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Application Instructions

Please read the entire application package material and the *Performance Tested Methods^K* Program POLICIES AND PROCEDURES document before completing the application form.

- o An "Application Check List" is included to serve as a reminder to the applicant of the material and information to be submitted.
- o Complete the application form to include the requested information on the firm and test kit for which application is being made. **Complete a separate application form for each test kit model for which application is being made.**
- o Be sure to provide the requested information concerning compliance with any regulatory requirements on the first page of the application. If the primary use of the test kit is to determine compliance with regulatory requirements, those regulatory agencies may be required to participate in the performance testing and review process.
- o The test kit manufacturer is required to submit manufacturer-generated data for the parameters listed on the "Data Submission Requirements", where applicable.
- o The test kit manufacturer is required to submit copies of test kit labels, manuals and test kit information insert containing the information listed in the "Descriptive Insert Requirements" sheet.
- o The manufacturer is required to submit the manufacturing quality assurance and quality control practices as outlined in the *Performance Tested Methods^K* Program POLICIES AND PROGRAM document.
- o The manufacturer is required to include the appropriate application fee as stated on the Fee Schedule. Do not include a laboratory fee at the time of making the application. The manufacturer will be invoiced for the laboratory fee after all parties have agreed on the study protocol.
- o Please review the **Certification Mark License Agreement**. This Agreement doesn't need to be signed now, but it will be required before the *Performance Tested Method^K* certification mark is issued after a successful validation.
- o Submit the application package to:
 - Managing Director
 - AOAC Research Institute
 - 481 N. Frederick Ave, Suite 500
 - Gaithersburg, MD 20877-2417 USA
- o The test kit manufacturer is required to submit at least three test kits after the data submission is accepted and expert reviewers have been assigned. The AOAC Research Institute will provide further instructions and addresses when appropriate. Additional test kits will be requested after the evaluation protocol has been designed, and an independent laboratory has been selected.

AOAC Research Institute

PERFORMANCE TESTED METHODSK PROGRAM

POLICIES and PROCEDURES

Notice: AOAC Research Institute reserves the right to modify the program at any time. Participants will be required to comply with the current program in effect at time of initial application or renewal.

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POLICIES and PROCEDURES

1. Purpose

The purpose of the AOAC Research Institute *Performance Tested Methods*^K program is to provide an independent third-party review of producers' test kit performance claims. Upon application and independent testing, test kits found to be in conformance with their claims will be granted *Performance Tested Methods*^K status by the AOAC Research Institute. By granting *Performance Tested*^K status to a test kit the AOAC Research Institute assures the test kit user that an independent assessment has been made that the kit performs as claimed, within prescribed parameters.

Performance Tested Methods^K status must be annually renewed by the kit producer. Also, details regarding kit changes must be submitted regularly for Institute review in order to maintain the *Performance Tested Methods*^K status. Among other reasons, outlined in section 4.6, the program provides for revocation of *Performance Tested*^K status on kits for which producers do not adequately address or take corrective action on user complaints.

Test kits reviewed under the Institute *Performance Tested Methods*^K program may incorporate various technologies and, in general, will include kits used in the analysis of substances affecting food, agriculture, public health and safety, and the environment. The Institute reserves the right to refuse to accept applications involving test kits outside the Institute's areas of expertise.

2. Background

The AOAC Research Institute is an independent nonprofit corporation with a mission to promote and carry out activities related to the development, improvement, and understanding of analytical practices and procedures affecting public health and welfare. The Institute is a subsidiary of AOAC INTERNATIONAL (formerly the Association of Official Analytical Chemists) established specifically to independently administer the *Performance Tested Methods*^K program.

3. Program Operation

3.1 Description

An applicant wishing to obtain *Performance Tested Methods*^K status for a test kit must submit an application; an sponsor's method validation study report package; operators manuals; and quality assurance program synopsis to the AOAC Research Institute. An application fee must be submitted with the application. Applications will be accepted only from kit producers.

A preliminary review will be made by the program staff to determine if the application and data package are complete. If the application is incomplete or the data package does not meet the submission requirements of section 4.1 , the application and fee will be returned with an explanation. Reapplication may be made upon correction of the deficiencies.

The AOAC Research Institute will treat all submitted data as confidential, meaning the information will not be revealed to anyone who is not normally involved in the test kit review process without the written permission of the applicant. Those normally involved in the process include the applicant, the staff of the Institute, outside expert reviewers, and the independent testing laboratory. Each entity involved in the evaluation process will be required to sign a nondisclosure agreement.

Applicants should keep the size of the submission package to a minimum. It is envisioned the entire application and data package should be less than twenty pages in most instances.

Following a preliminary staff review that the application and data package are complete, the AOAC Research Institute Manager will identify expert reviewers and appropriate General Referee and make preliminary arrangements for a qualified independent laboratory to conduct tests for the evaluation of the test kit performance claims. The independent testing will be performed according to a test protocol designed by the expert reviewers General Referees.

Upon completion of testing by the independent laboratory, the entire data package will be presented to the test kit sponsor. The sponsor shall develop a "Method Validation Study Report" in the AOAC INTERNATIONAL journal style including data from the sponsor's in-house method study validation and data from the independent laboratory study.

The kit sponsor is responsible for submitting a Method Validation Study Report that is acceptable for publication in the journal of the AOAC INTERNATIONAL. Refer to Appendix 1 for a description of this report format. Expert Reviewers and Ground Referees will review the "Method Validation Study Report" to determine acceptability as a Performance Tested Methods^K. The reviewers will provide a written report and make recommendations to the AOAC Research Institute Manager for the granting or denial of *Performance Tested Methods^K* status to the kit by the AOAC Research Institute. If the kit's performance is found unacceptable, a denial report will be returned to the applicant, including the reason(s) for denying *Performance Tested Methods^K* status. If the kit performed according to the producer's stated performance specifications, a one-year *Performance Tested Methods^K* certificate will be granted, provided applicant has executed a copy of the certification mark License Agreement. *Performance Tested Methods^K* certificates will be extended for one year periods if the applicant certifies that no changes have been made in the test kit and that it performs as originally demonstrated. If changes are made, additional testing may be required, depending on the extent of change (see section 6).

3.2 Time Line

Generally, the AOAC Research Institute will initiate review of test kits in the order that applications are received. However, the Institute reserves the right to set discretionary priorities, to refuse acceptance of any or all applications during certain periods, and to establish test kit queues and queue periods based on the intended purpose of the kits.

Depending on difficulties in locating expert reviewers, the complexity of the testing protocol, the ability of all parties to agree on the protocol, etc., some kits may require more time than others to pass through the review process.

3.3 Definitions

Proprietary - A "proprietary method" is any analytical procedure which contains an essential, unique and sole-sourced reagent, component or device, integral to the running of the method, such that the method cannot be performed without that proprietary element. Examples of such proprietary methods include but are not limited to test kits and unique biochemical reagents available from only one manufacturer.

Analyte - As used in this program, an analyte is the chemical, microbial, or biological substance, physical parameter, or other test parameter that is being measured by the test kit.

Insert - Insert is the descriptive material accompanying the test kit providing the user with information on intended use, performance specifications, manufacturer's name and test kit identification, and instructions on using the test kit. The insert information may be printed on the test kit package or contained on a separate sheet of paper.

PERFORMANCE TESTED METHODS^K - term is used to communicate to the test kit users that the test kit performed in independent testing as claimed by the manufacturer.

Test Kit - A test kit is a commercially packaged system of the principal or key components of an analytical method used to determine the presence of a specific analyte(s) in a given matrix(es). Test kits include directions for their use and are often self contained, complete analytical systems; but they may require supporting supplies and equipment. The key components frequently represent proprietary elements or reagents that may be readily prepared only by the producer of the kit.

Sponsors Method Validation Study Report - a report developed by the kit sponsor that includes data supporting test kit performance claims. Data requirements are specified in the Data Submission Requirements.

Compiled Method Validation Study Report - a report developed by the kit sponsor that includes data developed by the sponsor and independent data developed by the AOAC Research Institute program.

4. Procedures

See Appendix 2 for General Flowchart.

4.1 Application

Manufacturers wishing to obtain *Performance Tested Methods*^K status for test kits must submit a complete application containing all of the required forms, agreements, and guideline documents for **each** test kit to be evaluated. Application Packages containing all of the required forms, agreements, and guidelines may be obtained from the AOAC Research Institute technical coordinator.

Applications for test kit evaluations must contain the following:

- o Completed Application Form, (Appendix 3)
- o Signed Review Agreement (Appendix 4)
- o Sponsor's Method Validation Study Report
- o Test kit inserts and Operator's manual
- o Description of manufacturing quality assurance program
- o Application fee

Applicants are encouraged to recommend potential expert reviewers and potential independent laboratories. However, the AOAC Research Institute is not obligated to accept the recommendations of the applicant. Neither the independent laboratory nor the expert reviewers can be connected with the applicant or related entities in any way, other than as a customer.

Once the application is accepted by the Institute and the independent testing laboratory evaluation protocol is designed and accepted, the applicant will be requested to provide special supplies or equipment as needed, including test kits, to the AOAC Research Institute. Any non-consumed supplies or equipment will be returned to the applicant once the evaluation has been completed; although unused test kits may be maintained for data verification purposes for some time. When training in kit usage is required of or normally provided to purchasers of kits, the applicant may be required to demonstrate or provide training to the independent laboratory.

4.1.1 Sponsor's Method Validation Study Report

Applicants are required to submit a report, written in the AOAC style, supporting product performance claims. Reports are expected to comply with the parameters specified in the Data Submission Requirements (Appendix 5). The Data Submission Requirements defines the information that the AOAC Research Institute considers compulsory for the validation of performance claims.

4.1.2 Descriptive Insert Requirements

The AOAC Research Institute requires that the packaging and/or the test kit descriptive insert of a *Performance Tested Methods^K* test kit contain the following: (1) the name, address, and telephone number of the producer of the kit; (2) the descriptive name, trade name, type or model number, and serial number or production code of the test kit -- to facilitate traceability; (3) the intended use(s) and user(s) of the test kit; and (4) clearly identifiable and stated performance characteristics. Refer to the Descriptive Inserts Requirements (Appendix 6) document for more detailed explanations of labeling requirements.

4.1.3 Fees

The AOAC Research Institute charges an application fee (Appendix 7 - Fee Schedule) to cover the cost of operating the *Performance Tested Methods^K* program. The fee must be submitted with the application for Performance Tested Methods^K status. If the application is returned following the preliminary staff review, the full fee will be returned to the applicant.

If the applicant withdraws the application after assignment of expert reviewers but prior to acceptance of the laboratory testing protocol, a refund of one-half of the application fee will be made. No refund will be made once the testing protocol is accepted.

A fixed application fee will be charged for each test kit application representing a single test kit type or model. An additional variable fee will be charged back to the applicant for reimbursement of the Institute for the services of the independent laboratory; the amount to be determined at AOAC Research Institute's sole discretion, depending on the complexity of the testing protocol that is used. A fixed processing fee will be charged for each annual renewal of *PERFORMANCE TESTED^K* certificates (see 4.1.1, 5.3).

AOAC Research Institute reserves the right in its sole discretion to add additional fees in the future for the application process or the use of the certificate mark.

4.1.4 Certification of QA Program and QC Practices

Applicants must submit a description of the quality assurance program and quality control practices used in the manufacturing, production, storage, and delivery of the test kits. This description must include the sampling system followed, with particular reference to the tests used to verify that test kit production meets established production standards. To avoid revealing proprietary information, this certification may be submitted in the form of a signed letter with a four to six page description of the QA/QC program.

The applicant shall use a performance monitoring system that will provide production management with the information necessary to assure the test kits continue to meet the requirements of the specifications to which the kits were originally evaluated and granted *Performance Tested Method^K* status. The system shall include the methods, procedures, controls, records, and maintenance of the system to provide continuing assurance of compliance with the performance specifications advertised. The extent of this system will depend on the characteristics of the test kit and on the performance specifications.

The kit producer shall immediately notify the AOAC Research Institute if the kit or its descriptive insert is modified in any way (see section 6).

4.1.5 Check List and Guidance for Application Data Package

The check list contained in the Application Package is intended for use by the applicant and the AOAC Research Institute Manager to determine if the basic submission requirements have been satisfied. (Appendix 8)

Guidance for applicants submitting technical data is included in the Application Package.

4.1.6 Certification Mark License Agreement

An officer of the kit sponsor's company must execute the Certification mark License Agreement (Appendix 9) to use the Performance Tested mark (Appendix 10). Applicants are not required to sign the Agreement until the Performance Tested Methods^K review is complete and this list is granted Performance Tested Methods^K status. However, kit sponsor's are highly encouraged to review the license agreement before submitting an application to the AOAC Research Institute. The Agreement is standard and required for all licensees. Refer to 4.4.3 for more detailed information about the certification Mark License Agreement.

4.2 Program Administration

4.2.1 AOAC Research Institute

The *Performance Tested Methods^K* program is operated by the AOAC Research Institute, a nonprofit corporation organized under the laws of the Commonwealth of Virginia. The AOAC Research Institute is an independent subsidiary of AOAC INTERNATIONAL (formerly the Association of Official Analytical Chemists).

4.2.2 AOAC Research Institute Staff and Duties

The AOAC Research Institute staff consists of an AOAC Research Institute staff consists of an AOAC Research Institute Managing Director, Technical Coordinator and clerical support.

The AOAC Research Institute Technical Coordinator has the following responsibilities:

- o Provide application materials and assistance to potential applicants.
- o Establish and maintain a log and tracking system for performance testing applications.
- o Conduct a preliminary review of the application materials for completeness of the package.
- o Establish and maintain an expert reviewers pool and assign reviewers to specific performance testing applications.
- o Select independent testing laboratories, negotiate fees and contracts, and monitor their work.
- o Coordinate and expedite the performance testing process with applicants, independent laboratories, and expert reviewers.
- o Receive and dispense materials required by the independent laboratory.
- o Complete and issue required forms and reports.
- o Collect fees based on established fee structure.
- o Manage annual certificate renewal process.
- o Maintain a data base of applications and *Performance Tested Methods^K* certificates and provide status reports as appropriate.

- o Grant or deny *Performance Tested Methods^K* certificates, as appropriate, based on final review of the data packages and the expert reviewer reports and recommendations.
- o Assign additional reviewers to provide a deciding recommendation in situations where the original reviewers do not agree on the recommendation.

4.2.3 Expert Reviewer Duties

For each application or group of similar applications for *Performance Tested Methods^K* status, at least two expert reviewers will be assigned to perform the following duties:

- o Review the application, application package, and sponsor's Method Validation Study Report for adequacy.
- o Determine if the test kit insert meets the test kit insert requirements (see section 4.1.2).
- o Determine whether the applicant's data support and confirm the performance claims contained in the descriptive insert.
- o Develop a protocol for the independent laboratory to follow during the test kit evaluation process; including a statistical evaluation scheme for comparison of the applicant's performance data to that of the independent lab.
- o Review the Compiled Validation Study Report and determine, in accordance with the agreed upon statistical evaluation scheme, if the independent laboratory's data corroborate the conclusions/claims of the producer.
- o Provide the AOAC Research Institute Technical Coordinator with a report and recommendation to grant or deny *Performance Tested Methods^K* status.

Applicants are encouraged to recommend individuals as expert reviewers; however, the final assignment will be at the sole discretion of the AOAC Research Institute Managing Director. Those experts selected to evaluate specific test kits must not have a relationship (including as a financial investor, member of board of directors, or consultant) with the applicant, competitors, or closely related parties and may have no business relationship other than as a customer.

Technical guidance for reviewers is included in the "Reviewer Package". If the originally assigned expert reviewers cannot reach agreement on a recommendation to grant or deny *Performance Tested Methods^K* status, the AOAC Research Institute Technical Coordinator may assign additional reviewer(s) to provide a deciding recommendation.

4.2.4 Choosing Expert Reviewers

The AOAC Research Institute will recruit expert reviewers from the AOAC INTERNATIONAL network of method volunteers, use announcements in the AOAC INTERNATIONAL monthly magazine - *Inside Laboratory Management* and in *The Journal of the AOAC INTERNATIONAL*, and accept recommendations of the applicant and others to establish and maintain a pool of interested scientists to serve as expert reviewers. Those assigned as expert reviewers will be entitled, but not required, to receive a fixed honorarium from the AOAC Research Institute for services performed.

Experts wishing to serve as reviewers should make a written request to the AOAC Research Institute Manager, including a curriculum vitae.

Those selected to be in the expert reviewer pool must:

- o Comply with AOAC Research Institute policies and procedures on conflict of interest, including signing a conflict of interest policy acknowledgment form (see "Reviewer Package").
- o Be willing to devote the time necessary to conduct the data reviews and design testing protocols in a timely manner, as determined by the AOAC Research Institute.
- o Have knowledge of method evaluation processes and have the ability to design and evaluate method evaluation protocols.
- o Have a working knowledge of method evaluation statistics.

Experts selected for a particular test kit review, in addition to the above, must:

- o Not be employed by or have financial ties with the applicant, competitors, or closely related entities.
- o Not have a regulatory relationship with the applicant firm seeking *Performance Tested Methods^K* status.
- o Have technical expertise in the general subject area of the test kit technology under review.
- o Not routinely use in their work the test kit that is under evaluation.

4.2.5 General Referees

Performance Tested Methods^K reviews are coordinated with the appropriate General Referee from the AOAC Official Methods^K program to ensure consistency between programs. General Referees are expected to:

- o Review the Sponsors Method Validation Study Report to determine adequacy and to determine consistency with the AOAC Official Methods^K program.
- o Assist in the development of independent laboratory testing protocols to ensure that in-house and independent laboratory data are adequate and consistent with Official Methods program requirements.
- o Review the computed Methods Validation Study Report to determine adequacy and consistency with AOAC Official Methods program requirements.

4.2.6 Statistical and Manufacturing QA Assistance

Experts in the areas of statistics and manufacturing quality assurance may be utilized by AOAC Research Institute to provide assistance to the Expert Reviewers when such assistance is determined necessary by the AOAC Research Institute Manager.

4.3 Independent Laboratory Testing

The testing protocol will not duplicate the entirety of performance studies conducted by the producer but will attempt to reproduce certain results and verify selected performance parameters. Testing that is not relevant to verification of producer-generated data or to kit performance specifications as claimed by the producer will not be included. The protocol will define the criteria for acceptance or rejection of the kit by the AOAC Research Institute, and the protocol must be agreed to by all parties before testing begins. The services of the independent laboratory will be paid for by the Institute which will bill the applicant for reimbursement, separate from the application fee.

The applicant will be responsible for providing the following:

Test kits representative of normal production variables, and special equipment for use in the evaluation process.

Analytical reference standards, with certified purity, obtained from an independent source. (If analytical standards are not available from an independent source, the standards will be supplied by the applicant, produced and/or evaluated under the applicant's QA/QC program.)

Naturally contaminated test materials. (Test materials used in the applicant's evaluation and the independent laboratory's evaluation of the test kits should include naturally contaminated materials when practical and available. Naturally contaminated materials must be characterized using an independent method, an AOAC *Official Method*SM if available. In certain situations, it may not be possible to obtain naturally contaminated materials, in which cases fortified test samples prepared independently and made to simulate natural conditions may be used. Limitations may be placed on the application of the test kit if it has not been evaluated using naturally contaminated materials.)

The applicant will be required to demonstrate or provide training to the independent laboratory if training is required of or normally provided to kit purchasers.

4.3.1 Elements for Choosing an Independent Laboratory

Preference will be given to qualified laboratories accredited to the Organization for International Standards Guide 25 requirements for the appropriate field(s) of testing. The Institute must be assured that the following general criteria are satisfied in the selection of an independent laboratory. In addition to these general criteria, the AOAC Research Institute will consider factors specific to the test kit under evaluation. Test kits will involve different technologies; therefore some laboratories may be more capable than others to evaluate certain test kits.

A laboratory will not be selected to evaluate a particular test kit if that laboratory routinely uses the test kit under evaluation. Also, the laboratory must not have a financial, corporate, or regulatory relationship with the applicant and must not be a competitor.

If evidence of appropriate accreditation is not presented, on-site visits by the Institute's Technical Coordinator, or their designate, may be conducted as part of the initial laboratory screening process at the

Sponsor's expense, and periodically thereafter, to assess the laboratory's compliance with the General Criteria for Independent Laboratories (Appendix 11).

4.3.2 Contract Elements and Duties of Independent Laboratory

The contract between the AOAC Research Institute and the independent laboratory shall contain the following elements (See "Independent Laboratory Package" for a sample contract):

- o Certification as to the absence of conflict of interest, or disclosure to the AOAC Research Institute of any potential or perceived conflict between the independent laboratory and the test kit producer.
- o Certificate of insurance, including workman's compensation.
- o A testing protocol describing the task to be accomplished. This will include a description of the test kit to be evaluated, number of fortification levels, replicate analyses, total number of tests, number of kits, multiple day testing, etc. The protocol will be developed by the expert reviewers in conjunction with the contractor and will be appended to the contract.

- o A statement that the independent laboratory will provide all personnel, facilities, equipment, and supplies, except as otherwise noted.
- o Statement on staff qualifications requirement.
- o Time line for completing the task.
- o Independent laboratory's fee and responsibility for cost of procured materials and services such as shipping and mailing fees.
- o Data reporting requirements.
- o Record keeping requirements.
- o Material retention requirements (kits, supplies, test samples, etc.).
- o Statement that test kits and other specific supplies and/or equipment will be supplied by the applicant requesting *Performance Tested Methods^K* status.
- o Statement that the independent laboratory will supply uncontaminated matrix materials, and the kit producer will provide naturally contaminated samples for test kit evaluations, if available and applicable.
- o Reference to any applicable documents required in the evaluation.
- o A requirement that the independent laboratory have documented quality assurance/quality control programs and procedures. Additional specific quality control procedures may be outlined in the evaluation protocol.

4.3.3 Independent Laboratory Data Reporting

Data will be reported in the format specified in the evaluation protocol. This may require the calculation of statistics as defined in the protocol for each test kit evaluated. All independent laboratory data will be reported to the AOAC Research Institute Manager.

4.4. Criteria for Granting *Performance Tested Methods^K* Status

The purpose of the AOAC Research Institute *Performance Tested Methods^K* program is to provide independent third-party review of producers' claims regarding their test kits' performance. Accordingly, the producer of each kit model determines the performance specifications to which the model must conform and, as a result, the specifications to which the AOAC Research Institute will independently test for conformance. Therefore, a criterion for designing the independent testing protocol and for granting *Performance Tested Methods^K* status is that the producer's performance specifications for each kit model must be clearly presented and stated in the test kit descriptive insert (see requirements in "Application Package").

In review of the applicant's data package and design of the testing protocol, the expert reviewers panel will look to the test kit descriptive insert for the kit's performance specifications. An appropriate statistical evaluation will be included in the testing protocol and used to compare data submitted by the applicant and by the Institute's independent laboratory. All parties -- the Institute, the applicant, and the independent testing laboratory -- must accept the testing protocol for testing to proceed.

The criteria for granting *Performance Tested Methods^K* status will be: (1) the applicant's performance data supports and confirms all claims made in the kit's descriptive insert and (2) the independent laboratory's performance data corroborates the applicant's performance data within the statistical limits specified in the testing protocol. The selection of the most appropriate parameters to be compared will be determined by the expert reviewers panel on an application-by-application basis depending on the technology of the particular test kit model. Within a given analyte/matrix area and technology, the statistical performance criteria should be the same from kit to kit.

4.4.0.1 Certificate

A *Performance Tested Methods^K* Certificate is issued by the AOAC Research Institute to the applicant for each kit model granted this status. The certificate carries a unique certificate number and includes a specific description of the test kit model.

4.4.1 *Performance Tested Methods^K* Mark

A license agreement between the AOAC Research Institute and the producer of the test kit model will be executed covering use of the Institute-owned *Performance Tested Methods^K* certification mark. This agreement will specify the rights, obligations, rules, and procedures in the use of the Institute's *Performance Tested Methods^K* mark.

The issuance of a *Performance Tested Methods^K* certificate to a test kit model authorizes the producer, under license, to use the Institute-owned *Performance Tested Methods^K* mark on the approved test kit, test kit packaging and insert, and informational and promotional literature. The mark denotes that the test kit model's performance was evaluated by the AOAC Research Institute and that the evaluation confirmed that the kit performs as stated in the producer's specifications contained in the kit's descriptive insert.

The following statement is required to be referenced by an asterisk within the *Performance Tested Methods^K* mark and appear as an adjacent footnote to the mark whenever it is reproduced:

"PRODUCER-SUPPLIED SAMPLES OF THIS TEST KIT MODEL WERE INDEPENDENTLY EVALUATED BY THE AOAC RESEARCH INSTITUTE AND WERE FOUND TO PERFORM TO THE PRODUCER'S SPECIFICATIONS AS STATED IN THE TEST KIT'S DESCRIPTIVE INSERT. THE PRODUCER CERTIFIES THIS KIT CONFORMS IN ALL RESPECTS TO THE SPECIFICATIONS ORIGINALLY EVALUATED BY THE AOAC RESEARCH INSTITUTE AS DETAILED IN *Performance Tested Methods^K* CERTIFICATE NUMBER XXXXXX."

Where room does not permit the full reproduction of this statement immediately adjacent to the mark, a short adjacent footnote (such as *See Descriptive Insert) referencing where the statement is readily located will be included in any reproductions of the mark.

The footnoted statement will always be included with reproductions of the mark. Also, the statement will be clearly distinguishable from any other claims, markings, or labels not related to the authorized use of the mark.

The use of the Institute's mark must be discontinued if the *PERFORMANCE TESTED^K* certificate is canceled, is not renewed (see section 7) or if the License Agreement is terminated or not renewed. The test kit producer must cease to display in any form or otherwise use the *Performance Tested Methods^K* mark prior to production of the next lot, within 60 days after notification, or within a time specified in the License Agreement, whichever is earlier, after:

- o Lapse of the *Performance Tested Methods^K* certificate, or suspension or cancellation of *PERFORMANCE TESTED METHODS^K* status;
- o Producer has made a change in the test kit model or the production quality assurance system; either of which has not been accepted by the AOAC Research Institute and which could reasonably be expected to affect the model's performance;
- o Producer has modified the test kit model in a manner that could be expected to affect performance;
- o Any other circumstances that could reasonably be expected to affect adversely the producer's quality control system.

5. Post Granting of *Performance Tested Methods^K* Status

5.1 Publication

5.1.1 Announcements

Initially, information regarding the AOAC Research Institute and the *Performance Tested Methods^K* program will be published in the AOAC INTERNATIONAL monthly magazine, *Inside Laboratory Management*. Published announcements are expected to include: (1) the number of applications received during the previous month; (2) the number of test kits under current review; (3) a listing of test kits granted *Performance Tested Methods^K* status the previous month, by test kit name and model and producer's name; and (4) notification of test kits with recently expired or canceled *Performance Tested Methods^K* status. Test kits failing to receive initial *Performance Tested Methods^K* status will not be listed.

As may be agreed to between the AOAC Research Institute and the applicant, selected performance and/or independent laboratory data for test kits receiving *Performance Tested Methods^K* status may be published in standard 2-3 page summary formats. Proprietary information and internally generated data submitted by the applicant is considered the property of the applicant and therefore will not be published by the AOAC Research Institute unless the applicant agrees to publication.

5.1.2 Technical Communication

The test kit sponsor will prepare a Method Validation Study Report in the AOAC format for publication as a Technical Communication in house *Journal of the AOAC International*. AOAC Research Institute Staff will coordinate and supervise publication of this Technical Communication.

5.2 Roster of *Performance Tested Methods^K* Kits

The AOAC Research Institute will maintain, publish, and distribute, by subscription, a regularly updated listing and description of test kits holding *Performance Tested Methods^K* status.

5.3 Annual Renewal Process

In all cases, *Performance Tested Methods^K* status is granted for a period of one year. Not more than 60 days and not less than 30 days prior to the expiration date, application (Appendix 12) must be made to the AOAC Research Institute by the applicant-producer to renew the *Performance Tested Methods^K* status. The AOAC Research Institute will provide the applicant of record with timely notice of the pending certificate expiration by regular mail; however, it is ultimately the responsibility of the applicant to submit timely application for renewals.

The AOAC Research Institute Technical Coordinator is responsible for conducting the annual renewal review. Test kits will lose *Performance Tested Methods^K* status if the application for renewal is not made within the time period noted above. If the applicant satisfactorily certifies that no changes have been made to the test kit since originally receiving *Performance Tested Methods^K* status and that the kit performs as originally evaluated, the applicant will be granted a one year certificate renewal.

A new or supplemental QA/QC package must be submitted with the renewal application if changes have been made in the manufacturing or QC testing processes. The AOAC Research Institute Manager reserves the right to request and review QA/QC records to verify that the consistency of test kit performance is maintained throughout the life of the test kit.

Renewal will not be granted without additional test data and satisfactory resolution of complaints if serious adverse comments, supported by data, have been received from kit

users indicating the kit does not consistently perform as claimed. Neither will a certificate be renewed if changes made in the test kit are judged to be major changes (see section 6).

A certificate renewal fee (see current fee schedule) must be submitted with the certificate renewal application. In situations where *Performance Tested Methods*^K status has expired within the previous six months, the applicant may make application for reinstatement by submitting the usual certificate renewal application and fee plus an additional late fee (see the current fee schedule).

6. Changes in Test Kit

6.1 Notification

It is the responsibility of the test kit licensee to notify the AOAC Research Institute when changes are made in the kit which affect in any way: (1) the instructions for using the kit or (2) the kit's performance. Failure to appropriately notify the AOAC Research Institute of changes may result in cancellation of the *Performance Tested Methods*^K certificate.

Licensees are contractually obligated to provide the AOAC Research Institute documentation if changes are made in a certified test kit. The AOAC Research Institute, generally in consultation with appropriate experts, will determine if the changes are of sufficient magnitude to warrant a complete re-evaluation of the kit. If so, the licensee must submit a complete application with the corresponding fee.

6.2 Review Levels and Administrative Fees

Administrative fees to review modifications to test kits are based on the amount of time required on the part of the AOAC Research Institute and its Expert Reviewers to evaluate the changes. Modification Reviews are classified into three levels:

Level 1 Reviews - require only an internal AOAC Research Institute review. The test kit sponsor must submit a written explanation of the change(s) including a statement that the modification does not alter the validated performance of the test kit. In some cases, detailed the ***Test Kit Definitions and Modifications Guideline***, data may be required to substantiate claims of unaltered performance. Manufacturers must notify the AOAC Research Institute within 60 days of commercial introduction of certified test kit models with Level 1 changes. Changes requiring only an internal review by the AOAC Research Institute are assessed an administrative fee of US \$1,500 (unless otherwise indicated).

Level 2 Reviews - require submission of a complete evaluation application with appropriate data submission and labeling, and assignment of an expert reviewer to review data submitted by the test kit sponsor. An evaluation application covering the modification must be submitted and approved by the AOAC Research Institute **before** a manufacturer may use the certification mark on a modified test kit model. Evaluations requiring a review of submitted data by an expert reviewer are charged 50% of the current application fee.

Level 3 Reviews - require submission of a complete evaluation application with appropriate data submission and labeling, assignment of expert reviewers to review data submitted by the applicant, and independent testing. An evaluation application covering the modification must be submitted and approved by the AOAC Research Institute **before** a manufacturer may use the certification mark on a modified test kit model. Level 3 Reviews are assessed 75% to 100% of the current application fee depending on the extent of the required evaluation and testing.

More detailed information and guidance about the classification of changes to test kits may be obtained from the AOAC Research Institute Managing Director. Ask for the ***Test Kit Definitions and Modifications Guideline***.

6.3 Approval of Modifications

The AOAC Research Institute will issue a new Certificate of *Performance Tested Methods*^K status, and a new certification mark with an appended license number (i.e., 830702 and 830702A) for all approved

Level 2 and 3 modifications. A level 1 approval does not require a new certificate or a new certification mark.

Test kits will be reviewed on the expiration date of the relevant Certificate of *Performance Tested Methods^K* status.

7. Cancellation of **PERFORMANCE TESTED METHODS^K** status

The AOAC Research Institute may cancel *Performance Tested Methods^K* status, revoke the *Performance Tested Methods^K* certificate, and cancel any license for the use of the certification mark at any time for the following reasons, to be determined in AOAC Research Institute's sole discretion:

- o The test kit producer has not complied with the original agreement relative to use of the Institute's certification mark.
- o The test kit producer has not responded adequately or has not taken timely corrective action relative to poor performance of the test kit as reported by test kit users or others.
- o The test kit producer modified the test kit in a manner that could reasonably be expected to affect its performance characteristics and failed to notify the Institute.
- o The test kit producer fails to make application for annual renewal. (see section 4.1.1, 5.3)
- o The test kit producer requests that *Performance Tested Methods^K* status be discontinued.
- o The program requirements change and the producer either will not or cannot ensure conformance to the new requirements within a reasonable amount of time. The producer will be allowed up to sixty (60) days, but not later than the expiration of the current certificate, to comply with any new program requirements.
- o The producer ceases to produce the test kit.
- o The applicant-producer fails to meet financial obligations to the AOAC Research Institute.

The applicant of record will be notified of cancellation of *Performance Tested Methods^K* status by registered letter. Failing applicant appeal of the action within the prescribed time period (see section 9), notification of the cancellation will be published in the AOAC INTERNATIONAL monthly magazine, *Inside Laboratory Management*, and in other appropriate media.

8. Complaints

Formal applicant complaints must be in writing and directed to the AOAC Research Institute Managing Director in care of the AOAC Research Institute. The AOAC Research Institute Managing Director will initiate appropriate action to resolve the complaint.

Formal test kit user complaints must be in writing and will be directed to the kit sponsor for initial resolution. The kit sponsor must include a statement in the test kit's descriptive insert declaring where complaints can be lodged and technical assistance obtained. The producer shall maintain a record of complaints and their resolution, which will be made available to the AOAC Research Institute on request. Failure to adequately address user complaints will result in the Institute initiating an inquiry and could lead to cancellation of the kit's *Performance Tested Methods^K* certificate.

9. Appeals Process

9.1 Right to and Basis for Appeal

Manufacturers who have submitted test kits to the AOAC Research Institute (AOAC RI), with a valid application for formal review, may appeal certain **final** decisions of the AOAC RI. The appeals process is not open to parties which have not submitted test kits to the AOAC RI nor to those seeking to appeal AOAC RI decisions regarding test kits submitted by other manufacturers.

Appellants must comply with all relevant AOAC RI administrative procedures necessary to obtain an AOAC RI **final** decision before a formal appeal can be made to the AOAC RI.

Appellants may appeal an AOAC RI decision to: (1) refuse acceptance of an application; (2) deny *Performance Tested Methods*^K status; (3) revoke *PERFORMANCE TESTED METHODS*^K status; or (4) refuse renewal of *Performance Tested Methods*^K status. Appellants may appeal such final decision(s) of the AOAC RI on the basis of alleged scientific or procedural error. Failure to agree on a testing protocol or the lapsing of a certificate are not appealable.

All decisions of the AOAC RI with regard to the action under appeal shall be stayed until the completion of the appeals process described herein.

9.2 Appeals

The appellant shall submit, in writing, the original and five (5) complete copies of the appeal within 30 calendar days after the date of notification of the **final** action being appealed. All appeals must be delivered, by registered mail to:

**Managing Director
AOAC Research Institute
481 N. Frederick Ave., Suite 500
Gaithersburg, MD 20877-2417 USA**

All appeals must include a U.S. one-thousand dollar (US\$1000) deposit which will be deposited in an identifiable internal account by the AOAC RI. The deposit will be returned to the appellant or applied to the expenses of conducting the appeal, pending the outcome of the appeal (see section 9.7).

All appeals must be written in English and must include statements or materials regarding:

- (1) The **specific** decision being appealed;
- (2) The **specific** nature of the objection(s) to the decision, including any adverse effects;
- (3) The basis for the appeal, including the section(s) of the procedure(s) and/or protocol(s) and/or evaluation(s) that are at issue;
- (4) **All data and other evidence in support of the appeal (New or existing data or evidence which was not made available to the AOAC RI prior to it reaching the decision under appeal will not be considered; i.e., the Appeals Panel will not reverse final decisions of the AOAC RI based on "new" information that was not made available to the AOAC RI);**
- (5) The **specific** remedial action(s) that would satisfy the appellant's objection(s);
- (6) All previous efforts to resolve the objection(s) and the results of each effort;
- (7) A list of at least five appeals panel nominees who qualify under the conditions of section .3, and are acceptable to the appellant.

Upon receipt, the AOAC RI Managing Director will immediately forward a copy of the appeal to the Chair of the AOAC RI Board of Directors (BoD).

9.3 Appeals Panel

The Chair of the AOAC RI BoD will determine whether the appeal is complete and acceptable within the requirements of section 9.2. If the Chair determines the appeal to be incomplete or unacceptable, the appeal will be returned to the appellant with instructions on how to correct the deficiencies.

If the Chair finds the appeal acceptable, the Chair will appoint an Appeals Panel of three persons within thirty (30) calendar days of the date the appeal is received at the AOAC RI headquarters. The Chair will appoint one member of the Appeals Panel to serve as the Panel Chairman. At least two members of the Panel must be acceptable to the appellant and at least two members must be acceptable to the Managing Director of the AOAC RI.

The Appeals Panel shall consist of three individuals who have not been directly involved in the matter under appeal, who will not be materially or directly affected by any decision made by the Appeals Panel, and, generally, who possess expertise in the scientific area(s) which are the subject of the

appeal. All Appeals Panel members shall be required to execute an agreement to adhere to the AOAC RI's "Trade Secret Non-disclosure Policy", "Conflict of Interest Policy", and "Anti-Trust Policy".

9.4 Conduct of the Appeal

Appeals may be conducted solely by telephone or written or electronic correspondence at the discretion of the Appeals Panel; in consultation with the parties.

The appellant has the burden of demonstrating AOAC RI errors, AOAC RI unreasonable or arbitrary actions or inactions, and the appropriateness of the remedial action requested. The AOAC RI Managing Director has the burden of demonstrating the AOAC RI took all actions in compliance with its policies and procedures; that the decision reached by the AOAC RI was reasonable and, where applicable, substantiated by scientific facts and data; and/or that the proposed remedial action requested by the appellant would be inappropriate.

The AOAC RI Managing Director shall prepare and submit a response to the appeal to the Appeals Panel Chairman and the appellant within thirty (30) calendar days from the date the appeal is received at AOAC RI headquarters. The Appeals Panel will review all pertinent information and, if necessary, may conduct an oral hearing by either telephone conferencing or a formal meeting of the parties.

9.5 Preliminary Finding

The Appeals Panel shall produce a preliminary report within thirty (30) calendar days of being formed or of receiving the AOAC RI's response to the appeal; whichever is later. The preliminary report shall contain the Appeals Panel's preliminary finding, and an explanation of the preliminary findings. The appellant and the AOAC RI shall have fourteen (14) calendar days to submit a response to the preliminary report to the Appeals Panel Chairman.

9.6 Final Decision

The Panel shall make a final decision, by simple majority vote, within fourteen (14) calendar days of receiving the responses to the preliminary report. Within an additional fourteen (14) calendar days of announcing this final decision, the Chairman of the Appeals Panel shall issue a final written report. The final report shall include the original appeal, the AOAC RI's response to the appeal, the Panel's preliminary findings and explanations, the appellant's and the AOAC RI's responses to the preliminary report, and the Panel's final decision.

If the Appeals Panel finds for the appellant, the final report shall remand the action to the AOAC RI with specific findings and opinions of the facts and circumstances which demonstrate an incorrect decision was reached or an unreasonable or arbitrary action was taken **and with instructions to implement specific remedial action(s)**.

If the Appeals Panel finds for the AOAC RI, the final report shall contain specific findings and opinions of the facts and circumstances which demonstrate the AOAC RI acted properly and/or reached a reasonable decision based on the information available to it.

The decision of the Appeals Panel shall be final and non-appealable.

9.7 Expenses

If the Appeals Panel finds in favor of the appellant, the entire amount of the \$1000 deposit shall be promptly returned to the appellant. If the Appeals Panel finds in favor of the AOAC RI, the \$1000 deposit shall be applied to the expenses associated with the conduct of the appeal including the cost of any investigations, hearings and/or meetings conducted by the Appeals Panel. Costs to conduct the appeal that exceed the \$1000 deposit will be billed to the appellant. Any amount of the \$1000 deposit remaining after all expenses have been satisfied will be returned to the appellant.

9.8 Exceptions to the Procedures

The Appeals Panel may grant to itself and the parties, at its sole discretion, reasonable extensions of deadlines specified in these procedure. The Appeals Panel must notify, in a timely manneor one of the parties.

The Appeals Panel serves at the pleasure of the Chair of the AOAC RI BoD. Any or all members of the Panel may be removed and replaced for failure to act in a timely or professional manner.

Appendices:

- 1 Method Validation Study Report Format
- 2 General Flow Chart
- 3 Application Form
- 4 Review Agreement
- 5 Data Submission Requirements
- 6 Descriptive Inserts Requirements
- 7 Fee Schedule
- 8 Check List
- 9 Certification Mark License Agreement
- 10 *Performance Tested* Certification Mark
- 11 General Criteria for Independent Laboratories
- 12 Renewal Application

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