**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
Office of Research and Development
Washington, D.C. 20460

ETV

# ENVIRONMENTAL TECHNOLOGY VERIFICATION PROGRAM
# VERIFICATION STATEMENT

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| TECHNOLOGY TYPE: | **POLYCHLORINATED BIPHENYL (PCB) FIELD ANALYTICAL TECHNIQUES** |
| APPLICATION: | **MEASUREMENT OF PCBs IN SOILS AND SOLVENT EXTRACTS** |
| TECHNOLOGY NAME: | **RaPID ASSAY SYSTEM FOR PCB ANALYSIS** |
| COMPANY: | **STRATEGIC DIAGNOSTICS INC.** |
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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) RaPID Assay System for polychlorinated biphenyl (PCB) Analysis.

## PROGRAM OPERATION

The 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 Environmental Management program, selected Oak Ridge National Laboratory (ORNL) as the testing organization for the performance verification of 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 ORNL in Oak Ridge, Tennessee, from July 22 through July 29. The study was conducted under two climatic 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., RaPID Assay System for PCB Analysis*, EPA/600/R-98/111.

## TECHNOLOGY DESCRIPTION

The RaPID Assay System applies the principles of enzyme-linked immunosorbent assay to the determination of PCBs. The sample to be tested is added, along with an enzyme conjugate, to a disposable test tube, followed by paramagnetic particles coated with PCB-specific antibodies. Both the analyte PCB (which may be in the sample) and the labeled PCB (the enzyme conjugate) compete for the antibody binding sites on the paramagnetic particles. At the end of an incubation period, a magnetic field is applied to hold the paramagnetic particles (which contain the analyte PCB and labeled PCB bound to the antibodies in proportion to their original concentration) in the tube and allow the unbound reagents to be decanted. After decanting, the particles are washed with washing solution. The presence of PCBs is detected by adding the enzyme substrate (hydrogen peroxide) and the chromogen (3,3',5,5'-tetramethylbenzidine). The enzyme-labeled PCB conjugate bound to the PCB-specific antibody catalyzes the conversion of the enzyme substrate/chromogen mixture to a colored product. After an incubation period, the reaction is stopped and stabilized by the addition of acid. Because the labeled PCB (enzyme conjugate) is in competition with the analyte PCBs (in the sample) for the antibody sites, the color development is inversely proportional to the concentration of PCB in the sample (e.g. the darker the color, the less analyte PCB is present in the sample).

## VERIFICATION OF PERFORMANCE

The following performance characteristics of the RaPID Assay System were observed:

***Detection limits:*** EPA defines the method detection limit (MDL) as the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero. The MDL was calculated to be 1.5 ppm based on the performance evaluation sample analyses. This was slightly higher than SDI's specified MDL of 0.5 ppm.

***Throughput:*** Throughput was 10 to 11 samples/hour. 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 trained operator. Minimal training (2 to 4 hours) is required to operate the RaPID Assay System, provided the user has a fundamental understanding of basic chemical and field analytical techniques.

***Completeness:*** The RaPID Assay System generated results for all 232 PCB samples for a completeness of 100%.

***Blank results:*** No PCBs were detected in either the soil or extract blanks above the RaPID Assay's MDLs; therefore, the percentage of false positive results was 0%. Two false negative results (1%) were reported for the nonblank soil samples.

***Precision:*** The RaPID Assay System exhibited a significant "site effect" in terms of precision. The overall precision, based on average relative standard deviations (RSDs), was 25% (under outdoor conditions) and 12% (under chamber conditions) for soil samples. The outdoor precision was comparable to the reference laboratory's precision (21% RSD), while the chamber precision was better. The RaPID Assay's precision was comparable to the reference laboratory's (12% and 14%, respectively) for extract samples.

***Accuracy:*** Accuracy was assessed using PE soil and extract samples. The data showed that the RaPID Assay System exhibited both positive and negative bias depending on the Aroclor type present in the sample. Because the bias was evenly distributed (positive and negative), this was not reflected in the overall accuracy (which was based on average percent recoveries) of 103% for the PE soil samples. Extract measurements were relatively unbiased, with an overall average percent recovery of 101%. Evaluation of the data generated at each site indicated that there were no significant differences between the two data sets based on environmental conditions.

***Comparability:*** This demonstration showed that the RaPID Assay System generated data that exhibited a linear correlation to the reference laboratory data. The coefficient of determination ($R^2$), which is a measure of the degree of correlation between the reference laboratory and the RaPID Assay data, was 0.754 when all soil samples (0 to 700 ppm) were considered. For the concentration range from 0 to 125 ppm, the $R^2$ value was 0.716. Approximately 36% of the soil sample results had percent difference values within the range of ±25%. For extract samples, the data were highly correlated with the reference laboratory, $R^2$ of 0.977.

***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 µg/100cm$^2$ for surface wipes. For PE and environmental soil samples in the range of 40 to 60 ppm, the precision was 21% RSD with a mean accuracy of 126% recovery. For extract samples representing surface wipe sample concentrations of 100 µg/100cm$^2$ and 1000 µg/100cm$^2$ (assuming a 100 cm$^2$ wipe sample), measurements were precise (12% RSD) and accurate (101% recovery).

***Data quality levels:*** The overall performance of the RaPID Assay System was characterized as slightly biased and precise, under a given set of environmental conditions. Although there was a significant "site effect" in terms of the precision, it should be noted that the RaPID's worst-case precision (25% RSD) was comparable to the best case precision (21% RSD, excluding suspect values) for the reference laboratory.

The results of the demonstration show that the SDI RaPID Assay System for PCB analysis 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*.

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