temperature 18 to 30°C (64 to 86°F), use the Kit Controls to ensure proper performance of the test.
f. Individual infected with HIV-1 and/or HIV-2 who is receiving highly active antiretroviral therapy (HAART) may produce false negative results.

VI. Precautions

1. Safety Precautions
   a. Handle the specimens and materials contacting specimens as if capable of transmitting infection.
   b. Do not eat, drink or smoke in the area where specimens and kit reagents are handled. Avoid any contact with hands, eyes or mouth during specimen collection and testing.
   c. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling specimens.
   d. Dispose of all specimens and materials used in the test procedure in a biohazard waste container. Lancets should be placed in a puncture-resistant container prior to disposal. The recommended method of disposal of biohazard waste is autoclaving for a minimum of 1 hour at 121ºC. Disposable materials may be incinerated. Liquid wastes may be mixed with appropriate chemical disinfectants. A freshly prepared solution of 10% bleach (0.5% solution of sodium hypochlorite) is recommended. Allow 60 minutes for effective decontamination. **NOTE: Do not autoclave solutions that contain bleach.**
   e. For additional information on biosafety, refer to “Universal Precautions for prevention of transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other bloodborne pathogens.” [1] And "Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis [13]
   f. Use 10% bleach or other appropriate disinfectant to wipe all spills. The bleach solution should be made fresh each day.

2. Handling Precautions
   a. If Desiccant Packet is missing, DO NOT USE, discard test device and a new test device should be used.
   b. Do not use any test device if the pouch has been perforated.
   c. Each test device is for single use only.
   d. Do not use the reagents beyond the expiration date printed on the pouch. Always check expiration date prior to testing.
   e. Do not mix reagents from different lot numbers of Kits.
   f. Adequate lighting is required to read the Test Results.

VI. Limitations of the Test

a. The Chembio HIV 1/2 STAT-PAK™ test must be used in accordance with the instructions in this Product Insert to obtain accurate results.
b. The Chembio HIV 1/2 STAT-PAK™ Assay must be used with capillary (fingerstick) or venous whole blood, serum or plasma only. Use of other types of specimens or testing of venipuncture whole blood specimens collected using a tube containing an anticoagulant other than citrate, heparin or EDTA may not yield accurate results. For serum samples, collect blood without anticoagulant.

c. Reading Nonreactive Test Results earlier than 15 minutes or any Test Results later than 20 minutes may yield erroneous results.
d. Do not open the sealed foil pouch until just prior to use.
e. Do not use Kit contents beyond labeled expiration date.
f. For the collection of the fingerstick whole blood specimen, ensure that finger is completely dry before performing fingerstick.
g. Read results in a well-lit area.
h. A Reactive Test Result using the Chembio HIV 1/2 STAT-PAK™ test suggests the presence of antibodies to HIV-1 and/or HIV-2 in the specimen. The Chembio HIV 1/2 STAT-PAK™ Assay is intended as an aid in the diagnosis of infection with HIV-1/2. AIDS and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically.
i. For a Reactive Test Result, the intensity of the test line does not necessarily correlate with the titer of antibody in the specimen.
j. A person who has antibodies to HIV-1 or HIV-2 is presumed to be infected with the virus, except that a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV.
k. A Nonreactive Test Result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to recent exposure may take several months to reach detectable levels.
l. This assay has not been evaluated for newborn screening, cord blood specimens, individuals less than 18 years and greater than 64 years of age.

VII. Alternative Practices and Procedures

Detection of antibodies against HIV epitopes can be done in a variety of ways, including western Blot, EIA and immunochromatographic assays. Imunochromatographic assays may be either lateral or transverse flow. Most rapid HIV assays are based on lateral flow. The signal mechanism for immunochromatographic tests may utilize enzymatic or chemiluminescent reactions or entail visualization of a metal colloid; primarily gold, although selenium has also been used. Capture antigens may be peptides, proteins, fusion peptides or viral lysates. Samples for these tests are serum, plasma, whole blood, urine or saliva. Usually a qualitative or semi-quantitative result is reported. Most tests are utilized as screening assays and require confirmation. Rapid tests may also be used as part of a diagnostic testing algorithm. The Chembio HIV 1/2 STAT-PAK™ Assay is a lateral flow immunochromtatographic assay which utilizes colloidal gold to determine the presence of HIV-1/2 antibodies in serum, plasma or whole blood.

VIII. Potential adverse effects of the Device on Health

There have been no known adverse effects found to date with the Chembio HIV 1/2 STAT-PAK™ Assay.

IX. Summary of Preclinical Studies

The Chembio HIV 1/2 STAT-PAK™ Assay was evaluated in non-clinical studies against a number of well defined panels of specimens.

Reactivity with HIV-1 Specimens from Various World Wide Geographic Regions

To assess sensitivity of the Chembio HIV 1/2 STAT-PAK™ Assay for HIV-1 specimens from various worldwide geographic regions, 1,894 confirmed HIV antibody-positive specimens were obtained. Of the 1,859 specimens evaluated from Africa, Asia, Latin America, Europe, and Belgium, 1,854 were reactive using Chembio HIV 1/2 STAT-PAK™ Assay. The remaining 35 confirmed positive specimens, from two worldwide panels were evaluated, consisting of naturally occurring plasma specimens from diverse geographical locations (Spain, Ghana, Cote d' Ivoire, Mozambique, Uganda, Zimbabwe, China, Thailand, India, USA and Argentina with HIV-1 genotypes: A, B, C, D, E, F, G, O, B/D and HIV-2). All 35 were reactive using Chembio HIV 1/2 STAT-PAK™ Assay.

Reactivity with Seroconversion Panels

The Chembio HIV 1/2 STAT-PAK™ Assay was tested against 15 different seroconversion panels. Each panel consisted of sequential collections from a single individual who seroconverted. Samples were confirmed using Western Blot (WB) and two licensed EIA tests. As shown in Table 1, the Chembio HIV 1/2 STAT-PAK™ test performed similarly to currently licensed assays in detecting seroconversion.

Table 1

Comparison of the Chembio HIV 1/2 STAT-PAK™ Assay to
two licensed EIA assays and Western Blot in detecting seroconversion.
(Where NR = Nonreactive and RR = Repeatedly Reactive)

Panel	Relative Day of Bleed	Chembio HIV 1/2 STAT-PAK™ Assay	EIA 1	EIA 2	WB
PRB-927 (AB)	0	NR	NR	NR	NR
	28	NR	RR	NR	NR
	33	NR	RR	NR	NR
	35	R	RR	NR	NR
	40	R	RR	RR	R
PRB-928 (AC)	0	NR	NR	NR	NR
	111	NR	RR	NR	NR
	120	R	RR	RR	R
	125	R	RR	RR	R
	130	R	RR	RR	R
PRB-930 (AE)	0	NR	NR	NR	NR
	3	NR	NR	NR	NR
	7	NR	RR	NR	NR
	10	NR	RR	RR	IND
PRB-931 (AF)	0	NR	NR	NR	NR
	2	NR	NR	NR	NR
	7	NR	NR	NR	NR
	9	NR	NR	NR	NR
	15	NR	NR	NR	NR
	28	R	RR	NR	NR
	33	R	RR	RR	IND
	35	R	RR	RR	R
	42	R	RR	RR	R
PRB-934 (AI)	0	NR	NR	NR	NR
	7	R	RR	NR	IND
	11	R	RR	RR	IND
PRB-938 (AM)	0	NR	NR	NR	NR
	3	NR	NR	NR	NR
	9	NR	RR	NR	IND
PRB-944 (AT)	0	NR	NR	NR	NR
	2	NR	NR	NR	NR
	7	NR	NR	NR	NR
	9	NR	NR	NR	NR
	14	R	RR	NR	IND
	16	R	RR	NR	IND
PRB-959 (BI)	0	NR	NR	NR	NR
	7	NR	NR	NR	NR

Panel	Relative Day of Bleed	Chembio HIV 1/2 STAT-PAK™ Assay	EIA 1	EIA 2	WB
PRB-959 (BI)	9	NR	RR	NR	NR
	14	R	RR	RR	R
	19	R	RR	RR	R
	21	R	RR	RR	R
	26	R	RR	RR	R
PRB-904 (D)	0	NR	NR	NR	NR
	21	NR	NR	NR	NR
	49	NR	NR	NR	NR
	92	R	RR	RR	R
	99	R	RR	RR	R
PRB-910 (J)	0	NR	NR	NR	NR
	14	NR	NR	NR	NR
	26	R	RR	RR	R
	28	R	RR	RR	R
	32	R	RR	RR	R
	35	R	RR	RR	R
	40	R	RR	RR	R
PRB-914 (N)	0	R	RR	NR	IND
	4	R	RR	RR	IND
	7	R	RR	RR	IND
	25	R	RR	RR	R
	31	R	RR	RR	R
PRB-916 (P)	0	NR	NR	NR	NR
	4	NR	NR	NR	NR
	9	NR	NR	NR	NR
	15	NR	NR	NR	NR
	30	R	RR	RR	R
	35	R	RR	RR	R
PRB-917 (Q)	0	NR	NR	NR	NR
	53	NR	NR	NR	NR
	57	NR	NR	NR	NR
	60	N/A*	RR	NR	NR
	65	R	RR	NR	IND
	67	R	RR	NR	IND
	72	N/A	RR	RR	R
PRB-919 (S)	0	NR	NR	NR	NR
	9	R	RR	NR	R
	11	R	RR	RR	R
PRB-922 (V)	0	NR	RR	NR	NR
	4	NR	RR	NR	NR
	7	R	RR	NR	NR
	11	R	RR	NR	R

* N/A- Not Available.

Reactivity with HIV-1 Low Titer Panels

A total of 30 specimens from two characterized Low Titer panels were used to evaluate the ability of the Chembio HIV 1/2 STAT-PAK™ Assay to detect antibodies to HIV-1. The results of testing are presented in Table 2 and demonstrate that the Chembio HIV 1/2 STAT-PAK™ Assay detected the presence of antibody in a manner similarly to one or both of the licensed EIAs.

Table 2

Comparison of the Chembio HIV 1/2 STAT-PAK™ Assay to
two licensed EIA assays and Western Blot in using Low Titer panels
(Where NR = Nonreactive and RR = Repeatedly Reactive)

Panel	Chembio HIV 1/2 STAT-PAK™ Assay	EIA 1	EIA 2	WB
PRB107-1	NR	RR	NR	NR
PRB107-2	NR	RR	RR	IND
PRB107-3	NR	RR	NR	NR
PRB107-4	NR	RR	RR	NR
PRB107-5	NR	NR	NR	NR
PRB107-6	R	RR	RR	NR
PRB107-7	NR	RR	NR	NR
PRB107-8	NR	RR	RR	NR
PRB107-9	NR	RR	NR	NR
PRB107-10	R	RR	RR	NR
PRB107-11	R	RR	RR	R
PRB107-12	NR	RR	NR	NR
PRB107-13	NR	RR	NR	IND
PRB107-14	R	RR	RR	R
PRB107-15	R	RR	RR	IND
PRB108-1	R	RR	RR	R
PRB108-2	NR	NR	NR	NR
PRB108-3	NR	RR	RR	IND
PRB108-4	R	RR	RR	R
PRB108-5	R	RR	RR	R
PRB108-6	R	RR	RR	IND
PRB108-7	R	RR	RR	R
PRB108-8	R	RR	RR	R
PRB108-9	R	RR	RR	R
PRB108-10	NR	RR	NR	IND
PRB108-11	R	RR	RR	R
PRB108-12	NR	RR	NR	NR
PRB108-13	NR	RR	NR	IND
PRB108-14	NR	RR	NR	NR
PRB108-15	R	RR	RR	IND

Reactivity with HIV-1 Mixed Titer Panels

The sensitivity of Chembio HIV 1/2 STAT-PAK™ Assay was evaluated by testing three well characterized panels composed of specimens ranging from nonreactive to strong reactive for anti-HIV-1 antibody. The results are presented in Table 3 and indicate that the Chembio HIV 1/2 STAT-PAK™ Assay was able to detect antibodies to HIV-1 similarly to the licensed EIA and WB.

Table 3

Comparison of the Chembio HIV 1/2 STAT-PAK™ Assay to
two licensed EIA assays and Western Blot using Mixed Titer Panels
(Where NR = Nonreactive and RR = Repeatedly Reactive)

Panel	Chembio HIV 1/2 STAT-PAK™ Assay	EIA 1	EIA 2	WB
PRB202-1	NR	RR	RR	IND
PRB202-2	R	RR	RR	R
PRB202-3	R	RR	RR	R
PRB202-4	R	RR	RR	R
PRB202-5	R	RR	RR	R
PRB202-6	R	RR	RR	R
PRB202-7	R	NR	RR	R
PRB202-8	R	RR	RR	R
PRB202-9	NR	NR	NR	NR
PRB202-10	R	RR	RR	R
PRB202-11	R	RR	RR	R
PRB202-12	R	RR	RR	R
PRB202-13	NR	RR	RR	R
PRB202-14	R	RR	RR	R
PRB202-15	R	RR	RR	R
PRB202-16	R	RR	RR	R
PRB202-17	R	RR	RR	R
PRB202-18	R	RR	RR	R
PRB202-19	R	RR	RR	R
PRB202-20	R	RR	RR	R
PRB202-21	NR	NR	NR	NR
PRB202-22	R	RR	RR	R
PRB202-23	NR	RR	NR	IND
PRB202-24	R	RR	RR	R
PRB202-25	R	RR	RR	R
PRB203-1	R	RR	RR	R
PRB203-2	R	RR	RR	R
PRB203-3	NR	NR	NR	NR
PRB203-4	NR	RR	NR	IND
PRB203-5	R	RR	RR	R
PRB203-6	R	RR	RR	R
PRB203-7	R	RR	RR	R
PRB203-8	R	RR	RR	R
PRB203-9	R	RR	RR	R
PRB203-10	R	RR	RR	R
PRB203-11	R	RR	RR	R
PRB203-12	R	RR	RR	R
PRB203-13	R	RR	RR	R

Panel	Chembio HIV 1/2 STAT-PAK™ Assay	EIA 1	EIA 2	WB
PRB203-14	NR	RR	NR	NR
PRB203-15	R	RR	RR	R
PRB203-16	R	RR	RR	R
PRB203-17	R	RR	RR	R
PRB203-18	R	RR	RR	R
PRB203-19	R	RR	RR	R
PRB203-20	NR	NR	NR	NR
PRB203-21	R	RR	RR	R
PRB203-22	R	RR	RR	R
PRB203-23	R	RR	RR	R
PRB203-24	R	RR	RR	R
PRB203-25	R	RR	RR	R
PRB204-1	NR	RR	NR	NR
PRB204-2	R	RR	RR	R
PRB204-3	NR	NR	NR	NR
PRB204-4	R	RR	RR	R
PRB204-5	R	RR	RR	R
PRB204-6	R	RR	RR	R
PRB204-7	R	RR	RR	R
PRB204-8	R	RR	RR	R
PRB204-9	NR	RR	NR	NR
PRB204-10	R	RR	RR	IND
PRB204-11	R	RR	RR	R
PRB204-12	R	RR	RR	R
PRB204-13	NR	RR	RR	IND
PRB204-14	R	RR	RR	R
PRB204-15	R	RR	RR	R
PRB204-16	R	RR	RR	R
PRB204-17	R	RR	RR	R
PRB204-18	R	RR	RR	IND
PRB204-19	R	RR	RR	R
PRB204-20	R	RR	RR	R
PRB204-21	R	RR	RR	R
PRB204-22	R	RR	RR	R
PRB204-23	NR	NR	NR	NR
PRB204-24	NR	RR	NR	IND
PRB204-25	NR	RR	NR	IND

Effect of Potentially Interfering Substances and Unrelated Medical Conditions

To evaluate the influence of unrelated medical conditions or interfering substance on the specificity and sensitivity of the Chembio HIV 1/2 STAT-PAK™ Assay. 208 specimens representing unrelated medical conditions, and 110 specimens representing potential interfering substances were tested (Table 7). The specimens were spiked with either saline (Nonreactive) or an HIV-1 reactive serum specimen to a low level of reactivity. All HIV-1 spiked specimens gave reactive results while all unspiked samples, with the exception of one elevated albumin specimen and 14 syphilis specimens, gave nonreactive results. The one elevated albumin specimen and all of the 14 unspiked syphilis specimens with reactive results were subsequently confirmed as infected with HIV-1 using a licensed Western Blot assay. An additional ten known HIV-1 nonreactive, syphilis reactive specimens were tested and yielded expected results.

Table 4

Chembio HIV 1/2 STAT-PAK™ assay reactivity against specimens from unrelated medical conditions or containing potential interfering substances.

Chembio HIV 1/2 STAT-PAK™ Assay		
Description	**Saline (Nonreactive)**	**HIV-1/2 (Weak Reactive)**
Cirrhosis	20 / 20	20 / 20
CMV IgM	20 / 20	20 / 20
Recent flu vaccination[1]	11 / 11	11 / 11
HBV	21 / 21	21 / 21
HCV	19 / 19	19 / 19
HTLV-I	11 / 11	11 / 11
HTLV-II	10 / 10	10 / 10
Multiparous	9 / 9	9 / 9
Myeloma	10 / 10	10 / 10
Rheumatoid Factor	10 / 10	10 / 10
Syphilis[2]	15 / 29	29 / 29
Tuberculosis	38 / 38	38 / 38
Elevated Albumin[3]	9 / 10	10 / 10
Elevated Bilirubin	10 / 10	10 / 10
Citrate	10 / 10	10 / 10
DNA	10 / 10	10 / 10
EDTA	10 / 10	10 / 10
Hemolyzed	10 / 10	10 / 10
Heparin	10 / 10	10 / 10
Icteric	10 / 10	10 / 10
Lipemic	10 / 10	10 / 10
Elevated Protein	10 / 10	10 / 10
Elevated Triglycerides	10 / 10	10 / 10

[1]Collected within 6 months of vaccination
[2]Fourteen samples were confirmed reactive, using a licensed WB assay
[3]One sample was confirmed as containing HIV antibodies by using a licensed WB assay

Reproducibility Studies

Reproducibility was tested at three independent sites using three lots of Chembio HIV 1/2 STAT-PAK™ Assay. A panel of five blinded samples representing nonreactive, low reactive HIV-1, low reactive HIV-2, high reactive HIV-1 and high reactive HIV-2 were run on three separate days by three separate technicians at each site. Testing was performed according to the Product Insert of the Chembio HIV 1/2 STAT-PAK™ test. Results were read at 15 minutes. Results were read semi-quantitatively using a common strip evaluation scale. A total of 405 data points was taken. There was 100% reproducibility (405/405) across all parameters.

Animal Studies

No animal studies were performed using the Chembio HIV 1/2 STAT-PAK™ assay.

X. Summary of Clinical Studies

HIV-1 Sensitivity

The sensitivity of the Chembio HIV 1/2 STAT-PAK™ Assay to detect infection with HIV-1 was evaluated using 603 specimens from individuals known to be infected with HIV-1 and from 776 individuals at high risk for infection with HIV-1 (Table 5). 637 individuals were identified as positive for infection with HIV-1 using a licensed confirmatory Assay, and/or FDA approved NAT assay. Of these, 635 tested reactive on the Chembio HIV 1/2 STAT-PAK™ Assay. The calculated sensitivity of Chembio HIV 1/2 STAT-PAK™ assay in these studies was 99.7% (635/637 = 99.5% with 95% CI = 98.9% - 100%).

Table 5
Detection of antibody to HIV-1 in specimens from individuals known to be infected with HIV-1, and at high risk for infection with HIV-1

Study Population	Samples	HIV 1/2 STAT-PAK™ Assay Reactive	Licensed EIA Repeatedly Reactive	Licensed WB Reactive	True Positive[1]
Known Positive	603	599	601	601	601
High-Risk	776	36	41	35[2]	36[3]
TOTAL	1379	635	642	636	637

[1]Based on licensed WB and NAT assay results (when positive and EIA is repeatedly reactive).
[2]Two specimens were indeterminate by Western Blot (one was initially reactive only on EIA and Nonreactive on HIV 1/2 STAT-PAK™, and one was repeatedly reactive on EIA and Nonreactive on HIV 1/2 STAT-PAK™).
[3]One specimen was repeatedly reactive on EIA and Reactive on HIV 1/2 STAT-PAK™, indeterminate on WB, and positive on NAT.

HIV-2 Sensitivity

The Sensitivity of the Chembio HIV 1/2 STAT-PAK™ Assay to detect HIV-2 antibody was determined by testing 202 serum/plasma specimens that were positive for HIV-2 antibodies only. These specimens were obtained from repository sources. A total of 488 specimens from an area endemic for HIV-2 infection were also tested (Table 6). All specimens reactive with the Chembio HIV 1/2 STAT-PAK™ in these studies were also reactive by a licensed anti-HIV-1/2 EIA. The sensitivity of HIV 1/2 STAT-PAK™ for detection of antibodies to HIV-2 in these studies was calculated to be 100% (203/203 = 100% with 95% CI = 98.2% - 100%).

Table 6
Detection of antibody to HIV-2 in known HIV-2 reactive specimens and endemic samples

Study Population	Samples	HIV 1/2 STAT-PAK™ Assay Reactive	True HIV-2 Positive Only[1]
Known HIV-2 Positive	202	202	202
Endemic Samples	488	27[2]	1
TOTAL	690	229	203

[1]Confirmation based on results using a research use HIV-2 Western blot.
[2]Of these 27 HIV-1 EIA and HIV-2 EIA reactive specimens; 23 were reactive on HIV-1 WB only, three were reactive on HIV-1 and HIV-2 WB, and one was indeterminate on HIV-1 WB and reactive on HIV-2 WB.

Specificity
The specificity of Chembio HIV 1/2 STAT-PAK™ Assay was evaluated by testing specimens from low risk and high risk populations for infection with HIV-1 from three clinical study sites. The results are summarized in Table 7.

Table 7
Performance of the Chembio HIV 1/2 STAT-PAK™ Assay
on specimens from individuals presumed to be negative for HIV-1 infection

Study Population	Samples	HIV 1/2 STAT-PAK™ Assay Nonreactive	Licensed EIA Nonreactive	True Negative[1]
Low-Risk	**691**	**690**	**687[2]**	**691**
High-Risk	**776**	**740**	**735[3]**	**740**
TOTAL	**1467**	**1430**	**1422**	**1431**

[1]Confirmation performed by licensed HIV-1 Western Blot, IFA or NAT. One specimen was EIA repeatedly reactive, WB indeterminate, and NAT positive. One specimen was EIA repeatedly reactive and WB indeterminate. These two specimens were not included in the specificity calculations.
[2]Four specimens were repeatedly reactive on EIA and nonreactive on Chembio HIV 1/2 STAT-PAK™ Assay and Western Blot.
[3]Five specimens were repeatedly reactive on EIA and nonreactive on Chembio HIV 1/2 STAT-PAK™ Assay and Western Blot .

Based on these studies, the specificity of Chembio HIV 1/2 STAT-PAK™ Assay in these studies was calculated to be 99.9% (1430/1431 = 99.9% with 95% CI = 99.6% - 100%).

XI. Conclusions drawn from the Study

Risk Benefit Analysis
CDC estimates that of the 850,000–950,000 people in the United States living with HIV/AIDS, 80,000–280,000 do not know they are infected. Each year at publicly funded testing sites, 27,000–30,000 HIV test results are reactive. Of those who test reactive at CDC-funded public testing sites, 31% do not return for their results. The use of rapid HIV tests allows more patients who might otherwise not return for follow up counseling and evaluation to be treated. HIV rapid tests also permit better management of prenatal and post natal care for HIV reactive mothers by allowing HIV drug therapy to be initiated prior to labor. As of June 2000, CDC had received voluntary reports of 56 U.S. HCP with documented HIV seroconversion temporally associated with an occupational HIV exposure. An additional 138 episodes in HCP are considered possible occupational HIV transmissions. Rapid HIV testing allows prophylactic treatment of these types of exposure. Finally, as noted in the June 14, 2001 BPAC Advisory panel meeting, simple, rapid self-contained HIV tests further cost effective public health by allowing testing in non-traditional settings.

Safety
There have been no known adverse effects found to date with the Chembio HIV 1/2 STAT-PAK™ Assay.