

Cooperative Agreement Updates

Work to Support Human & Animal Food Testing
Laboratories

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Association of Public Health Laboratories (APHL)

AAFCO 2020 Annual Meeting – Albuquerque, NM

Overview

Resources

Accreditation
Consultation

GenomeTrakr
Efforts

OTED
Framework and
Course
Development



RESOURCES



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Highlighting Successes



ACCREDITATION PROVIDES STRONG DATA
TO TAKE ACTION ON CONTAMINATED PET FOOD



Animal food testing laboratories are working diligently to protect animals and humans, conducting surveillance testing on various raw animal food products to intercept contaminated products before they cause illness. This routine testing has resulted in several positive findings in laboratories around the country (see references). While various animal food manufacturers have voluntarily recalled their products out of an abundance of caution, some have questioned laboratory results.

Nebraska Department of Agriculture

The Nebraska Department of Agriculture (NDA) Laboratory had their testing questioned by a company whose raw animal food product tested positive for *Salmonella* in a random sampling. The company alleged that, since only one sample was positive while four subsequent samples were negative, the initial sample must have been cross-contaminated at some point in the analysis. Given its ISO/IEC 17025 accreditation status and rigorous testing standards, NDA was able to refute the company's allegations.

The laboratory emphasized that the inspector who collected the sample and the laboratory personnel who conducted the testing used appropriate chain of custody procedures. No other testing was performed in the laboratory at the same time to reduce the risk of cross-contamination. Positive and negative controls were used to confirm that the testing was performed properly. Molecular subtyping (performed by the Nebraska Public Health Laboratory) confirmed the sample culture as *Salmonella* Cerro, with the laboratory utilizing *Salmonella* Arizonae as its positive control. Sally Flowers, laboratory administrator for NDA, said "Being accredited to ISO/IEC 17025 means

<https://www.aphl.org/aboutAPHL/publications/Documents/FS-2019Jun-Raw-Pet-Food-Update.pdf>



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Highlighting Successes

FOOD SAFETY

Detecting *Cyclospora* in Food: FDA's Success with a New Method during Outbreaks

by Robyn Randolph, senior specialist, Food Laboratory Accreditation

Protecting our food supply and preventing human illness is a core mission for the US Food and Drug Administration (FDA). In summer 2018, FDA led several investigations into multistate outbreaks of Cyclosporiasis, an intestinal illness caused by the parasite *Cyclospora cayentanensis* that sickened hundreds of people. Luckily, a newly-developed FDA food testing method allowed investigators to identify the pathogen in food or food articles, and remove implicated product from shelves quickly.

Public Health Significance

C. cayentanensis is not a newly emerging threat, as outbreaks have been associated with the parasite for years. However, both sporadic case reports and outbreaks of Cyclosporiasis are increasing based on surveillance data from the US Centers for Disease Control and Prevention (CDC). These increases could be due to improvements in surveillance methods, better diagnostic testing methods for human illness, or actual increases in illness due to yet-unknown factors. Whatever the reason for the reported increase in Cyclosporiasis cases, FDA's development of a new *Cyclospora* food testing method was timely given last year's large-scale outbreaks. Having a method to confirm the parasite's presence in food commodities helps identify potentially contaminated products and hasten their removal from commerce.

Validation of the New Method

FDA has not been able to detect *Cyclospora* in food since the early 2000s, as the previous detection method relied on supplies that are no longer commercially available. Following large, multi-state Cyclosporiasis outbreaks in 2013, FDA's Center for Food Safety and Applied Nutrition (CFSAN) created the Foodborne Parasitology Research Program to develop

method for detection of *C. cayentanensis* in fresh produce such as leafy greens and berries. The Parasitology Program conducted a multi-laboratory validation to ensure the method's accuracy and reproducibility. The method was published in 2017 in FDA's Microbiological Methods & Bacteriological Analytical Manual (BAM)¹, which lists the FDA's preferred methods for pathogen detection. All seven FDA Office of Regulatory Affairs (ORA) Human and Animal Food (HAF) laboratories can conduct the *Cyclospora* analysis, with an ongoing expansion to state laboratories.

Cyclospora Outbreaks in Summer 2018

Summer 2018 was a busy season with two large multi-state outbreaks attributed to *C. cayentanensis*.

In June 2018, FDA² and CDC³ worked together on a Cyclosporiasis multi-state

outbreak in four states. As of September 2018, the CDC had been notified of 250 laboratory-confirmed cases of Cyclosporiasis from four states. Epidemiologic evidence pointed to pre-packaged vegetable trays. Unfortunately, traceback analysis was unable to determine the specific component of the vegetable tray that was responsible for the contamination.

In July 2018, an even larger outbreak surfaced, with 511 laboratory-confirmed cases⁴ from 15 states and New York City. Cases reported consuming salads from a major fast-food chain. FDA⁵ was able to utilize the newly developed method to confirm the presence of *C. cayentanensis* in an unopened package of salad mix (romaine and carrots) distributed to the chain restaurants. Although a single source of contamination was not identified, FDA worked with the chain to stop selling salads in 14 states; the



<https://view.joomag.com/lab-matters-spring-2019/0293620001558533214?short>



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ISO/IEC 17025 Resources

ISO/IEC 17025:2005

ISO/IEC 17025:2017

(If you are from a governmental food or animal feed laboratory and are unable to login with the above link, please contact the Food Safety Department at foodsafety@aphl.org)

At the link, find resources pertaining to:

ISO/IEC 17025:2005 Standard

- 4.1 Ethics
- 4.3 Document Control
- 4.4 Contract Review
- 4.5 Subcontracting
- 4.6 Purchasing Services and Supplies
- 4.7 Customer Service
- 4.8 Customer Complaints
- 4.9 Quality Event Management
- 4.10 Improvement
- 4.11 Root Cause Analysis and Corrective Action
- 4.12 Preventive Action
- 4.13 Record Control
- 4.14 Internal Audits
- 4.15 Management Review
- 5.2 Training and Competency
- 5.3 Accommodations & Environmental Conditions
- 5.4 Validation-Verification

ISO/IEC 17025:2017 Standard

- 4.1 Impartiality
- 4.2 Confidentiality
- 6.2 Personnel
- 6.3 Facilities and environmental conditions
- 6.4 Equipment
- 6.5 Metrological traceability
- 6.6 Externally provided products and services
- 7.1 Review of requests, tenders and contracts
- 7.2 Selection, verification and validation of methods
- 7.3 Sampling
- 7.4 Handling of test or calibration items
- 7.5 Technical records
- 7.6 Evaluation of measurement uncertainty
- 7.7 Ensuring the validity of results

https://www.aphl.org/programs/food_safety/laboratory-accreditation/Pages/Accreditation-Resources.aspx



Best Practice Resources

GOODSamples: Guidance On Obtaining Defensible Samples



Human and Animal Testing Laboratory Practices Manual

Human and Animal Food Regulatory Compliance Review Checklist

Coversheet

(Package should contain further information and data at the pages indicated)

	Page(s):
Sample Number(s)	Page(s):
	Page(s):
Labeling	Page(s):
Allowable Limit	Unit
10. Relevant Regulations / Legal Authority	Page(s):

Best Practices for Submission of Actionable Human and Animal Food Testing Data Generated in State and Local Laboratories

JANUARY 2019

APHL ASSOCIATION OF
PUBLIC HEALTH LABORATORIES®



Laboratory Sampling Working Group
AAFCO, AFDO, and APHL
June 2018

<http://www.aafco.org/Publications/GOODTestPortions>

Data Auditing Webinars

- [Why is Data Auditing Important?](#) (June 2019)
- [Data Auditing Series: Organic Data](#)
(August 2019)
- [Data Auditing Series: Inorganic Data](#)
(February 5, 2020)
- Data Auditing Series: Microbiology Data
(TBD)



Supporting GOOD Test Portions laboratory trainings

- Working with AAFCO to provide support for three *GOOD Test Portions* trainings
 - NY Department of Agriculture & Markets (December 2018)
 - VA Division of Consolidated Laboratory Services (June 2019)
 - FDA ORA Laboratory, Lenexa, KS (June 2019)
- An additional training will be held in 2020.



ACCREDITATION CONSULTANT



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Accreditation Consultant

Working with 10 laboratories:

- Alabama Department of Agriculture
- Hawaii Department of Health (Accredited!)
- Michigan Department of Health (Accredited!)
- New Hampshire Division of Public Health Services
- New Mexico Department of Health
- New Mexico State University
- Oklahoma Department of Agriculture
- Pennsylvania Department of Health
- South Dakota State University (Accredited!)
- Washington Department of Health (Accredited!)



GENOMETRAKR EFFORTS

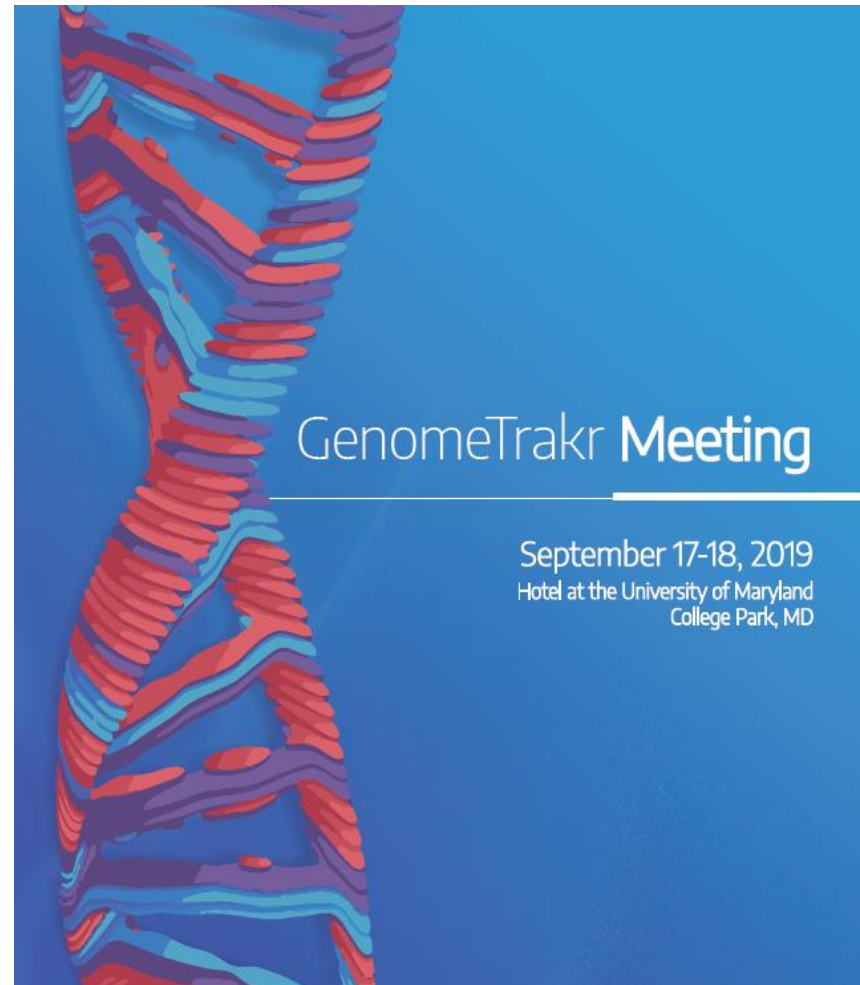


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GenomeTrakr Trainings & Meetings

- 2019 GenomeTrakr Meeting
 - September 17 – 18, 2019
 - College Park, MD
- Galaxy Training
 - September 16 – 17, 2019
 - Held at Joint Institute for Food Safety and Applied Nutrition (JIFSAN)
 - 30 attendees



NCBI Best Practices Document

- The document includes:
 - Relevant NCBI databases
 - Community Standards for sequence and metadata quality
 - SOP for using FDA's GalaxyTrakr for quality control
 - Detailed SOP for NCBI submissions
 - Community standards and SOP for data curation

OTED FRAMEWORK AND COURSE DEVELOPMENT



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Laboratory Framework



Human and Animal Food Laboratory Professionals Curriculum Framework - July, 2019



Senior Administration	Accreditation / Certification	Advocacy	Budget	Change Management	Continuity of Operations	Facility Management	Human Resource Management	ISO (Section 4)	Legislative Affairs	Leadership / Executive Program	Organizational Culture	Policy Making	Program / Grant Management	Public Relations	Risk Analysis (Management & Communication)	Stakeholder Support	Systems Analysis	Instructor Development	Project Management			
Supervisor / Manager Program Specific	Advanced Chemistry			Advanced Microbiology					Leadership / Executive Program	Organizational Culture	Policy Making	Program / Grant Management	Public Relations	Risk Analysis (Management & Communication)	Stakeholder Support	Systems Analysis						
Supervisor / Manager	Conflict Resolution and Mediation		Incident Command System (ICS)		Negotiation		Risk Communication Introduction															
Expert (Program Specific)	Certificates & Certifications																					
	Animal Food		Human Food			Shellfish		Instrument Repair	Laboratory Evaluation Officer	Coaching	Nano-technology	Animal Health	Animal Food	Human Food	Shellfish	Chemistry		Microbiology				
Expert	Acidified Foods		Advanced Leadership		Allergens		Evidence-Based Decision Making		Grant Writing		Internal Audit		Labeling		Measurement Uncertainty		Method Modification / Development		Risk Analysis		Validation Methods	
Mid (Program Specific)	Certificates & Certifications																					
	Animal Food	Animal Health	Dairy	Environmental	Human Food	Shellfish	Audit	Hazardous Material Shipping	Infectious Agent Shipping	Waste Management	Animal Food Safety	Animal Health	Food Safety	Environmental Conditions	Milk and Dairy Product Safety	Shellfish						
	Gas Chromatography - Mass Spectrometry (GCMS)			Inductively Coupled Plasma Mass Spectrometry (ICPMS)			Liquid Chromatography - Mass Spectrometry (LCMS)			National Laboratory Networks Methods			Radiological		Advanced Technologies			National Laboratory Networks Methods				
Mid	Advanced Communication Skills		Advanced Quality Techniques		Basic Leadership Skills		Critical Thinking		Evidentiary Integrity		Human and Animal Food Incident Response		Laboratory Networks and Partnerships		Legal Proceedings		Method Evaluation and Selection		Root Cause Analysis			
	M1		M2		M3		M4		M5		M6		M7		M8		M9		M10			
Entry (Program Specific)	Certificates & Certifications																					
	Animal Food			Biosafety Level 3				Dairy Regulatory Programs				Select Agents			Shellfish Regulatory Programs							
	EP10			EP11				EP12				EP13			EP14							
	Basic Chromatography		Basic Separation / Extraction Techniques			Basic Mass Spectrometry		Basic Spectroscopy		Environmental Monitoring and Investigations		Aseptic Techniques		Basic Foodborne Pathogens		Environmental Conditions		Microbiological Testing				
	EP1		EP2			EP3		EP4		EP6		EP9		EP7		EP8		EP8				
Entry	Accreditation/ Certification	Basic Communication Skills	Basic Laboratory Math	Basic Laboratory Statistics	Basic Laboratory Techniques	Chain of Custody	Ethics	Incident Command System (ICS)	Integrated Food Safety System (IFSS)	Laboratory Information Management System (LIMS)	Laboratory Sampling	Method Resources	Public Health (One Health) Approach	Quality Management Systems	Regulatory Programs	Regulatory Sampling	Safety	Waste Management				
	E1	E2	E3	E4	E5	E6	E7	E8	E9	E10	E11	E12	E13	E14	E15	E16	E17	E18				

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The Laboratory Framework is being built out through a Cooperative Agreement with FDA, AFDO, AAFCO, and APHL.



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Mid	M1		M2		M3		M4		M5		M6		M7		M8		M9		M10			
Entry (Program Specific)	Certificates & Certifications																					
Entry (Program Specific)	Animal Food EP10			Biosafety Level 3 EP11				Dairy Regulatory Programs EP12				Select Agents EP13				Shellfish Regulatory Programs EP14						
Entry (Program Specific)	Basic Chromatography EP1		Basic Separation / Extraction Techniques EP2			Basic Mass Spectrometry EP3		Basic Spectroscopy EP4		Environmental Monitoring and Investigations EP6		Aseptic Techniques EP9		Basic Foodborne Pathogens EP7		Environmental Conditions EP8		Microbiological Testing EP8				
Entry	Accreditation/ Certification E1	Basic Communication Skills E2	Basic Laboratory Math E3	Basic Laboratory Statistics E4	Basic Laboratory Techniques E5	Chain of Custody E6	Ethics E7	Incident Command System (ICS) E8	Integrated Food Safety System (IFSS) E9	Laboratory Information Management System (LIMS) E10	Laboratory Sampling E11	Method Resources E12	Public Health (One Health) Approach E13	Quality Management Systems E14	Regulatory Programs E15	Regulatory Sampling E16	Safety E17	Waste Management E18				

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LCF Course Development

- Laboratory Ethics (under review)
- Laboratory Safety (expected Spring 2020)
- Basic Laboratory Statistics (TBD 2020)
- Basic Laboratory Techniques (TBD 2020)
- Basic Laboratory Math (TBD 2020)
- Waste Management (TBD 2020)
- Method Resources (TBD 2020)



Laboratory Ethics



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Resources

- [APHL Accreditation Resources](#)
- [AAFCO Laboratory Resources](#)
- [AFDO Directory of State & Laboratory Officials](#)



Thank you



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