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:	**LeadPaintCheck**	
COMPANY:	**Industrial Test Systems, Inc.**	
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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 Industrial Test Systems LeadPaintCheck test kit.

TECHNOLOGY DESCRIPTION

Following is a description of the LeadPaintCheck test kit technology, based on information provided by the vendor. The information provided below was not verified in this test.

LeadPaintCheck is a semi-quantitative test kit that can detect the presence or absence of lead in paint. To evaluate a sample, a half-inch circle paint sample is collected, the paint sample is cut up in smaller pieces, and then homogenized in the ACID-1 acid solution. Lead in the Homogenized Paint (HP) sample is solubilized as $Pb^{+}2$ by the acid. The HP sample is then diluted 1/500 (100 microliters [µL] per 50 milliliters [mL] of water).

The procedure for measurement of lead in the diluted sample uses 4 mL of the HP extract, which are added to the built-in photocell of the eXact® LEADQuick™ Photometer. The sample is zeroed, two drops of Pb-2 Buffer are added to make the solution mildly alkali, and an eXact® Strip Pb-3 is then dipped in the sample for 20 seconds. The PB-3 strip simultaneously adds a porphyrin colorimetric indicator and mixes the solution. After one minute, the eXact® LEADQuick™ Photometer measures the optical density (color) as an absorbance number (abs). The abs value will be dependent on the amount of lead that is present: the higher the abs value, the higher the lead concentration in the sample. The test kit determines when lead levels are below 1.0 mg/cm^2. The test also identifies semi-quantitatively if the lead concentrations in the paint are 1, 1.5, 2, or 3 (and above) mg/cm^2.

The LeadPaintCheck Startup Kit is priced at $1999.99. The reagent replacement set is $99.99 for 50 tests. After the initial Startup investment the cost per paint test is $2. The estimated time to run the test, which includes the sampling, homogenizing, diluting, and testing time, is under 15 minutes per paint sample.

VERIFICATION TEST DESCRIPTION

This verification test of the LeadPaintCheck 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 technical stakeholder panel, based on the potential of certain colors to interfere or not 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 LeadPaintCheck 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 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 LeadPaintCheck 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 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 www.epa.gov/etv/este.html.

VERIFICATION RESULTS

False Positive/Negative Rates: The overall observed false negative rate for the LeadPaintCheck test kit on PEMs with confirmed lead levels ≥1.2 mg/cm^2 was 2% for the technical and 1% for the non-technical operator. The overall observed false positive rate on PEMs with confirmed lead levels of ≤ 0.8 mg/cm^2 was 14% for the technical operator and 16% for the non-technical operator.

Precision: The LeadPaintCheck 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 consistently positive 40-64% of the time. Inconsistent results were also obtained for 1.0 mg/cm^2 lead on plaster PEMs, with positive results 74% of the time. Results for all other lead levels were highly consistent, between 93-100% and 0-8%. Only the evaluation of metal PEMs returned consistent results for all lead levels overall. Results for the non-technical operator showed fewer inconsistencies than those for the technical operator.

Results from the LeadPaintCheck test kit indicated 100% precision in evaluating PEMs with no lead. Because of the strong consistent results noted for the LeadPaintCheck test kit, the precision of this test kit was high across both lead paint types. For white lead PEMs, the LeadPaintCheck test kit produced consistent responses 90% of the time. For yellow lead PEMs, the LeadPaintCheck test kit was precise 83% of the time.

***Sensitivity*:** The overall sensitivity of the LeadPaintCheck test kit was at the 1.0 mg/cm^2 lead level. The kit provided consistent positive responses at 1.0 mg/cm^2 across both operators and lead paint types in all cases except for yellow lead PEMs evaluated by the technical operator. In this case, the lowest level for which the test kit provided consistent positive responses was 1.4 mg/cm^2.

Modeled Probability of Test Kit Response: The modeled probability curve results indicate that at 0.8 mg/cm^2, there was no substrate type where the upper prediction bound provided a false positive rate of ≤10%. At 1.2 mg/cm^2, no false negative rates ≤5% were obtained for any substrates based on the lower prediction bound.

***Matrix Effects*:** After controlling for the significant covariates, the likelihood of a positive test result is positively and significantly associated with higher lead levels and metal and plaster substrates. It is not significantly and positively associated with drywall and wood substrates.

Operational Factors: Both the technical and non-technical operator found the LeadPaintCheck 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 LeadPaintCheck test kit as supplied for this verification test came with an eXact® LEADQuick™ Photometer, all necessary reagents (including the quality check standard and the photometer strips), a homogenizer kit by Omni that included all components necessary to operate the homogenizer, a 500 mL wash/squirt bottle, 15 mL plastic conical tubes with lids, 50 mL plastic conical tubes with lids, ½ inch cork bore, cork bore sharpener, 100 µL pipette and associated disposable tips, ¼ inch cork bore (for applications not part of this verification test), scissors, forceps, rod and base to hold the homogenizer, small brush, funnel system for paint chip collection, scalpel with blades, masking tape, and a cork bore remover. All of these components approximate the LeadPaintCheck test kit startup kit, which supplied everything listed here in sufficient quantities for 50 tests.

The HP sample solution, diluted HP sample solution, rinses for the photometer, eXact® Strip Pb-3 strips, and pipette tips were produced as waste for a single test.

The LeadPaintCheck test kit provided clear and user-friendly instructions, but required multiple steps. Operation of the test kit took approximately 22 minutes for the technical operator and approximately 27 minutes for the non-technical operator, not including clean-up time. The non-technical operator considered the LeadPaintCheck test kit to be inconvenient for use. A regular power supply was needed for the operation of the homogenizer. Four AAA batteries were needed for the operation of the eXact® LEADQuick™ Photometer.

Signed by: Sally Gutierrez – December 03, 2010

Sally Gutierrez Date
Director
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