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Innovative Technology Verification Report

Envirogard PCB Test Kit, Millipore, Inc

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Executive Summary

This innovative technology evaluation report (ITER) presents information on the demonstration and evaluation of the EnviroGard PCB Test produced by Millipore, Inc. (Millipore). The EnviroGard PCB Test is designed to detect polychlorinated biphenyl (PCB) contamination in soil. The demonstration was conducted by PRC Environmental Management, Inc. (PRC), under contract to the Environmental Protection Agency's (EPA) Environmental Monitoring Systems Laboratory-Las Vegas (EMSL-LV). The demonstration was developed under the Monitoring and Measurement Technologies Program (MMTP) of the Superfund Innovative Technology Evaluation (SITE) Program.

The EnviroGard PCB Test was demonstrated and evaluated in August 1992 at a site in Kansas City, Missouri. The demonstration of the test was done in conjunction with the demonstration of three other innovative field screening technologies: the Clor-N-Soil PCB Test Kit and the L2000 PCB/Chloride Analyzer, both manufactured by the Dexsil Corporation, and the Field Analytical Screening Program PCB Method developed under the Field Investigative Team Contract, with the EPA Superfund Program. The demonstration results for these other technologies are presented in separate ITERs .

The EnviroGard PCB Test is designed to quickly provide semiquantitative results for PCB concentrations in soil samples. The technology can be customized to report specific results over a particular range of concentrations. As part of the SITE demonstration, the technology also was evaluated for its ability to produce quantitative results.

The EnviroGard PCB Test is an immunoassay system that uses polyclonal antibodies to produce compound-specific reactions to PCBs allowing their detection and quantitation. An anti-PCB antibody is fixed to the inside wall of a test tube to bind PCB compounds. An enzyme conjugate containing a PCB derivative labeled with horseradish peroxidase is added to the test tube where it competes with PCBs for anti-PCB antibody binding sites. Reagents are then added to the test tube where they react with the enzyme conjugate, causing a color change. Results can be estimated by observing the degree of color change. For a more precise quantitative measurement of the PCB concentration in the sample, the color of the solution can be compared to Aroclor standards using a differential photometer.

The EnviroGard PCB Test is portable, easy to operate, and useful under a variety of site conditions. The differential photometer requires electricity but can be operated using a rechargeable battery. Reagents must be kept refrigerated.

Calibrating the technology was initially difficult because of the small volume of Aroclor standards required. As the operator gained experience in using the EnviroGard PCB Test, the calibrations became easier. The EnviroGard PCB Test costs $1,495, which includes the differential photometer and other equipment needed to run the test. Additional disposable equipment and reagents needed to perform 12 analyses cost $253. The differential photometer required to obtain quantitative results costs $799.

The developer reports that the detection limit is 3.3 milligrams per kilogram (mg/kg) for Aroclor 1248. This was the detection limit used during the demonstration. The detection limit differs depending on the Aroclor. The highest number of samples analyzed in an 8-hour day was 52; the average number analyzed per 8-hour day was 25.

Results produced with the EnviroGard PCB Test may be affected by the cross-reactivity of compounds other than PCBs to the anti-PCB antibody binding sites. The developer has evaluated a number of compounds to determine their levels of cross-reactivity, although this evaluation was not independently assessed during this demonstration.

PRC evaluated field and laboratory duplicate samples to determine the technology's precision in the semiquantitative mode. Thirty-seven duplicate sample pairs were used in this semiquantitative evaluation. Of these 37 duplicate sample pairs, the EnviroGard PCB Test produced the same results 35 times. One laboratory duplicate and one field duplicate did not agree with their respective soil sample results. Based on this data, the precision of the EnviroGard PCB Test was found to be 95 percent. This meets the demonstration's criteria for acceptable precision.

PRC evaluated the accuracy of the test in its semiquantitative mode by comparing its data to that of the confirmatory laboratory. This comparison showed that 71 percent of the time the technology was correct. The other 29 percent of the time, the technology gave false positive results. It never gave a false negative result. The technology is conservative when used in the semiquantitative mode. Using an absolute definition of accuracy, it was accurate only 71 percent of the time. The production of false positive results, though, may not affect its use in environmental assessments. False positive results will incorrectly label soil as being contaminated above a test's threshold level. At worst, this would lead to the overestimation of contaminated area or volume.

To assess this technology's precision in a quantitative mode, PRC evaluated the results produced from the analysis of laboratory and field duplicate sample pairs. The EnviroGard PCB Test had 27 duplicate sample pairs in which both a sample and its duplicate had positive results. PRC used the data from the duplicate sample analyses to establish precision control limits. The control limits were set at 0 and 91 percent. All but two of the 27 relative percent differences (RPD) fell within the control limits. This equates to a precision of 93 percent, which is below the 95 percent precision deemed acceptable for this demonstration. However, the technology's precision would have exceeded this threshold if only one more duplicate sample pair had fallen within the control limits. When PRC used the Dunnett's Test to compare the RPDs between the EnviroGard PCB Test's data and the confirmatory laboratory's data, a probability of 97.5 percent resulted. This indicates that the technology is as precise as the confirmatory laboratory.

PRC used linear regression analysis to assess the accuracy of the technology in its quantitative mode when compared to the confirmatory laboratory's data. The regression of 83 matched pairs of positive sample results defined a correlation coefficient (3) of 0.87, indicating that a relationship did exist between the two data sets. The regression line calculated had a y-intercept of 17.8 mg/kg and a slope of 0.76. These results indicate that the results from this technology are not accurate. Although the technology was found to be inaccurate in its quantitative mode, the results produced by the technology were linear, indicating that the results can be corrected mathematically. If 10 to 20 percent of the soil samples are sent to a confirmatory laboratory, then the results from the other 80 to 90 percent can be corrected. This could result in a significant savings in analytical costs. The Wilcoxon Signed Ranks Test was used to verify these results. It indicated, at a 95 percent confidence level, that the EnviroGard PCB Test's data was significantly different from that of the confirmatory laboratory. This confirmed the linear regression analysis and indicated that the EnviroGard PCB Test's data was not accurate.