THE ENVIRONMENTAL TECHNOLOGY VERIFICATION PROGRAM

ETV

EPA
U.S. Environmental Protection Agency

ornl
Oak Ridge National Laboratory

Joint Verification Statement

TECHNOLOGY TYPE:	**IMMUNOASSAY**	
APPLICATION:	**MEASUREMENT OF PCBs IN CONTAMINATED SOIL AND SOLVENT EXTRACTS**	
TECHNOLOGY NAME:	**DELFIA™ PCB Assay**	
COMPANY:	**Hybrizyme**	
ADDRESS:	**2801 Blue Ridge Rd** **Raleigh, NC 27607**	**PHONE: (919) 783-9595** **FAX: (919) 782-9585**
WEB SITE:	**www.hybrizyme.com**	
EMAIL:	**rallen@hybriyzme.com**	

The U.S. Environmental Protection Agency (EPA) has created the Environmental Technology Verification Program (ETV) to facilitate the deployment of innovative or improved environmental technologies through performance verification and dissemination of information. The goal of the ETV Program is to further environmental protection by substantially accelerating the acceptance and use of improved and cost-effective technologies. ETV seeks to achieve this goal by providing high-quality, peer-reviewed data on technology performance to those involved in the design, distribution, financing, permitting, purchase, and use of environmental technologies.

ETV works in partnership with recognized standards and testing organizations and stakeholder groups consisting of regulators, buyers, and vendor organizations, with the full participation of individual technology developers. The program evaluates the performance of innovative technologies by developing test plans that are responsive to the needs of stakeholders, conducting field or laboratory tests (as appropriate), collecting and analyzing data, and preparing peer-reviewed reports. All evaluations are conducted in accordance with rigorous quality assurance protocols to ensure that data of known and adequate quality are generated and that the results are defensible.

Oak Ridge National Laboratory (ORNL) is one of the verification organizations operating under the Site Characterization and Monitoring Technologies (SCMT) program. SCMT, which is administered by EPA's National Exposure Research Laboratory, is one of six technology centers under ETV. In this verification test, ORNL evaluated the performance of polychlorinated biphenyl (PCB) detection technologies. This verification statement provides a summary of the test results for Hybrizyme's DELFIA™ PCB Assay.

VERIFICATION TEST DESCRIPTION

This verification test was designed to evaluate technologies that detect and measure PCBs in soil and solvent extracts. The test was conducted at ORNL in Oak Ridge, Tennessee, from August 21 through 24, 2000. Spiked samples of known concentration were used to assess the accuracy of the technology. Environmentally contaminated soil samples collected from U.S. Department of Energy sites in Ohio, Kentucky, and Tennessee and ranging in concentration from 0 to approximately 700 parts per million (ppm) were used to assess several performance characteristics. Tests were 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. Solutions of PCBs were also analyzed to simulate extracted surface wipe samples. The extracts were not analyzed by the reference laboratory. The results of the soil analyses conducted by the technology were compared with results from analyses of homogeneous replicate samples conducted by conventional EPA SW-846 methodology in a reference laboratory. Details of the test, including a data summary and discussion of results, may be found in the report entitled *Environmental Technology Verification Report: PCB Detection Technology—Hybrizyme, DELFIA™ PCB Assay*, EPA/600/R-01/052.

TECHNOLOGY DESCRIPTION

The DELFIA PCB Assay is a solid-phase time-resolved fluoroimmunoassay based on the sequential addition of sample extract and europium-labeled PCB tracer to a monoclonal antibody reagent specific for PCBs. In this assay, the antibody reagent and sample extract are added to a strip of microtiter plate wells and allowed to react. The strips have been specially treated to trap the antibody reagent or antibody-PCB complexes that may have formed. A wash step removes sample matrix from the captured antibody. This step significantly reduces any potential matrix interferences before the addition of the PCB tracer, resulting in an unusually robust assay system. The PCB tracer is then added and allowed to bind to the antibodies that are not complexed with sample PCBs. A wash step is used to separate antibody-bound tracer from the tracer free in solution. The addition of an enhancement solution forms highly fluorescent chelates with the bound europium ions. The amount of fluorescence measured is inversely proportional to the concentration of PCBs in the sample. The lowest reporting level is typically 0.5 ppm.

VERIFICATION OF PERFORMANCE

The following performance characteristics of the DELFIA PCB Assay were observed:

Precision: The mean relative standard deviations (RSDs) for the soil and extract samples were 20% and 15%, respectively, indicating that the analyses for both matrices were precise.

Accuracy: Accuracy was assessed using the nominal concentrations of the spiked soils. The percentages of recovery were significantly different for data generated under the outdoor and the chamber conditions. The results were biased slightly high under the outdoor conditions (mean % recovery = 124%), and biased slightly low under the chamber conditions (mean % recovery = 72%). Additional testing of the data demonstrated that the results generated under the outdoor and the chamber conditions were statistically different, indicating that the DELFIA PCB Assay performed differently under different environmental conditions. For the extracts, all samples were biased high, with larger bias observed under the outdoor conditions.

False positive/false negative results: No false positives were reported for the soil and extract blanks. In addition, false positive and false negative results were determined by comparing the DELFIA PCB Assay result to the reference laboratory result for the environmental and the spiked samples. None of the results were reported as false positives, but 2% (4 of 192 samples) were false negatives relative to the reference laboratory.

Completeness: The DELFIA PCB Assay generated results for all 208 soil samples and 24 extract samples, for a completeness of 100%.

Comparability: A one-to-one sample comparison of the DELFIA PCB Assay results and the reference laboratory results was performed for all samples (spiked and environmental) that were reported as detections. The correlation coefficient (r) for the comparison of the entire soil data set was 0.50 [slope (m) = 0.20]. If six justifiably suspect values are excluded from the data set, the r value improves to 0.89, with a slope of 0.78. As stated in the Accuracy section, the DELFIA PCB Assay's performance was different under the outdoor and the chamber conditions. When the performance of the field technology is compared with the results from the reference laboratory (rather than with the nominal concentrations, as was used in the accuracy assessment), there is no statistical difference between the data sets generated outdoors and in the chamber. The comparison with the reference laboratory results did not show statistical differences because of the uncertainty (i.e., variability) in the two data sets.

Sample Throughput: Operating both in the field and in the chamber, the Hybrizyme team accomplished a sample throughput rate of approximately six samples per hour for the soil and extract analyses. Two operators were used for the PCB analyses, but the technology can be run by a single trained operator.

Regulatory Decision-Making: One objective of this verification test was to assess the technology's ability to perform at regulatory decision-making levels for PCBs—specifically, 50 ppm for soils, including both performance evaluation and environmental samples. The performance of the DELFIA PCB Assay for this concentration range was precise (mean RSD = 14%), unbiased (mean % recovery = 94%), and comparable to the reference laboratory (mean % difference = 27%).

Overall Evaluation: The verification team found that the DELFIA PCB Assay was relatively simple for the trained analyst to operate in the field, requiring less than an hour for initial setup. The overall performance of the DELFIA PCB Assay for the analysis of PCBs in soil and extract samples was characterized as biased (dependent on environmental conditions) but precise. 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

W. Frank Harris, Ph.D.
Associate Laboratory Director
Biological and Environmental Sciences
Oak Ridge National Laboratory