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:	**D-Lead® Paint 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 ESCA Tech, Inc. D-Lead® Paint Test Kit.

TECHNOLOGY DESCRIPTION

Following is a description of the D-Lead® Paint Test Kit technology, based on information provided by the vendor. The information provided below was not verified in this test.

The D-Lead® Paint Test Kit (Patent Pending) is a rapid chemical spot test that detects the presence or absence (more or less than 1.0 mg/cm^2) of lead in surface coatings. This test selectively dissolves the lead from the paint sample with a proprietary solvent followed by a color change reaction with sulfide ion. A visual comparison to a color standard is then used to determine the presence of lead and its level. The test uses pre-measured test reagents.

The D-Lead® Paint Test Kit test procedure consists of collecting a 3/16" diameter circle paint sample with the sample tools provided in the kit, and transferring the sample to a bottle of Solution 1; Solution 2 is then added to the bottle. Color is observed through the viewing window and compared to the color standard printed on the bottle. When the test is completed the sample and used supplies are placed in the waste disposal bag. The bag contains a neutralizing absorbent that renders the used test supplies non-hazardous.

Most paint samples that contain lead will give an immediate color reaction for a complete test in 2 to 4 minutes. If the test is not conclusively positive immediately after the addition of Solution 2, the paint sample is set aside for 10 minutes, shaken, and a final determination is made.

The D-Lead® Paint Test Kit, item number PTKIT-24-1.0 includes 24 tests, with 144 tests per case. At the time of the writing of this report, the 24 test kit has a suggested retail price of $84.50. A home version (Part number PTKIT-6-1.0) includes six tests and has a suggested retail price of $28.97.

VERIFICATION TEST DESCRIPTION

This verification test of the D-Lead® Paint 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 D-Lead® Paint 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, demonstrational DVD, and

other materials typically 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 that 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 D-Lead® Paint 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 ≤ 0.8 mg/cm^2 was present. A false negative response was defined as a negative response when paint with a lead concentration ≥ 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. 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 www.epa.gov/etv/este.html.

VERIFICATION RESULTS

False Positive/Negative Rates: The overall observed false negative rate on PEMs with confirmed lead levels $\geq$1.2 mg/cm^2 was 0% for both the technical and non-technical operator.

The overall observed false positive rate for the D-Lead® Paint Test Kit on PEMs with confirmed lead levels of $\leq$ 0.8 mg/cm^2 was 16% for the technical operator and 29% for the non-technical operator. The highest individual observed false positive rate came from the non-technical operator testing PEMs with yellow lead paint.

Precision: The D-Lead® Paint Test Kit provided overall consistent responses (either positive or negative) for both the technical and non-technical operator for all lead levels except 0.6 mg/cm^2. At this level, responses were consistent 54% of the time (i.e., consistently positive 54% of the time). Across all substrates, lead types, and operators, responses produced by the D-Lead® Paint Test Kit on PEMs with confirmed lead levels near 1.0 mg/cm^2 or greater were consistently positive $\geq$90% of the time. Results on PEMs with lead levels near 0.3 mg/cm^2 or less were consistently negative 94% of the time or more. Results from the D-Lead® Paint Test Kit indicated 100% precision on PEMs containing no lead and 85% precision on yellow and white lead PEMs.

Sensitivity: The D-Lead® Paint Test Kit was also sensitive down to 1.0 mg/cm^2 lead for both operator types and all lead levels. This is the lowest sensitivity attainable based on the test design and qualitative nature of the test kits. The D-Lead® Paint Test Kit does, however, provide graded responses to lead concentrations <1.0 mg/cm^2. The kit has indications for both low lead and no lead responses.

Modeled Probability of Test Kit Response: Based on the lower bound estimates of the modeled probability of the D-Lead® Paint Test Kit, the results indicate that, for all possible variable combinations but one, a false negative rate of $\leq$5% is predicted at 1.2 mg/cm^2. The highest predicted false negative rate is 5.4% for a technical operator evaluating lead paint with a white topcoat on wood. The modeled probability curve results indicate that at 0.8 mg/cm^2, there is no combination of variables (operator, substrate, or topcoat) where the upper prediction bound provides a false positive rate of $\leq$10% for the D-Lead® Paint Test Kit.

***Matrix Effects*:** 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 non-technical operator, drywall and metal substrates, and a grey topcoat. It is not significantly and positively associated with testing by a technical operator, plaster and wood substrates, or red and white topcoats.

Operational Factors: Both the technical and non-technical operator found the D-Lead® Paint 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 D-Lead® Paint Test Kit came in boxes of 24 tests. Each kit included sample catch trays, a scoring tool, a cleaning rod, a razor blade with a safety handle, 25 individually wrapped D-Wipe® Towels, a waste disposal bag, 24 bottles of Solution 1, and one bottle of Solution 2. All of these components were housed in a cardboard box that had hazard warnings for the solutions printed on the front and a color indicator chart printed on the inside of the lid. The user was expected to supply a hammer to tap the scoring tool into the sample and collect a paint chip.

The Solution 1 bottle and liquid, the used D-Wipe® Towel, and the used sample catch tray were produced as waste for a single test. The D-Lead® Paint Test Kit came with its own waste disposal bag. This consisted of a gallon-size zip-top bag containing an absorbent and neutralizing material. Instructions for using the waste disposal bag were printed on a label attached to the outside of the bag. The bag was designed to contain the waste from all 24 tests within a kit.

Interpretation of the color change for the D-Lead® Paint Test Kit was sometimes difficult. The color of the sample had to be read against a white background to make a proper interpretation. When the color of the sample was similar to the standard color, it was difficult to determine if the sample was the same color as the standard or possibly slightly lighter or slightly darker. In all samples, it was up to the judgment of the user to determine the color of the sample in comparison to the color of the standard.

The D-Lead® Paint Test Kit was quick to use. Operation of the test kit took up to 13 minutes, depending on the sample results, 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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