The AOAC International Rapid Methods Validation Process

Scott Coates
Managing Director
AOAC Research Institute

Zerlinde B. Johnson
Manager, Technical Programs
AOAC Research Institute
Overview of Presentation

- AOAC International
- AOAC Research Institute
- Consensus Programs
- Validation Programs
- Publications & Documentation of Approved Methods
- Survey of PTM & OMA approved methods
AOAC INTERNATIONAL

- Non-profit organization with international membership
- Consensus organization
- Established in 1874 to review, validate & publish analytical methods
- 125th Anniversary in 2009!
- best known in food and agriculture
- chemistry and microbiology methods for *Official Methods of Analysis*®SM status (OMA) “Big Red Book of Methods”
- OMA methods are recognized in the U.S. Code of Federal Regulations and are legally defensible in court worldwide
- staff of approx. 40 in Gaithersburg, Maryland, USA
AOAC Research Institute

- Incorporated in December 1991 as a subsidiary of AOAC INTERNATIONAL
- Non-profit, international, scientific organization
- Administers the Performance Tested Method℠ Program
- Chemistry and microbiology methods
- Provides rapid entry point into the AOAC validation process and provides a rapid approval process
- Provides an independent third-party review of test kit performance claims
- Staff with industry experience
AOAC Consensus Programs

- Helping solve scientific-based problems with scientific-based solutions
- AOAC brings together people from industry, government, public health, academia and end users to discuss health, business and trade issues
- Setting of acceptance criteria for methods for particular target analyte (\textit{B. anthracis, F. tularensis, Y. pestis}, drug residues in commodities to name a few issues)
AOAC Validation Programs

- AOAC International
  - *Official Methods of Analysis*\textsuperscript{SM} (OMA)
- AOAC Research Institute
  - *Performance Tested Methods*\textsuperscript{SM} (PTM)
- Harmonized Program
  - PTM-OMA
Method Validation Guidelines

For Microbiology:

- ISO 16140: Protocol for the validation of alternative methods

For Chemistry:

- Used by ISO, AOAC, NMKL, and many others

Used when applicable by both AOAC validation programs
Two Phase Validation: Pre-Collaborative and Collaborative

Number of Collaborative Labs Required:
- Quantitative method: 8 laboratories minimum
- Qualitative method: 10 laboratories minimum

Data Review by Appropriate Methods Committee and General Referee

Validation Time: **12-18 Months Minimum to First Action**

Final Action can be obtained two years after First Action
Pre-Collaborative Studies

- Inclusivity
- Exclusivity
- Method Comparison
  - 15-20 foods
  - USDA, FDA, ISO or other appropriate reference methods may be used

Collaborative Study

- Method Comparison
  - 8-10 labs
  - 6 foods
  - USDA, FDA, ISO or other appropriate reference methods may be used
Method Comparison Study

- Determines matrices that can be claimed to be validated
- A method can NOT be validated for all foods
  Qualitative methods:
  - Pre-Collaborative Study and Performance Tested Method studies require 20 replicates at each inoculation level and 5 uninoculated controls or 20 replicates of naturally contaminated foods
  - Collaborative Study (Ring Trial) requires 6 replicates at each inoculation level and 6 uninoculated controls per laboratory
  - MUST obtain fractionally positive results
- Quantitative methods require five replicates at each of three inoculated levels and five uninoculated controls or 3 lots of naturally contaminated foods
- For OMA approval, the candidate method must perform equal to or better than the reference method
Evaluation of the test kit performance claims

Two-part Validation – Internal Studies and Independent Study

One Independent Laboratory required – contracted by AOAC RI

Data review by two Expert Reviewers and General Referee

Companies licensed to use certification mark in advertisements and packaging for one year increments – annual reviews

Validation Time: can be less than 6 months


Consulting service available for drafting of the validation study
Test Kit Claims
- Variety of Foods
  - Requires testing of 2 foods per food groups; total of 10 foods
- Groups of Foods
  - Requires testing several foods from the particular food group
- Select Foods
  - Requires testing of all select foods
- Individual Foods
  - One matrix claim
- Environmental Surfaces
  - 9 surfaces
- Pure / Mixed Cultures
Food Categories
- Meat products
- Poultry products
- Fish & seafood products
- Dairy products
- Chocolate & bakery products
- Animal feeds
- Pasta
- Miscellaneous (dressings, spices, mayonnaise, eggs/egg derivates, cereals and rice)

Environmental Surfaces
- Stainless steel
- Food-grade painted surfaces
- Ceramic, glass or other earthen-glazed material
- Cast iron
- Plastic
- Rubber
- Sealed concrete
- Wood
- Air filter material
Validation Study Design

Internal Study
- Conducted by the test kit manufacturer
- Inclusivity Panel (30-50 strains; 100 strains for *Salmonella* spp.)
- Exclusivity
- Method Comparison
  - choice of reference methods
  - FDA, USDA, ISO or other appropriate reference method
- Ruggedness
- Stability
- Lot-to-Lot Variation
Independent Study

- Conducted in a lab contracted by AOACRI
- Intended to verify the internal study data
- Subset of internal study work
- Method Comparison
  - 1 laboratory
  - 1-2 foods
Performance Tested Methods℠
Independent Laboratories

- Several laboratories to choose from.
- Each laboratory is screened and trained.
- Submits a bid for the study based upon approved testing protocol.
- Contracted with AOAC RI, the lab performs evaluation based upon protocol and kit package insert.
- Report submitted to Research Institute.
Performance Tested Methods℠ Expert Reviewers

- AOAC General Referee
  - Approves all testing protocols and reviews the final Validation Report
- Two Expert Reviewers
  - 50% of Expert Reviewers are from outside of the US
  - Reviews Validation Report
Performance Tested Methods℠

Review Process

● Test Kit Manufacturer
  ● Compiles validation report of internal report and independent laboratory information
  ● Reply to reviewers’ comments and/or suggestions

● Reviewers
  ● Review validation report for technical and editorial criteria and package insert
  ● Provide commentary on report and/or insert
  ● Performance Tested℠ status granted upon consensus
Performance Tested Methods℠ Certification

- Test kit manufacturers review & respond to all certification documentation
- License agreement and use of the certification mark
- Article in AOAC Magazine *Inside Laboratory Management* (ILM)
- Publication of study in *Journal of AOAC INTERNATIONAL*
- Test kit is listed on the AOAC RI validated methods website
- Certificate and study report made available on the AOAC validated methods website for users to download
- Annual renewal to ensure test kit has not been changed since validated
Performance Tested Methods℠ Certificate

Certificate of Performance Tested℠ Status

Certificate No. 070701

The AOAC Research Institute hereby certifies that the performance of the test kit designated as:

Assurance GDS for Listeria species

manufactured by

BioControl Systems, Inc.
12822 SE 32nd Streeet
Burlington, WA 98233

has been reviewed under the AOAC Research Institute’s Performance Tested Methods℠ Program, and found to perform as stated by the manufacturer contingent to the comments contained in the Certification Report. This certificate authorizes the manufacturer to display the AOAC Performance Tested℠ certification mark along with the statement - “THIS TEST KIT’S PERFORMANCE WAS REVIEWED BY AOAC RESEARCH INSTITUTE AND WAS FOUND TO PERFORM TO THE MANUFACTURER’S SPECIFICATIONS” - on the above mentioned test kit for a period of one year from the date of this certificate (January 1, 2008 – December 31, 2008). Removal may be granted at the end of one year under the rules stated in the licensing agreement.

Signed for AOAC Research Institute:

Scott G. Oakes
Managing Director
Harmonized Program

- Administered through AOAC Research Institute
- PTM studies are equivalent to the OMA Pre-Collaborative Study
- Obtain Certification Mark first
- Continue on to Collaborative Study to obtain OMA First Action
Harmonization Overview

1) AOAC Research Institute Consulting
2) Performance Tested Methods Study
3) OMA Collaborative Study
4) Official Methods of Analysis

OUTCOMES:
- 2 AOAC approvals (PTM & OMA)
- 2 published studies in *Journal of AOAC Int*l
- Use of Certification Mark
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
- Relative Standard Deviation
Method Publications

• **Official Methods of Analysis**\(^{SM}\)
  - Method published in *Official Methods of Analysis of AOAC INTERNATIONAL* (OMA)
  - Published in *Journal of AOAC INTERNATIONAL*
  - Article published in the AOAC magazine *Inside Laboratory Management* (ILM)

• **Performance Tested Methods**\(^{SM}\)
  - Published in *Journal of AOAC INTERNATIONAL*
  - Article published in the AOAC magazine *Inside Laboratory Management*
  - Published on the AOAC validated methods website
List of Approved Performance Tested Methods℠

<table>
<thead>
<tr>
<th>TEST KIT NAME</th>
<th>MANUFACTURER</th>
<th>CATALOG NUMBER</th>
<th>LICENSE NUMBER</th>
<th>ORIGINAL CERTIFICATION DATE</th>
<th>ANALYTES</th>
<th>MATRICES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delvotest P</td>
<td>DSM Foods</td>
<td>5980 D (5 pack) 5980 B (Mini)</td>
<td>930703</td>
<td>November 15, 1993</td>
<td>amoxicillin, ampicillin, cephapirin, cefotibrucil, penicillin</td>
<td>bulk tank bovine milk</td>
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<tr>
<td>Delvotest SP</td>
<td>DSM Foods</td>
<td>5982 B (26 ampul tests) 5982 C (100 ampul tests)</td>
<td>930704</td>
<td>September 26, 1993</td>
<td>amoxicillin, ampicillin, cephapirin, cefotibrucil, penicillin</td>
<td>bulk tank bovine milk</td>
</tr>
<tr>
<td>Penzyme Milk</td>
<td>Neogen Corporation</td>
<td>5009</td>
<td>930706</td>
<td>October 25, 1993</td>
<td>amoxicillin, ampicillin, cephapirin, penicillin</td>
<td>bulk tank bovine milk</td>
</tr>
<tr>
<td>Penzyme III</td>
<td>Neogen Corporation</td>
<td>8849</td>
<td>930707</td>
<td>October 25, 1993</td>
<td>amoxicillin, ampicillin, cephapirin, penicillin</td>
<td>bulk tank bovine milk</td>
</tr>
</tbody>
</table>
Survey of Performance Tested Methods℠

- Survey is not all inclusive
- Intended to provide a snapshot of approved kits
- Approved methods come and go.
- Visit the AOACRI website to find out if a kit is PTM approved
Applied Biosystems

- TaqMan® *Salmonella enterica* Detection Kit
BioControl Systems, Inc

- SimPlate for TPC (Total Plate Count)
- Assurance GDS™ for *Salmonella*
- Assurance GDS™ for *Listeria* spp.
- Assurance GDS™ for *L. monocytogenes*
- Assurance EIA™ for *Listeria*
- VIP® *Listeria*
BD Diagnostics

- **BBL™ CHROMagar™**
  - Salmonella
  - Listeria
  - O157
  - Staph aureus
bioMerieux, sa

- VITEK® 2 GP
  (Gram Positive Identification Card)

- VITEK® 2 GN
  (Gram-Negative Identification Card)

- VITEK® 2 BCL
  (*Bacillus* Identification Card)
bioMerieux, sa

- VIDAS® *Listeria* (LIS) Assay
- VIDAS® *E. coli* O157 (ECO) Test with O157:H7 ID Agar: 8 Hour and 24 Hour Methods
- VIDAS® Staph enterotoxin II (SET2)
- VIDAS® *Listeria* species Xpress (LSX) with Ottaviani Agosti Agar (OAA)
- VIDAS Listeria DUO (LDUO) Ottaviani Agar
bioMerieux, sa

- TEMPO®
  - TVC (Total Viable Count) Method
  - EC (E. coli) Test
  - CC (Coliform Count)
  - EB (Enterobacteriaceae)
Bio-Rad Laboratories

- RAPID’ L.Mono
  - ‘ Salmonella Agar
  - ‘ *E.coli* O157:H7 Agar
  - ’ *E. coli* 2 Agar
  - ' *Staph* Agar
  - ' *Listeria* spp. Agar
Bio-Rad Laboratories

- iQ-Check *Listeria* spp. Real-Time PCR Test Kit
- iQ-Check™ *Salmonella* II Real-Time PCR Test Kit
- iQ-Check™ *E. coli* O157:H7 II Real-Time PCR Test Kit
Chisso Corporation

- Sanita-kun Total Plate Count
- Sanita-kun Coliforms
Centrus International / FOSS A/S

- Soleris/
  MicroFoss Coliform Test
Daiken Industries, Ltd.

- DOX-60F / 30F TVC Kit
BAX® System with Automated Detection PCR Assay for:

- *Staphylococcus aureus*
- Screening *L. monocytogenes*
- Screening *Listeria* genus
- Screening for *Salmonella*
- E. coli O157:H7 Kit
- Screening *E. coli* O157:H7 MP
- Campylobacter jejuni / coli / lari

BAX® System with Automated Detection PCR Assay & Collection Kit for:

- *Listeria* spp.
• DuPont Lateral Flow System
  • Listeria Test Kit
  • *E. coli* O157 Test Kit
  • *Salmonella* Test Kit
Idaho Technology, Inc.

- R.A.P.I.D® LT Food Security System for Salmonella Detection
PATHATRIX

- *Salmonella* species Pooling Test System
- *Listeria* species Pooling Test System
- *Listeria* species Test System
- *Listeria/Salmonella* species
- *Salmonella* species
- *E.coli* O157 Test System
- Combined *E.coli* and Total Coliform Test
Merck KGaA

- Singlepath®
  - *E. coli* O157 Lateral Flow Assay
  - Salmonella Lateral Flow Assay
  - Campylobacter Lateral Flow Assay
- Duopath® Verotoxin Lateral Flow Assay
Neogen Corporation

- **Reveal**
  - *Salmonella* spp.
  - Listeria Test System

- **GENE TRAK**
  - *Salmonella* DLP Assay
  - *Listeria* DLP Assay
Neogen Corporation

- GeneQuence
  - Salmonella Microwell assay
  - Listeria Microwell Test
  - *Listeria monocytogenes* Test
- *BetaStar®*
  - US beta-lactam Assay Test
Nissui Pharmaceutical Co.

- **Compact Dry**
  - Total Count
  - Compact Dry YM
  - Compact Dry CF
  - Compact Dry EC
Strategic Diagnostics Inc.

- RapidCheck for:
  - *E. coli* O157 (including H7) Lateral Flow Assay
  - *Salmonella* Assay
  - Select™ *Salmonella* Test
  - *Listeria* species Test
  - *Listeria* species Media
3M Microbiology

- 3M Petrifilm Environmental Listeria Plate
Romer Labs

- AgraQuant®
  Deoxynivalenol (DON) Assay
Survey of Performance Tested Methods℠

- Approved methods come and go.
- Visit the AOACRI website to find out if a kit is PTM approved
Rapid microbiobiology methods granted Official Methods of Analysis since 2000
BioControl Systems, Inc

2002.07
SimPlate® Total Plate

2002.11
SimPlate® Yeast and Mold Color Indicator (Y&M-CI)

2005.03
Simplate® Coliform and E. coli
2005.04
Assurance GDS™ for *E. coli* O157:H7

• 2005.05
Assurance GDS™ for Shigatoxin Genes
bioMérieux, Inc

- **2001.07** VIDAS Immuno-Concentration Salmonella Assay (ICS)
- **2001.08** VIDAS Immuno-Concentration Salmonella Assay (ICS) in Combination with Salmonella Selective Plating Media, XLD
- **2001.09** Salmonella in Foods, VIDAS Immuno-Concentration Salmonella (ICS) /VIDAS Salmonella Method, SLM
bioMérieux, Inc

- **2001.09** Salmonella in Foods, VIDAS Immuno-Concentration Salmonella (ICS) /VIDAS Salmonella Method, SLM
- **2004.02** VIDAS *Listeria monocytogenes II* (LMO2) Immunoassay Method
- **2004.03** VIDAS (SLM) Immunoassay
- **2004.06** VIDAS® *Listeria* (LIS) Immunoassay
Dupont Qualicon

- 2003.09
  BAX® System for the Detection of Salmonella

- 2003.12
  BAX® Automated System for the Detection of Listeria monocytogenes
Neogen Corporation

- **2000.13**
- REVEAL for *Escherichia coli* O157:H7 Screening Test

- **2007.02**
- GeneQuence™ *Salmonella*
Tecra
(Acquired by 3M)

- 2000.07
  TECRA Unique *Salmonella* Test

- 2002.09
  TECRA Listeria Visual Immunoassay
  (modification)
3M Microbiology

- Petrifilm™

2000.15
Rapid Enumeration of Coliforms

2001.05
Rapid S. aureus Count Plate
3M Microbiology

• Petrifilm™

2003.01
Enterobacteriaceae Count Plate

Staph Express Count Plate
AOAC Validation Completed

Thank You

www.aoac.org