AOAC INTERNATIONAL & AOAC Research Institute
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This presentation will describe the method validation and consensus programs that AOAC International and AOAC Research Institute offers. The method approval process is described as well as the publication and certification documents. This presentation also includes a survey of the approved *Official Methods of Analysis*SM methods and approved *Performance Tested Methods*SM methods. Please check the website for an updated list of approved *Performance Tested Methods*SM methods. AOAC member have free access to all approved *Official Methods of Analysis*SM methods on the AOAC website (www.aoac.org).

AOAC International is a non-profit organization with international membership. The organization was established in 1874 to review, validate and publish analytical methods. Next year, 2009, will be our 125th Anniversary. We are best known in the food and agriculture communities for validating and publishing the Official Methods of Analysis book; also known as the big red book of methods. Most recently AOAC has done many validations for the rapid microbiology methods for the US government. The *Official Methods of Analysis*SM methods are defensible in many courts worldwide.

The AOAC Research Institute is a smaller, sister non-profit organization of AOAC International which was founded in 1991. The AOAC Research Institute administers the *Performance Tested Methods*SM program, which provides an independent third-party review of proprietary test kit performance claims. The AOAC Research Institute has staff with industry experience; which ensure that the validations are conducted with scientifically-sound validation study designs.

AOAC has scientific members worldwide which we use as independent scientific volunteer experts to help regulatory or trade issues centered on the performance parameters of analytical methods in use. AOAC has lead efforts to set acceptance criteria for target analytes such as *B. anthracis* and other biological threat agents as well as drug residues in commodities.

AOAC has three validation programs for the evaluation and certification of analytical methods. The AOAC INTERNATIONAL administers the *Official Methods of Analysis*SM program; which is denoted by the blue logo. The AOAC Research Institute administers the *Performance Tested Methods*SM program; which is denoted by the green logo and the approved methods are denoted by the black certification logo. The combination of the two programs is called the harmonized program.

The AOAC expert reviewers and methods committees for both the *Official Methods of Analysis*SM and *Performance Tested Methods*SM program follow the microbiology and chemistry guidelines sited here. Both microbiology guidelines (AOAC & ISO 16140) are under revision

and it is anticipated that AOAC would approve the revised ISO 16140 for the validation of microbiological methods.

OMA Program

The *Official Methods of Analysis*SM method validation program consists of a two phase validation: 1) pre-collaborative study and 2) the collaborative study. Quantitative collaborative studies require a minimum of eight laboratories and qualitative collaborative studies require a minimum of ten laboratories. The validation study data is reviewed by the appropriate methods committee and general referee. The approximate time from start of a method validation to an approved first action *Official Methods of Analysis*SM status is twelve to eighteen months.

The first phase of the *Official Methods of Analysis*SM method validation study design is the pre-collaborative study. Data for the inclusivity, exclusivity, method comparison of 15-20 foods with an appropriate reference method (USDA, FDA, ISO or other) is collected in the pre-collaborative study. The second phase of the *Official Methods of Analysis*SM method validation study design is the collaborative study. Data on the method comparison of six foods with an appropriate reference method (USDA, FDA, ISO or other) is collected from eight to ten laboratories during the collaborative study.

The method comparison study is an important parameter in a method evaluation. It must be noted that a method can not be validated for a claim of all foods. For qualitative pre-collaborative and *Performance Tested Methods*SM studies require 20 replicates at each inoculation level with five control samples OR 20 replicates of naturally contaminated samples. The collaborative study requires six replicates at each inoculation level and six control samples per laboratory. Fractional positive results must be obtained for *Official Methods of Analysis*SM and *Performance Tested Methods*SM consideration; that means 5-15 positive samples. For quantitative studies five replicates at three inoculation levels and five controls or three lots of naturally contaminated foods are required. For *Official Methods of Analysis*SM and *Performance Tested Methods*SM approval the candidate method must perform equal to or better than the reference method.

The AOAC Research Institute administers the *Performance Tested Methods*SM program which evaluates proprietary microbiology and chemistry test kits for their performance claims. The validation is comprised of a two part validation study design with an internal study and independent study. The validation study report is reviewed by two Expert Reviewers and the General Referee; all reviewers must unanimously agree to grant the candidate method *Performance Tested Methods*SM certification. Once the method has been *Performance Tested Methods*SM approved the test kit manufacturer is licensed to use the AOAC *Performance Tested Methods*SM certification mark with the kits specific certificate number on marketing advertisements and packaging for one year increments. Each *Performance Tested Methods*SM method is reviewed annually for modifications. Validation time can be less than six months depending on the readiness of the company. The AOAC Research Institute offers a consulting package where our project managers draft the validation study design. All *Performance Tested Methods*SM methods are published on the AOAC website and are continually updated. Please visit the website for the list of approved methods http://www.aoac.org/testkits/testedmethods.html.

Foods", "Select Foods", "Individual Foods" and/or "Environmental Surfaces". To claim a "Variety of Foods" data must be collected from two foods per food groups for a total of ten foods. To claim "Groups of Foods" data must be collected from several foods in the particular the food group. To claim "Select Foods" data must be collected from each food which is being claimed. To claim an "Individual Food" data must be collected from the specific food. To claim "Environmental Surfaces" data must be collected from one or more surfaces. A method may also be evaluated for a claim from pure and/or mixed cultures.

The food categories are as follows: 1) meat products; 2) poultry products; 3) fish & seafood products; 4) dairy products; 5) chocolate & bakery products; 6) animal feeds; 7) pasta and miscellaneous (dressings, spices, mayonnaise, eggs/egg derivates, cereals and rice). The environmental surfaces are as follows: 1) stainless steel; 2) food-grade painted surfaces; 3) ceramic, glass or other earthen-glazed material; 4) cast iron; 5) plastic; 6) rubber; 7) sealed concrete; 8) wood and 9) air filter material.

The internal study for the *Performance Tested Methods*^{SM} program is conducted by the test kit manufacturer. The test kit manufacturer collects data on inclusivity, exclusivity, method comparison to an appropriate reference method, ruggedness, stability and lot-to-lot variation of the test kit.

The independent study is conducted by a laboratory that is contracted by the AOAC Research Institute. The independent study is intended to verify the internal study data; therefore, a portion of the internal method comparison matrices are required.
The AOAC Research Institute has several laboratories that have experience conducting AOAC validations. All new independent laboratories are required to attend the Microbiology Validation Workshop hosted by the AOAC Research Institute. Bids are gathered from independent laboratories and laboratory is contracted by the AOAC Research Institute on behalf of the test kit manufacturer. The independent study report is submitted to the AOAC Research Institute.

The *Performance Tested Methods*^{SM} program requires that the General Referee review and approve all testing protocols ad validation study reports. In addition to the General Referee, two other experts review the validation study reports for *Performance Tested Methods*^{SM} approval. Many of our expert reviewers are outside of the US.

The test kit manufacturer compiles the internal study data and the independent study data into one report and submits it to the AOAC Research Institute. The expert reviewers provide comments on the report and the test kit user guide for the test kit manufacturer to consider. The study report and user guide is revised according to the reviewers' comments. The test kit is granted *Performance Tested Methods*^{SM} certification when the reviewers reach consensus.

When a test kit is approved as a *Performance Tested Method*^{SM} manufacturer reviews and approves of all certification documents (certificate, certification mark, website entry and study reports) prior to the use of the certification mark. The manufacturer publishes an article in the AOAC magazine *Inside Laboratory Management* and the study report is published in the Journal of AOAC INTERNATIONAL. The test kit is listed on the AOAC validated methods website

which includes links to the certificate and the study report. The ability for users to download the certification documentation for each validated method makes it very useful to end users and accredited laboratories which must have documentation on the methods they employ. Lastly, all approved test kits undergo an annual review to ensure that the test kits have not been changed since the original validation. Should changes in the approved method be identified, a method modification maybe necessary to retain the *Performance Tested Methods*SM status. Test kits that do not renew their certification are removed from the list of AOAC validated methods.

This is an example of a Certificate of *Performance Tested*SM status.

The AOAC Harmonized program is administered by the AOAC Research Institute, mainly because the method enters the validation process through the PTM program. An approved *Performance Tested Methods*SM is equivalent to the OMA pre-collaborative study. The advantage to this program is that the manufacturer obtains the *Performance Tested Methods*SM certification mark before continuing onto the collaborative study to obtain an *Official Method of Analysis*SM first action status.

The AOAC Harmonized program consists of four phases: 1) AOAC Research Institute Consulting for the drafting of the validation protocols; 2) *Performance Tested Methods*SM study; 3) The *Official Methods of Analysis*SM collaborative study and 4) *Official Methods of Analysis*SM approval. The outcomes are two AOAC approvals (*Performance Tested Methods*SM and *Official Methods of Analysis*SM), two published studies in the *Journal of AOAC INTERNATIONAL* and the use of the AOAC Research Institute *Performance Tested Methods*SM certification mark.

The methods are evaluated for the following performance indicators: Inclusivity rate; Exclusivity rate; Sensitivity rate; Specificity rate; False Positive rate; False Negative rate; Repeatability; Reproducibility; Method Agreement or McNemar's Chi-Square; Limit of Detection or Limit of Quantitation and Relative Standard Deviation.

Approved *Official Methods of Analysis*SM methods are published in three places: 1) in the *Official Methods of Analysis*SM of AOAC INTERNATIONAL "the big red book of methods"; 2) in the *Journal of AOAC INTERNATIONAL* and 3) in the U.S. Code of Federal Regulations. The approved *Performance Tested Methods*SM methods are also published in three places: 1) in the *Journal of AOAC INTERNATIONAL*; 2) in the AOAC magazine *Inside Laboratory Management* and 3) on the AOAC validated methods website.

The following slides are meant to provide a survey of the approved *Performance Tested Methods*SM methods. The survey is not all inclusive, but is intended to provide a snap-shot of the current approved kits. Please visit the AOACRI website to find a current listing of the approved methods. http://www.aoac.org/testkits/testedmethods.html.