



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Office of Research and Development
Washington, D.C. 20460



**ENVIRONMENTAL TECHNOLOGY VERIFICATION PROGRAM
VERIFICATION STATEMENT**

TECHNOLOGY TYPE:	POLYCHLORINATED BIPHENYL (PCB) FIELD ANALYTICAL TECHNIQUES
APPLICATION:	MEASUREMENT OF PCBs IN SOILS AND SOLVENT EXTRACTS
TECHNOLOGY NAME:	D TECH PCB TEST KIT
COMPANY:	STRATEGIC DIAGNOSTICS INC.
ADDRESS:	111 PENCADER DRIVE NEWARK, DE 19702-3322
PHONE:	(302) 456-6789

The U.S. Environmental Protection Agency (EPA) has created a program to facilitate the deployment of innovative technologies through performance verification and information dissemination. The goal of the Environmental Technology Verification (ETV) Program is to further environmental protection by substantially accelerating the acceptance and use of improved and more cost-effective technologies. The ETV Program is intended to assist and inform those involved in the design, distribution, permitting, and purchase of environmental technologies. This document summarizes the results of a demonstration of the Strategic Diagnostics Inc. (SDI) D TECH PCB test kit.

PROGRAM OPERATION

EPA, in partnership with recognized testing organizations, objectively and systematically evaluates the performance of innovative technologies. Together, with the full participation of the technology developer, they develop plans, conduct tests, collect and analyze data, and report findings. The evaluations are conducted according to a rigorous demonstration plan and established protocols for quality assurance. EPA's National Exposure Research Laboratory, which conducts demonstrations of field characterization and monitoring technologies, with the support of the U.S. Department of Energy's (DOE's) Environmental Management (EM) program, selected Oak Ridge National Laboratory as the testing organization for the performance verification of polychlorinated biphenyl (PCB) field analytical techniques.

DEMONSTRATION DESCRIPTION

In July 1997, the performance of six PCB field analytical techniques was determined under field conditions. Each technology was independently evaluated by comparing field analysis results to those obtained using approved reference methods. Performance evaluation (PE) samples were also used to assess independently the accuracy and comparability of each technology.

The demonstration was designed to detect and measure PCBs in soil and solvent extracts. The demonstration was conducted at the Oak Ridge National Laboratory (ORNL) in Oak Ridge, Tennessee, from July 22 through July 29. The

study was conducted under two environmental conditions. The first site was outdoors, with naturally fluctuating temperatures and relative humidity conditions. The second site was inside a controlled environmental chamber, with generally cooler temperatures and lower relative humidities. Multiple soil types, collected from sites in Ohio, Kentucky, and Tennessee, were analyzed in this study. Solutions of PCBs were also analyzed to simulate extracted surface wipe samples. The results of the soil and extract analyses conducted under field conditions by the technology were compared with results from analyses of homogeneous replicate samples conducted by conventional EPA SW-846 methodology in an approved reference laboratory. Details of the demonstration, including a data summary and discussion of results, may be found in the report entitled *Environmental Technology Verification Report: Immunoassay Kit, Strategic Diagnostics, Inc., D TECH PCB Test Kit*, EPA/600/R-98/112.

TECHNOLOGY DESCRIPTION

The D TECH PCB test kit is designed to provide quick, semi-quantitative, and reliable test results for making environmental decisions. The D TECH kit utilizes immunoassay technology to detect trace amounts of PCBs in environmental samples. This test specifically detects Aroclors 1254, 1260, and 1262 equally; reacts well with Aroclors 1242, 1248, and 1268; reacts moderately with Aroclors 1232 and 1016; and shows little reactivity to Aroclor 1221. The test is calibrated for Aroclor 1254 and has conversions for Aroclors 1242 and 1248. The D TECH PCB test kit uses latex particles as the solid support component of the assay. With this immunoassay system, antibodies are immobilized on the thousands of latex particles that are free to interact and react with the sample solution. To initiate the test, a sample solution (soil extract) is added to a dry mixture of antibody-coated latex particles and enzyme conjugate. A competitive reaction for binding sites on the antibodies then occurs between the analyte PCBs (in the sample solution) and the added enzyme conjugate. When the reaction is complete, the particles are collected on the membrane surface of a collection cup and briefly washed. The test is completed by adding a color developing solution to the surface of the collection cup. As with the other immunoassay systems, the enzyme conjugate produces a color change reaction which can then be detected and measured. The darker the color, the less analyte PCB is present in the sample. Measurement of the test results can be completed instrumentally with a reflectance meter or visually with the included color card.

VERIFICATION OF PERFORMANCE

The following performance characteristics of the D TECH PCB test kit were observed:

Throughput: Throughput was 11 samples/hour in the chamber and 15 samples/hour outdoors. This rate included sample preparation and analysis.

Ease of Use: Three operators analyzed samples during the demonstration, but the technology can be run by a single operator. Minimal training (2 to 4 hours) is required to operate the D TECH kit, provided the user has a fundamental understanding of basic chemical and field analytical techniques.

Completeness: The D TECH kit generated results for all 232 PCB samples, for a completeness of 100%.

Blank results: PCBs were detected above the lowest reporting interval for five of the eight blank soil samples. Therefore, the percentage of false positive results was 62%. Two false positive results (25%) were reported for the extract samples. The D TECH kit reported 0.5% false negative results for soils and 0% for extracts.

Precision: The overall precision, based on the percentage of combined sample sets where all four replicates were reported as the same interval, was 44% for the PE soils, 21% for the environmental soils, and 25% for the extracts.

Accuracy: Accuracy was assessed using PE soil and extract samples. Accuracy, defined as the percentage of D TECH results that agreed with the accepted concentrations, was 56% for PE soils and 42% for extracts. The percentage of samples that was biased high was greater (28%) than the percentage that was biased low (17%) for the PE soil samples, while the percentage that was biased high or low was comparable (29%) for the extract samples.

Comparability: Comparability, like accuracy, was defined as the percentage of samples that agreed with, was above (i.e., biased high), or was below (i.e., biased low) the reference laboratory results. The percentage of samples that agreed with the reference laboratory results was 53% for all soils (PE and environmental) and 42% for extracts. The percentage of samples that was biased high was greater (28%) than the percentage that was biased low (20%) for the soil samples, while the percentage that was biased high or low was again comparable (29%) for the extract samples.

Regulatory decision-making: One objective of this demonstration was to assess the technology's ability to perform at regulatory decision-making levels for PCBs, specifically 50 ppm for soils and 100 $\mu\text{g}/100\text{cm}^2$ for surface wipes. For PE and environmental soil samples in the range of 40 to 60 ppm, 61% of the D TECH results agreed with the reference laboratory. By contrast, 7% were biased high, while 32% were biased low. For the extract samples representing surface wipe sample concentrations of 100 $\mu\text{g}/100\text{cm}^2$ and 1000 $\mu\text{g}/100\text{cm}^2$ (assuming a 100 cm^2 wipe sample), 42% of the D TECH results agreed with the extract spike concentration. In comparison, the percentage of extract samples biased high or low was comparable (29%).

Data quality levels: The performance of the D TECH PCB test kit was characterized as biased, with approximately 50% of the D TECH results agreeing with the accepted values (in terms of accuracy), and imprecise, with consistently less than 50% replicate sample results reported as the same interval.

The results of the demonstration show that the D TECH PCB test kit can provide useful, cost-effective data for environmental problem-solving and decision-making. Undoubtedly, it will be employed in a variety of applications, ranging from serving as a complement to data generated in a fixed analytical laboratory to generating data that will stand alone in the decision-making process. As with any technology selection, the user must determine if this technology is appropriate for the application and the project data quality objectives. For more information on this and other verified technologies, visit the ETV web site at <http://www.epa.gov/etv>.

Gary J. Foley, Ph.D.
Director
National Exposure Research Laboratory
Office of Research and Development

NOTICE: EPA verifications are based on an evaluation of technology performance under specific, predetermined criteria and the appropriate quality assurance procedures. EPA makes no expressed or implied warranties as to the performance of the technology and does not certify that a technology will always, under circumstances other than those tested, operate at the levels verified. The end user is solely responsible for complying with any and all applicable Federal, State, and Local requirements.