



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 homogenous 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., EnviroGard PCB Test Kit*, EPA/600/R-98/113.

## TECHNOLOGY DESCRIPTION

The EnviroGard PCB test kit is a competitive binding enzyme immunoassay that performs rapid, interval testing for PCBs in soils and solutions at specified action levels of 1, 5, 10, and 50 parts per million (ppm). These results are reported in intervals (e.g., < 1 ppm, 1 to 5 ppm, etc.) rather than in specific quantities (e.g., 6.7 ppm). The test kit is standardized using Aroclor 1248, but it can also detect Aroclors 1016, 1242, 1254, and 1260. The following items are needed to run a test: the EnviroGard PCB test kit, the Soil Extraction Bottle kit, the equipment contained in the Soil Field Lab, methanol, and water. The test procedure entails collecting a 5-g soil sample and extracting the PCBs from it using methanol. To initiate the PCB test, PCB-enzyme conjugate is added to the antibody-coated test tubes. The soil extract sample is then added to the test tube. After a 15-min incubation period, the tubes are rinsed and a color developing solution is added. Color development is inversely related to the PCB concentration (e.g. the darker the color, the less analyte PCB is present in the sample). PCBs are detected using a photometer that measures the absorbance of each tube.

## VERIFICATION OF PERFORMANCE

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

**Throughput:** Throughput was 18 samples/hour under outdoor conditions and 9 to 10 samples/hour under chamber conditions. 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 h) is required to operate the EnviroGard kit, provided the user has a fundamental understanding of basic chemical and field analytical techniques.

**Completeness:** The EnviroGard kit generated results for all 232 PCB samples for a completeness of 100%.

**Blank results:** All of the blank soil samples were reported as the lowest reporting interval, which included zero; therefore, the percentage of false positive results was 0%. One false positive result (13%) was reported for the extract samples. The EnviroGard kit reported no false negative results.

**Precision:** The overall precision—based on the percentage of combined sample sets where all four replicates were reported as the same interval—was 38% for the PE soils, 47% for the environmental soils, and 67% for the extracts.

**Accuracy:** Accuracy was assessed using PE soil and extract samples. Accuracy, defined as the percentage of EnviroGard results that agreed with the accepted concentration, was 51% for PE soils and 58% for extracts. In general, the percentage of samples that was biased high was much greater (47% for PE soils and 38% for extracts) than the percentage biased low (1% for PE soils and 4% for extracts).

**Comparability:** Comparability, like accuracy, was defined as the percentage of results that agreed with, was above (i.e., biased high), or was below (i.e., biased low) the reference laboratory result. The percentage of samples that agreed with the reference laboratory results was 53% for all soils (PE and environmental) and 63% for extracts. The percentage of samples that was biased high was again much greater (45% for soils and 38% for extracts) than the percentage that was

biased low (2% for soils and 0% for extracts).

**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<sup>2</sup> for surface wipes. For PE and environmental soil samples in the range of 40 to 60 ppm, 39% of the EnviroGard results agreed with the reference laboratory. In contrast, 59% were biased high and 2% were biased low. For extract samples representing surface wipe sample concentrations of 100 µg/100 cm<sup>2</sup> and 1000 µg/100 cm<sup>2</sup> (assuming a 100cm<sup>2</sup> wipe sample), 63% of the EnviroGard results agreed with the extract spike concentration. In comparison, the percentage of extract samples that was biased high was 38%, and the percentage of samples that was biased low was 4%.

**Data quality levels:** The performance of the EnviroGard PCB test kit was characterized as biased and imprecise about 50% of the time, because nearly half of the data were biased relative to the accepted concentration values (in terms of accuracy) and had replicate results that were not reported as the same interval (in terms of precision). It should be noted that there was an increased likelihood of results being biased high as a result of the conservatism that the manufacturer has incorporated into the calculation of results.

The results of the demonstration show that the EnviroGard 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>.

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