

AOAC Research Institute

Test Kit Definitions and Modifications Guideline

The following definitions and guidelines are intended to provide a framework for logical and consistent decisions on the affect of changes to test kits, and the additional evaluations that are required to ensure that modifications to test kits do not invalidate the conditions of the certification. This guideline is not expected to be all-inclusive, and may change from time to time to reflect the experience gained by the AOAC Research Institute. Test kit sponsors are advised to contact the AOAC Research Institute to ensure that this is the most recent version of this policy before submitting a request to review modifications to a certified test kit.

1.0 TEST KIT DEFINITIONS

1.1 Basic definition

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.

Test kits reviewed under the *Test Kit Performance Testing 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.

1.2 Test Kit Models

The "PERFORMANCE TESTED" certification maris licensed for use only on test kit models that have been reviewed and evaluated under the *Test Kit Performance Testing Program*, and have been specifically indicated in the *Certificate of "PERFORMANCE TESTED Status* issued at the completion of an evaluation. Use of the "PERFORMANCE TESTED" certification mark in conjunction with other test kit models not specifically indicated by the *Certificate of "PERFORMANCE TESTED Status* is expressly prohibited.

Evaluation applications must specify **all** catalog numbers, product codes, and/or other identification markings (hereafter collectively referred to as "catalog numbers") that the certification mark is intended to appear on, or in conjunction with. The AOAC Research Institute, and its Expert Reviewers, shall determine the number of test kit models that are contained in an application. The analytical methodology and the intended use of test kit models are the primary determinants employed to decide the number of individual test kit models contained in an application, and ultimately licensed to display a "PERFORMANCE TESTED" certification mark. Test kit models with identical analytical methodologies and the intended uses can be considered under one application, and licensed to use a single certification mark.

Catalog numbers may provide a basis for determining the number of test kit models contained in an application. Existence of separate catalog numbers for related test kits may be considered evidence that more than one test kit exists, with the exception of multiple catalog numbers for different unit sizes, and or multiple packaging configurations of the same analytical method.

- 1.2.1 Multiple packaging configurations of a single analytical methodology may be considered under one test kit application, and licensed to use a single certification mark, if all of the packaging configurations: (1) are based on the same analytical methodology; (2) have the same intended use; (3) are declared in the application form; and (4) are fully validated and reviewed under the *Test Kit Performance Testing Program*.
- 1.2.2 Test kit models that employ the **same exact reagents** with several different procedures and/or detection instruments can be certified as one test kit provided that all test kit models: (1) are based on the same analytical methodology; (2) have the same intended use; (3) are declared in the application form; and (4) all of the procedures/instruments are fully validated under the *Test Kit Performance Testing Program*.
- (a) same exact reagents - same compounds in the same concentrations in the same phase (liquid, lyophilized etc.) in the same format.
 - (b) instruments - manufacturers may designate a specific instrument/equipment brand and model, or indicate specifications for a range of brands and models of instruments/equipment intended to be used with the test kit provided the test kit manufacturer can furnish data to support that the test kit continues to performance as claimed with instruments/equipments operating at the extremes of the specification ranges.
- 1.2.3 A test kit model that is modified and re-approved by the AOAC Research Institute is considered an extension of the original *Certificate of "PERFORMANCE TESTED Status* if it uses the same analytical method and has the same intended use stated in the original application.

2.0 ADMINISTRATION

2.1 Notification

It is the responsibility of the test kit licensee to notify the AOAC Research Institute when changes are made in the kit which affects 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" certificate.

Licensees are contractually obligated to provide the AOAC Research Institute documentation (see ' 2.2 for documentation requirements) 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.

2.2 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:

- (1) **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 in section 3.0, 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).

- (2) **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.
- (3) **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.

2.3 Approval of Modifications

The AOAC Research Institute will issue a new *Certificate of "PERFORMANCE TESTED 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 Status*.

3.0 MODIFICATIONS TO TEST KITS

Changes to test kits generally fall into one of three categories: changes to labeling, changes to the components or reagents of a test kit, and changes to the manufacturing and/or quality assurance process.

3.1 Labeling Changes

All changes to the labeling of "PERFORMANCE TESTED certified test kits must be submitted to the AOAC Research Institute. Labeling includes all instructions accompanying test kits, operator's manuals, box and reagent labels.

3.1.1 Changes to Performance Claims

Deletions of validated claims require a **Level 1** review plus revised copies of the new labeling.

Restatements of existing validated claims require a **Level 1** review plus revised copies of the new labeling. The AOAC RI may elect to consult with an Expert Reviewer to confirm that the revised claim is equivalent to the validated claim.

Changes to existing validated claims may require a **Level 1**, **Level 2** or a **Level 3** review depending on the change to the existing claim. The test kit sponsor must submit a copy of the revised labeling plus other appropriate data. Label changes that narrow or limit a previously validated claim may only require a **Level 1** review. Label changes that expand, enlarge or increase existing validated claims may require either **Level 2** or **Level 3** reviews depending on the extent of the change of the claim. An exact determination of the extent of the review can only be made by the AOAC Research Institute after a written explanation of a change is reviewed by Expert Reviewers.

Additional performance claims not validated in the original certification of the test kit require **Level 3** reviews. An exact determination of the extent and cost of the review can only be made after a written explanation with a complete application and supporting data submission are received by the AOAC Research Institute and reviewed by Expert Reviewers.

3.1.2 Changes in Instructions for Use

Labeling changes that add or strengthen an instruction that is intended to enhance the safe use or efficacy of a test kit require a **Level 1** review plus revised copies of the new labeling. An administrative fee will not be assessed for review of instruction clarifications. The AOAC RI may elect to consult with an Expert Reviewer to confirm that the clarification is indeed equivalent to the validated procedure.

Modification of validated procedure may require a **Level 1**, **Level 2** or a **Level 3 Review** depending on the change to the existing procedure. The test kit sponsor must submit a copy of the revised labeling plus other appropriate data. An exact determination of the extent of the review can only be made by the AOAC Research Institute after a written explanation with a complete application and supporting data submission are received by the AOAC Research Institute and reviewed by Expert Reviewers.

Entirely new procedures require **Level 3** reviews. An exact determination of the extent and cost of the review can only be made after a written explanation with a complete application and supporting data submission are received by the AOAC Research Institute and reviewed by Expert Reviewers.

Deletion of a procedure may occur when a test kit has been certified for more than one procedure. A deletion of a procedure change requires a **Level 1** review plus revised copies of the new labeling.

3.1.3 Changes to Stability/Warning Statements

Increase/decrease in stability claims may require a **Level 1** or a **Level 2** review depending on the change to the existing claim. In some cases, especially in the case of new test kits, the AOAC Research Institute may agree to review, as a part of the original application fee, on-going stability studies so that a test kit manufacturer may increase, or correct, its shelf-life as real-time stability data becomes available. Test kit sponsors must obtain a written agreement at the time of the original test kit evaluation to qualify on-going stability studies as a part of the original application fee.

Otherwise, test kit sponsors must submit a copy of the revised labeling plus other appropriate data. Label changes that limit a previously validated stability claim may only require a **Level 1** review with data supporting the limited label claim. Label changes that increase existing validated stability claims require **Level 2** reviews.

Additional precautions/warnings, or labeling changes that strengthen a warning, precaution, require a **Level 1** review. An administration fee is not assessed when a manufacturer chooses to include an additional precaution or warning in its labeling. However, the test kit sponsor must provide the AOAC Research Institute a written explanation of the reason for the change, and a revised copy of the label.

Removal of precautions or warnings from a certified label require a **Level 2** or a **Level 3 Review** depending on the importance of the existing precaution. The test kit sponsor must submit a copy of the revised labeling plus other appropriate data. An exact determination of the extent of the review can only be made by the AOAC Research Institute after a written explanation with a complete application and supporting data submission are received by the AOAC Research Institute and reviewed by Expert Reviewers.

3.1.4 Changes to Other Label Information

Non-performance related changes such as address, telephone, or catalog numbers, and other non-technical label changes do not require a review or review fee. However, test kit sponsors must submit revised labeling to the AOAC Research Institute with a written explanation for the change.

3.2 Modification to Reagents, Equipment, Instruments and/or Disposable Components

3.2.1 Modification to reagents such as changes in formulation, concentration, phase (solid or liquid), or format require either **Level 2** or **Level 3** reviews depending on the extent of the change. An exact determination of the extent of the review can only be made by the AOAC Research Institute after a written explanation of a change is reviewed by Expert Reviewers.

3.2.2 Modifications to disposable components such as test tubes, test tube holders, and stirring rods require a **Level 1** review with data supporting the lack of effect of the change.

3.2.3 Modifications to, or changing of, detection and/or measuring equipment/instrumentation require either a **Level 2** or **Level 3** review depending on the nature of the change in the detection/measuring equipment/instrument. An exact determination of the extent of the change can only be made by the AOAC Research Institute after a written explanation of a change is reviewed by Expert Reviewers.

3.2.4 Modifications to packaging require a **Level 1** review with data supporting the lack of effect of the change.

3.2.5 Addition or deletion of reagents and/or measuring instrumentation require either a **Level 2** or **Level 3** review depending on the nature of the change in the detection/measuring equipment/instrument. An exact determination of the extent of the change can only be made by the AOAC Research Institute after a written explanation of a change is reviewed by Expert Reviewers.

3.3 Modifications to Manufacturing Process and/or QA/QC Programs

Changes in test kit QA/QC Programs such as changes in raw material/component specifications, or changes in quality control and or/quality assurance testing procedures, or changes in manufacturing procedure require at minimum a **Level 1** review. Changes in raw material/component specifications may require additional data and a **Level 2** review. An exact determination of the extent of the change can only be made by the AOAC Research Institute after a written explanation of a change is reviewed by Expert Reviewers.