THE ENVIRONMENTAL TECHNOLOGY VERIFICATION PROGRAM

U.S. Environmental Protection Agency

ETV Verification Statement

TECHNOLOGY TYPE:	**QUALITATIVE SPOT TEST KIT**	
APPLICATION:	**LEAD-BASED PAINT DETECTION**	
TECHNOLOGY NAME:	**LeadAVERT™ Test Kit**	
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The U.S. Environmental Protection Agency (EPA) supports the Environmental Technology Verification (ETV) Program 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 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. Information and ETV documents are available at www.epa.gov/etv.

ETV works in partnership with recognized standards and testing organizations, with stakeholder groups (consisting of buyers, vendor organizations, and permitters), and with 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 and laboratory tests (as appropriate), collecting and analyzing data, and preparing peer-reviewed reports. All evaluations are conducted according to rigorous quality assurance (QA) protocols to ensure that data of known and adequate quality are generated and that the results are defensible.

This verification test was conducted under the U.S. EPA through the ETV program. Testing was performed by Battelle, which served as the verification organization. This verification test was conducted in response to the call of the Renovation, Repair, and Painting (RRP) rule for an EPA evaluation and recognition program for test kits that are candidates to meet the false positive and negative goals of this rule. Per the RRP rule, a test kit should have a demonstrated probability (with 95% confidence) of a false negative response less than or equal to 5% of the time for paint containing lead at or above the regulated level, 1.0 mg/cm^2 and a demonstrated probability (with 95% confidence) of a false positive response less than or equal to 10% of the time for paint containing lead below the regulated level, 1.0 mg/cm^2. Battelle evaluated the performance of qualitative spot test kits for lead in paint. This verification statement provides a summary of the test results for Silver Lake Research LeadAVERT™ Test Kit.

TECHNOLOGY DESCRIPTION

Following is a description of the LeadAVERT™ Test Kit technology, based on information provided by the vendor. The information provided below was not verified in this test

The LeadAVERT™ Test Kit is an antibody-based test for the detection of lead in paint samples. The test uses specific monoclonal antibodies that recognize and bind to lead atoms extracted from paint with a weakly acidic, low-toxicity extraction solution. The antibodies are incorporated in a competitive immunoassay in a lateral-flow test strip format, so that the entire immunoassay is contained in a small test strip activated by the flow of sample. Results are read visually as blue lines appearing in the result window of the test strip. The LeadAVERT™ Test Kit is calibrated to give a "positive" or "negative," relative to the 1 mg/cm^2 standard for lead based paint.

The LeadAVERT™ Test Kit is provided as a 20-test package, and includes all components necessary to run the test: a reusable stencil to trace a specific area of paint, disposable test vials, an extraction solution in a dropper bottle, and a container of 20 single-use test strips. Paint is removed from the traced area into the test vial, and the extraction solution is added to the vial. After 3 minutes, the test strip is placed into the vial, and allowed to run for 10 minutes. Results are read by comparing the intensity of two blue lines appearing in the "result window" of the test strip. The entire procedure is completed in less than 15 minutes and requires no power sources or instrumentation.

The LeadAVERT™ Test Kit package is a container of approximately 5" X 8" X 1.5". Recommended storage is at room temperature (50-86°F / 10-30°C). The 20-test LeadAVERT™ Test Kit has a suggested retail price of $39.95 (as of May 2010).

VERIFICATION TEST DESCRIPTION

This verification test of the LeadAVERT™ Test Kit was conducted January through June 2010 at the Battelle laboratories in Columbus, Ohio. This timeframe included testing of the test kit and also completion of all ICP-AES and QC analyses.

Qualitative spot test kits for lead in paint were evaluated against a range of lead concentrations in paint on various substrates using performance evaluation materials (PEMs). PEMs were 3-inch by 3-inch square panels of wood (pine and poplar), metal, drywall, or plaster that were prepared by Battelle. Each PEM was coated with either white lead (lead carbonate) or yellow lead (lead chromate) paint. The paint contained lead targeted at 0.3, 0.6, 1.0, 1.4, 2.0, and 6.0 mg/cm^2. These lead concentrations were chosen with input from a stakeholder technical panel based on criteria provided in EPA's lead Renovation, Repair, and Painting (RRP) rule and to represent potential lead levels in homes. Paint containing no lead (0.0 mg/cm^2) was also applied to each substrate and tested.

Two different layers of paint were applied over the leaded paint. One was a primer designed for adhesion to linseed oil-based paint and the second coat was a typical interior modern latex paint tinted to one of three colors: white, red-orange, or grey-black. These colors were chosen by EPA, with input from a stakeholder technical panel, based on the potential of certain colors to interfere with lead paint test kit operations. The top-coat paint manufacturers' recommended application thickness was used. Two coats at the recommended thickness were applied.

The LeadAVERT™ Test Kit for lead paint was operated by a technical and non-technical operator. The technical operator was a Battelle staff member with laboratory experience who had been trained by the vendor to operate the test kit. The same technical operator operated this test kit throughout testing. Because this lead paint test kit is anticipated to be used by certified remodelers, renovators, and painters, it was also evaluated by a non-technical operator. The non-technical operator was a certified renovator with little to no experience with lead analysis. The non-technical operator was provided the instruction manual provided by the vendor with the test kit for training. He then viewed the materials himself to understand how to operate the test kit. He was also

permitted to ask questions or clarifications of the vendor on the operation of the test kit. This scenario approximated the training renovators are expected to receive under the RRP rule.

Tests were performed in duplicate on each PEM by each operator, technical and non-technical. Duplicates were tested in succession by each operator on a given PEM. PEMs were analyzed blindly. Test kit operators were not made aware of the paint type, lead level, or substrate of the PEM being tested. PEMs used for analysis were marked with a non-identifying number. PEMs were not tested in any particular order. To determine whether the substrate material affected the performance of the test kits, two unpainted PEMs of each substrate were tested using each test kit, in the same manner as all other PEMs (i.e., per the test kit instructions). Three PEMs at each lead level, substrate, and topcoat color were prepared for use in this test. Thus, a total of 468 painted PEMs were used in the verification test.

To confirm the lead level of each PEM used for testing, paint chip samples from each PEM were analyzed by a National Lead Laboratory Accreditation Program (NLLAP) recognized laboratory, Schneider Laboratories, Inc., using inductively coupled plasma-atomic emission spectrometry (ICP-AES) as the reference method. The paint chip samples for reference analyses were collected by Battelle according to a Battelle standard operating procedure (SOP), which was based on ASTM E1729. Lead levels determined through the reference analysis were used for reporting and statistical analyses.

The LeadAVERT™ Test Kit was verified by evaluating the following parameters:

- ***False positive and negative rates*** – A false positive response was defined as a positive result when paint with a lead concentration $\leq$0.8 mg/cm^2 was not present. A false negative response was defined as a negative response when paint with a lead concentration $\geq$1.2 mg/cm^2 was present. Consistent with the EPA's April 22, 2008 RRP rule, panels with lead levels between 0.8 and 1.0 mg/cm^2 were not used in the false positive analysis, and those with lead levels between 1.0 and 1.2 mg/cm^2 were not used in the false negative analysis.
- ***Precision***– Measured by the reproducibility of responses for replicate samples within a group of PEMs. Groups of PEMs evaluated for precision included lead concentrations and substrate material. Responses were considered inconsistent if 25% or more of the replicates differed from the response of the other samples in the same group of PEMs.
- ***Sensitivity*** – The lowest detectable lead level by the test kit. This parameter was identified based on the detection results across all PEM levels and was determined based on the lowest PEM lead level with consistent (>75%) positive responses.
- ***Modeled Probability of Test Kit Response*** – Logistic regression models were used to determine the probabilities of positive or negative responses of the test kit at the 95% confidence level, as a function of lead concentration and other covariates, such as substrate type, lead paint type, operator type, and topcoat color. In order to account for the uncertainty associated with measurement error of the PEMs, the final multivariable model for each test kit was subjected to a simulation and extrapolation (SIMEX) analysis.
- ***Matrix Effects*** – Covariate adjusted logistic regression models were used to determine whether any of the PEMs parameters (topcoat color, substrate, operator, or lead paint type) affected the performance of the test kit. Type III Statistics and comparison of likelihoods from logistic regression models were used to determine the statistical significance of these factors.
- ***Operational Factors*** – Ease of use, operator bias, helpfulness of manuals, technology cost, and sustainability metrics such as volume and type of waste generated from the use of the test kit, toxicity of the chemicals used, and energy consumption were noted and summarized.

QA oversight of verification testing was provided by Battelle and EPA. Battelle and EPA QA staff conducted technical systems audits, and a data quality audit of at least 10% of the test data to ensure that data quality requirements were met. This verification statement, the full report on which it is based, and the test/QA plan for this verification test are available at http://www.epa.gov/etv/este.html.

VERIFICATION RESULTS

False Positive/Negative Rates: Observed false negative rates for the technical operator of the LeadAVERT™ Test Kit on PEMs with confirmed lead levels of ≥ 1.2 mg/cm^2 were 37% overall, 71% on yellow lead PEMs, and 2% on white lead PEMs. Observed false negative rates for the non-technical operator were 56% overall, 96% on yellow lead PEMs, and 15% on white lead PEMs. Substrate and topcoat color did not appear to have an impact, as these observed false negative rates were similar to the overall rates found for each operator.

The overall observed false positive rate for the LeadAVERT™ Test Kit on PEMs with confirmed lead levels of ≤ 0.8 mg/cm^2 was 22% for the technical operator and 12% for the non-technical operator. Evaluation of white lead PEMs produced the highest observed false positive rate for both operators.

Precision: Across both operators and all substrates and lead paint type, responses from the LeadAVERT™ Test Kit were inconsistent across all lead levels except 0.0 and 0.3 mg/cm^2. These overall inconsistencies were influenced by the lack of positive responses for most yellow lead PEMs.

Results from the LeadAVERT™ Test Kit indicated 100% precision on PEMs that contained no lead and 90% precision on PEMs that contained yellow lead. The precision for yellow lead panels is indicative of the lack of positive responses across most of these type of PEMs, including those with detectable levels of lead. The technical operator provided results with 96% precision for the white lead PEMs, but those for the non-technical operator were 61%.

***Sensitivity*:** Across all lead paint types and operators, the LeadAVERT™ Test Kit did not generate consistent positive results at any lead level. When sensitivity was evaluated by operator type, the lowest lead level for which consistently positive results were found was 1.4 mg/cm^2 on white lead PEMs, but no consistently positive results were obtained at any lead level for yellow lead panels. Consistently positive responses were found at the 0.6 mg/cm^2 lead level for the technical operator on white lead PEMs. The 0.6 mg/cm^2 lead level is actually below the lead level that should produce a positive response, so sensitivity as measured through positive responses is actually indicating false positive associations in this case. Otherwise, the LeadAVERT™ Test Kit as operated by the technical operator did not generate any consistently positive responses for yellow lead PEMs, and the overall sensitivity for the LeadAVERT™ Test Kit as used by the technical operator was 6.0 mg/cm^2, above the desired 1.0 mg/cm^2 lead level.

Modeled Probability of Test Kit Response: Based on the lower bound estimates of the modeled probability of the LeadAVERT™ Test Kit, the results indicate that a false negative rate of ≤5% was not obtained at 1.2 mg/cm^2.

Based on the upper bound estimates of the modeled probability of the LeadAVERT™ Test Kit, the technology met the false positive criterion (≤10%) at 0.8 mg/cm^2 for yellow lead. Thus, a false positive rate of less than 10% would only be expected to be achieved by both the technical and non-technical operator on all substrates with yellow lead. The lowest false positive rates (from 1.7% to 2.7%) would be expected when the non-technical operator was using the LeadAVERT™ Test Kit to evaluate yellow lead paint on wood, drywall, plaster, and metal.

***Matrix Effect*:** After controlling for the significant covariates, the likelihood of a positive test result is positively and significantly associated with: higher lead levels, testing by a technical operator, metal and plaster substrates, and white lead. It is not significantly and positively associated with testing by a non-technical operator, wood and drywall substrates, and yellow lead.

Operational Factors: Both the technical and non-technical operator found the LeadAVERT™ Test Kit instructions to be clear, informative, and easy to follow. The solutions used for different steps were easily identifiable within the kit and the storage conditions of the reagents were readily marked. All reagents came prepared and ready to use.

The LeadAVERT™ Test Kit came in packs of 20 strips. Each kit included a stencil, 20 square test vials, one bottle of extraction solution, and one container of 20 test strips. The user was expected to supply a pencil (for tracing the stencil), tape (for adhering the vial to the sampling area), a utility knife (for cutting to paint from the sampling area), and a timer or stopwatch (for tracking the time periods noted in the instructions).
One test strip, one vial, and 11 drops of extraction solution are produced as waste for a single test.

Interpretation of the test strips for the LeadAVERT™ Test Kit was sometimes difficult. It was difficult to discern if the two lines were equal or if one line was darker than the other in some samples. In all samples, it was up to the discretion of the user to determine the darkness of lines on the test strip.

The LeadAVERT™ Test Kit was quick and easy to operate. Operation of the test kit took approximately 15 minutes for one sample for both the technical and non-technical operator. No power supply was needed for the operation of the test kit.

Signed by: Sally Gutierrez – December 03, 2010

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