

Application for Technology Verification
Recognition of Lead Test Kit for Use as a Negative Screen
Application deadline: September 15, 2008
Any submissions received after this date will not be accepted

This form provides information about a special verification testing program where vendors of test kits designed for detecting lead in paint may submit their lead-testing product for recognition as being suitable for use as a negative screen for lead-based paint (LBP) at the federal action level of 1 milligram of lead per square centimeter. This does not apply to test kits which are intended to be used as both a negative and positive screen as identified at 40 CFR 745.88.

This form describes the information and commitments needed for preparing, conducting, and reporting a verification test of your technology under this special verification testing program of the Environmental Protection Agency (EPA). Please provide the information requested and attach supporting documentation, and send the completed application to the submissions location indicated below. Please note that the submissions deadline is September 15, 2008. Please direct all questions to the email listed below.

Submissions to:
Kenneth T. White
Attn: Lead Test Kits
QuanTech
2020 N 14th Street, Suite 410
Arlington, VA 22201
703-312-7820 voice
703-312-5104 fax

Questions to:
Kenneth T. White
testkits@quantech.com

VENDOR NAME: _____

VENDOR ADDRESS: _____

SMALL BUSINESS (Y/N): _____ **US-OWNED BUSINESS (Y/N):** _____

TECHNOLOGY: _____

A. Verification Process

This special verification testing program will follow the process listed below:

1. **Call for participation.** This call for participation, posted on the EPA/ETV website, is directed towards current vendors of commercially available lead test kits. Vendors interested in obtaining EPA recognition for their lead test kit product as being suitable for use as a negative screen for lead-based paint can submit their technology for verification. QuanTech (EPA's contractor for this special verification testing program) will conduct a one-time evaluation of test kits submitted under this special verification testing program provided that all required items are received by the deadline date of September 15, 2008. All testing done under this special verification testing program will be similar to the work performed and reported by the National Institutes of Standards and Technology

(NISTIR 6398 *Spot Test Kits for Detecting Lead in Household Paint: A Laboratory Study*) referred to later in this application as the NIST study. All testing of any vendor's lead test kits under this special verification testing program is subject to the specific terms provided in this application. Additional information about the technology may be requested from the vendor to complete the evaluation.

2. **Definition of a negative screen.** To be suitable as a negative screen, a lead test kit must have a high probability that a negative result accurately indicates that lead is not present at or above the federal action level for LBP (1 milligram of lead per square centimeter). In the context of this special verification testing program, a lead test kit recognized as suitable for use as a negative screen is one that has (with 95% confidence) a less than 5% chance of obtaining a negative result (no lead present) when the true lead level in paint is at or above the federal action level for LBP. In addition, the lead test kit must have some specificity for detecting lead in paint. A lead test kit that has no chance of obtaining a negative result when lead is present only at low levels is excluded from this special verification testing program. Specifically, when the lead level in paint is 0.1 milligram lead per square centimeter or less, the kit must have less than a 50% chance of a positive result (with 95% confidence).
3. **Path to verification.** All submitters of applications will receive a confirmation of receipt of application by email. Vendor supplied test kit use instructions will be reviewed and re-formatted to fit into a testing protocol consistent with the needs of this special verification testing program. All modified instruction sets will be provided by email back to the vendor for comment. All comments on the instructions from the vendors are due back to QuanTech within 7 days of issuance. QuanTech will examine and provide a written response to each comment received. Vendor modification of their test kit use instructions especially for this special verification testing program that clearly go beyond those that accompany the commercially sold test kits will not be accepted. All responses to vendor's comments will be communicated by email.
4. **General requirements.** The following general requirements are applicable to this special verification testing program:
 - a. **Commercial availability.** Test kits included in this special verification testing program must be commercially available (sold) to the public for LBP testing as of August 15, 2008. Manufacturers of test kits under development and not yet for sale to the public will be given an opportunity to have their product tested under the regular EPA/ETV Advanced Monitoring Systems (AMS) Center starting in 2009.
 - b. **Exclusion of kits in the NIST study.** Lead test kits that were included in the NIST study that are still available to the public and have not been changed since that study will not be re-tested under this special verification testing program. Test kits in the NIST study that meet the negative screen requirements under this special verification testing program, are still available to the public, and have not been changed since that study, will receive EPA recognition for use as a negative screen.
 - c. **Exclusion of surface-only test kits.** Lead test kits designed to detect lead only on the top or upper surface of a paint coating (as opposed to all layers of a painted surface) will not be included in this special verification testing program.
 - d. **Equivalency among different test kits.** Lead test kits evaluated under this special verification testing program may be limited to those that have substantial differences (e.g., chemical reaction/detection or chemical application to the paint being tested) from other kits previously tested. For example, it is known that at least one currently available lead test kit is sold under more than one name. Under these circumstances, only one of these 'equivalent' test kits will be tested under this special verification testing program and the testing results will be applied to all these different named kits. Should such equivalency issues arise as a result of receipt of

applications from lead test kit vendors, QuanTech will discuss test kit equivalency with the applicable vendors and with EPA and a final equivalency decision on which test kits will be evaluated will be made as a result of those discussions.

5. **Specific requirements for vendors.** This special verification testing program will require the following specific commitments from participating vendors:
 - a. **Technology information.** Provide detailed information on your technology, including the type of chemistry being used for lead detection, the test kit's operating requirements or limitations, description of previous testing programs, and current use of the technology. This information will be used solely to plan verification testing. Material to be treated as confidential should be marked as such.
 - b. **Point of technical contact.** Identify a person from your organization to be QuanTech's technical point of contact, and to lead your participation in the verification test.
 - c. **Testing/Use protocols.** As discussed under 3 above, vendor supplied test kit use instructions will be re-formatted to fit into a testing protocol consistent with the needs of this special verification testing program and vendors will be given the opportunity to comment on these protocols. Vendors will be given 7 days respond to these protocols.
 - d. **Submission of example kits.** In addition to this application, each vendor is required to submit 2 example test kits for each test kit to be evaluated under this special verification testing program. The submitted pair of kits must be complete packaged kits identical to those being currently sold to the public. If the vendor sells the same kits in a number of different packages, only the package containing the fewest number of tests needs to be submitted. Ship all example lead test kits to the submissions address shown on the first page of this application.
 - e. **Retail purchase.** Provide at least 2 locations (websites, stores, etc.) where the public can purchase your test kit. If the vendor has only one location, please provide a signed statement that the kits are sold only under that one location.
 - f. **Review of draft recognition statement.** Vendors of lead test kits that meet the negative screen requirements under this special verification testing program will be given the opportunity to review the draft recognition statement prior to release to the public.
6. **Verification test products.** Participating vendors receive a *verification summary report* stating quantitatively the performance of the technology. Vendors of lead test kits that meet the negative screen requirements under this special verification testing program will also receive a draft *verification statement* summarizing results (see 5(f) above). Separate reports and statements are issued for each technology tested and each describes the performance of that technology only. There are no inter-comparisons of the verified technologies. A vendor can distribute the *verification statement* to attract prospective users of the technology and refer interested parties to the statement and report posted on EPA's ETV website (<http://www.epa.gov/lead>).
7. **Test benefits.** On April 22, 2008, EPA published (Federal Register: April 22, 2008, Volume 73, Number 78, pages 21691-21769) the Renovation, Remodeling and Paint (RRP) Rule. This Rule allows the interim use of test kits as negative screens for the presence of lead-based paint in residential structures. Obtaining EPA recognition for use as a negative screen will provide the vendor access to this significant market.

B. General Application Information

1. Please provide the name, complete mailing address, phone, fax, and email address for the following representative of your organization:

Person who will serve as the technical contact point:

NAME: _____

TITLE: _____

ADDRESS: _____

PHONE: _____ **FAX:** _____

EMAIL: _____

2. **Describe your technology.** Please attach a detailed description of your technology, as an aid in planning the verification test. Provide operating instructions, technical publications, schematics, drawings, photographs, or any other information you feel is pertinent to understanding the operation of your technology. Material to be treated as confidential should be marked as such.

3. **Previous evaluations.** Please attach information on any previous evaluations of your technology (excluding the NIST study). Provide copies of data or evaluation reports, or describe the testing including location, date, testing procedures, quality assurance/quality control activities, testing organization, and contact person.

4. **Use limitations.** List or summarize any limitations or known interferences

5. **Example test kits.** Attach two example test kits complete with the test kit's use instructions set. See section A.5(d).

6. **Sales outlets.** Provide locations (websites, stores, etc.) where the public can purchase your test kit. See section A.5(e).
