Proficiency Testing and Method Validation Platform – Update

Moffett Proficiency Testing Laboratory

Division of Food Processing Science & Technology
and
Institute of Food Safety and Health

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Innovation Through Collaboration

Laboratory Proficiency & Method Validation

Interlaboratory Studies- Strategic Goals

- Conduct mandated regulatory and food safety proficiency testing (PT) programs to support FDA-State cooperative programs.
- Play a proactive role in laboratory capability & capacity building, laboratory evaluation, and method performance assessments.
- Conduct method-independent PT schemes for the analysis of target analyte/matrix combinations that are not commonly available through commercial means for emergency preparedness.
- Integrate rapid introduction of new analytical methods and instrumentation.
- Maintain ISO/IEC 17043 accreditation - enable participating laboratories to meet their ISO/IEC 17025 or other laboratory accreditation requirements.
- Assist laboratories and analysts to improve their overall analytical performance.

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Leveraging Partnerships & Building Laboratory Infrastructure

- Certify analysts in state and federal regulatory laboratories:
  - **Milk - NCIMS/PMO requirements.**
  - **Shellfish & Shellfish growing area/wet storage UV treated process waters – NSSP/ISSC requirements.**
  - **Thermal processing & Package integrity.**

- Emergency preparedness and laboratory capability-capacity building:
  - **FERN: Food Emergency Response Network (FDA & USDA**).
  - **Vet-LIRN: Veterinary Laboratory Investigations and Research Network.**
  - **ICLN: Integrated Consortium of Laboratory Networks.**
  - **ORA/ORS: Health fraud and QC check sample program.**

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PT and MV studies
Fit for Purpose target/matrix combinations

Examples of Chemistry studies:

- **Toxic Elements in food**
- **Active Pharmaceutical Ingredient (API) in dietary supplements**
- **Mycotoxins in food, animal tissues**
- **Pesticides in food**
- **Additives in Food and Cosmetic products**
- **Surge/Emergency Preparedness**

Examples of Microbiology studies:

- **Detection and Enumeration of pathogens in variety of foods.**
  - *Cronobacter sakazakii*
  - *Listeria monocytogenes*
  - *Salmonella spp.,*
  - *Vibrio spp.,*
  - *Bacillus cereus*
  - *Staphylococcus aureus*
- **Capability/Emergency Preparedness - Triage Exercises.**
  - Bacillus anthracis
  - Yersinia pestis
  - Bacterial toxins

FY23 : 27 PT events - 617 packages - 7531 PT samples

525 laboratories - 983 analysts

100 unique laboratories and 300 unique analysts

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Beyond PT - Navigating New Methods

Method Development

- Developing a **new standard protocol**

Method Optimization

- **Optimize details** of the protocol
- Increase the **ruggedness** and **robustness** of the method

Single Lab Validation (SLV)

- More **specific study design requirements** than development & optimization
- Obtain **Key Performance Indicators (KPI),** such as **LOD, sensitivity** & **specificity** of the method for a single lab

Multi Lab Validation (MLV)

- Extend method study to multiple labs to **evaluate method performance across the laboratories**
- Obtain **specific parameters** of the method
- Not just "This method works!" More like **"This method has an LOD of 5 CFU, a sensitivity of 93% and a specificity of 100%."**

Method Implementation

- An **in-house verification study** must be performed before the new method can be implemented **in a new lab**
- **Verification of each new food matrix** outside the scope of the MLV

Proficiency Testing

Reliable Results

PTs can help!

Performing an in-house verification study, SLV or MLV can be a complex process.

Specially designed PTs that go beyond just "pass or fail" can help.

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Salmonella in Raw Pet Foods: Going Beyond PT

- Proficiency panel according to ISO 17043.
- Incorporating **ISO 16140-3** criteria allows for **individual method verification** of labs, **matrix extension**, and calculating the **eLOD** of each method/lab.
- 3 matrices with 8 samples per matrix = 24 total samples tested!
- 7 positive samples and 1 negative sample per matrix.

Salmonella in Raw Pet Foods: Going Beyond PT

Known, accurate low levels of inoculation:

- Preliminary trial work to calculate the **Level of Detection 50 (LOD_{50})** of each matrix.
- Final sample levels were calculated to have a **≥ 95% chance of being positive** in the given matrix.
- Inoculation with *Salmonella* Typhimurium BioBall®, a certified reference material enables reliable LOD_{50}

	LOD_{50}			LOD_{50} across all methods	RLOD	
Matrix	BAM	PCR	LAMP		BAM, PCR	BAM, LAMP
Freeze-dried Treats	0.9	0.9	1.0	0.9	1.0	1.1
Kibble	1.1	0.9	1.1	1.0	0.8	1.0
Patties	3.7	3.8	3.0	3.5	1.0	0.8

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Listeria monocytogenes in Queso Fresco Cheese
Focus on enumeration

- **Interlaboratory comparison of enumeration of *Listeria monocytogenes:***
  - To determine laboratoratory's ability to enumerate *Listeria monocytogenes*.
  - To evaluate performance characteristics of enumeration method.

Listeria monocytogenes in Queso Fresco Cheese

Participating labs.	Screening	Confirmation	Enumeration
Number Reporting	48	49	20
Reported Results	308	264	40
Satisfactory Results	304 (98.7%)	262 (99.2%)	**36 (90.0%)**
Warning Results	1 (0.3%)	0 (0.0%)	**5 (12.5%)**
All Results Correct	45 (93.8%)	48 (98.0%)	**17 (85.0%)**

- Most participants were proficient in enumeration of *Listeria monocytogenes*
- Quantitative results indicated deviations among some laboratories, suggesting improper handling of MPN dilution series and discrepancies in reporting of MPN values.
- Proficiency testing can be used to fill the data gaps i.e., lack of interlaboratory comparison data of enumeration methods and estimate precision characteristics along with evaluation laboratory and analyst's performance.

Z scores

M-07		M-08		No.
Result	*z*	Result	*z*	Action
4.3	-0.1	24	0.9	0
4.3	-0.1	9.3	0	0
9.3	0.4	4.3	-0.7	0
2	-0.7	1.8	-1.5	0
2.4	-0.6	11	0.2	0
93	2.2	1100	4.5	1
9.3	0.4	9.3	0	0
2400	4.6	11000	6.6	2
4.3	-0.1	9.3	0	0
4.3	-0.1	9.3	0	0
4.6	-0.1	2.4	-1.2	0
0.9	-1.3	4.6	-0.6	0
4.3	-0.1	4.3	-0.7	0
4.3	-0.1	9.3	0	0
0.9	-1.3	2.4	-1.2	0
9.3	0.4	7.5	-0.2	0
> 110	2.1	> 110	2.1	0
9.3	0.4	9.3	0	0
0.3	-2.2	9.3	0	0
240	2.9	240	3.1	1

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Unknown Toxicant PT

- **Mimic the real-world case diagnostic setting to identify lead toxicosis**
- **Integrative assessment - Pathology, Toxicology and Analytical Chemistry.**
- Laboratories received:
  - A case description with neurologic signs .
  - A digital histology slide.
  - Brain and liver specimens for possible chemistry analysis.
- Histopathology findings in combination with the case description and analytical results allowed toxicologists to identify the possible cause as a toxicant.
- **Final diagnosis: Lead toxicosis was correctly identified by 93% (13/14) laboratories.**

Laboratory Proficiency & Method Validation

ISO/IEC 17043 accredited proficiency testing program

Have an idea for a unique proficiency panel or an interlaboratory comparison study?

Let's collaborate!

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Moffett Proficiency Testing Laboratory Team Members

- **FDA Team**
  - Yang Chen
  - Shannon Kiener
  - Matthew Kmet
  - Robert Newkirk
  - Ravinder Reddy
  - Emily Smith
- **IFSH Team**
  - Catalina Paleaz
  - Sonali Patil
  - Jodie Ulaszek
  - Microbiologist (Vacant)
  - Chemist (Vacant)

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