FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

Laboratory Flexible Funding Model (LFFM) Program Overview

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GenomeTrakr Annual Meeting

November 3, 2026

Laboratory Flexible Funding Model

7th Year of the LFFM Program

First year of current 5-Year Cooperative Agreement

Cycle: July 1 – June 30, annually

16

Tracks (Projects) across Chemistry, Microbiology and Radiochemistry Disciplines

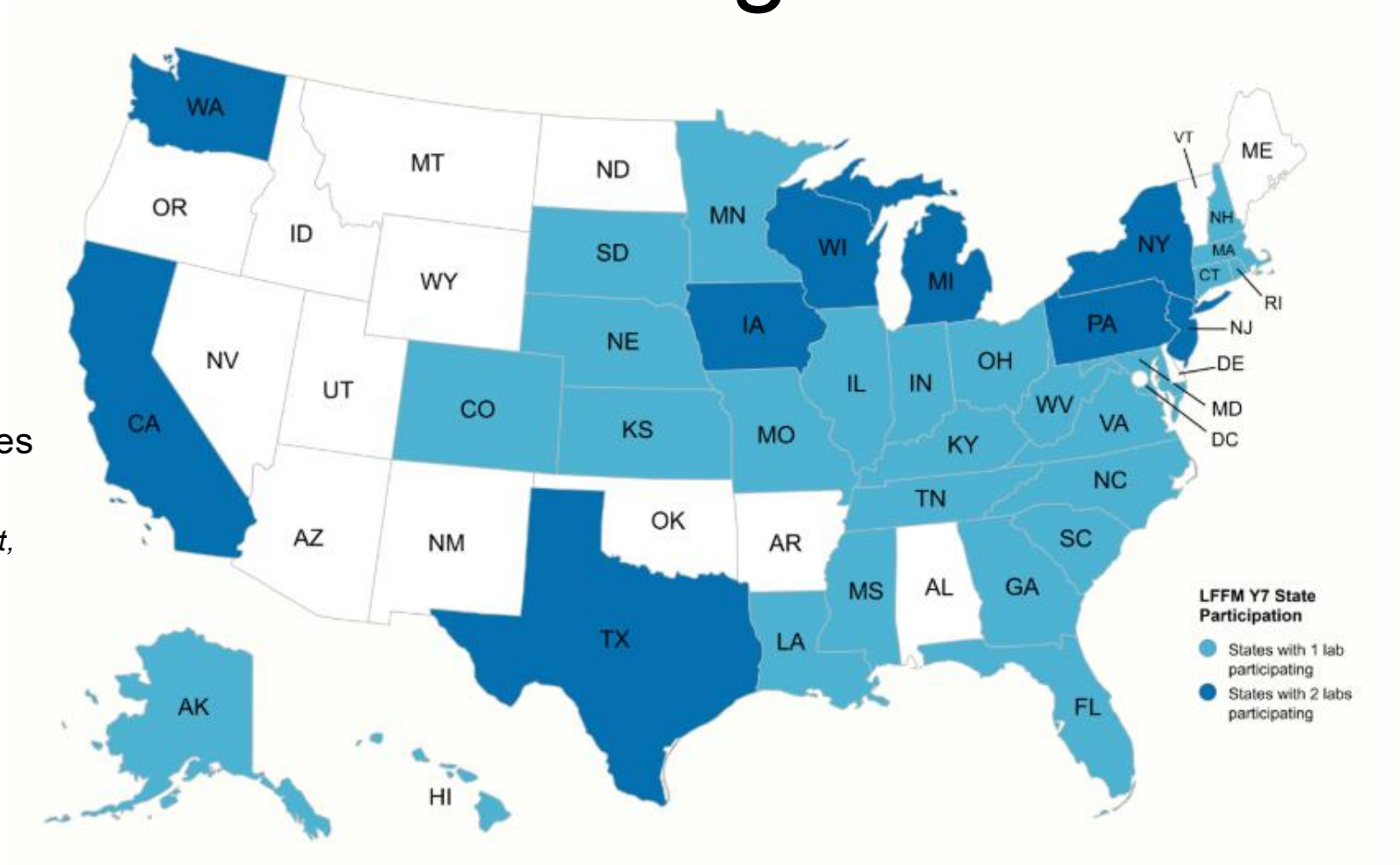
Food Defense, Product Testing, Whole Genome Sequencing (WGS), Capacity/Capability Development, Method Development/Validation (MDV)

44

Laboratories across all tracks

35

States



Year 7 Funding: ~$21M

Offsets were applied from YR6

WGS Track Accomplishments (2020 – 2025)

Year	# Labs	WGS Track Total Funding
YR3	31	$2.8M
YR4	31	$2.8M
YR5	31	$2.7M

Annual objectives:

- Annual GenomeTrakr PT
- Sequence food/env. isolates from surveillance, outbreaks, collaborations
- Support equipment, supplies, personnel, training associated with sequencing food/env. isolates

Year	# of labs	Planned isolates	Sequenced Isolates
YR1	28	7,900	3,566 (45%)
YR2	31	8,050	5,824 (72%)
YR3	31	7,900	5,980 (75%)
YR4	31	7,300	6,354 (87%)
YR5	31	7,150	6,826 (103%)*

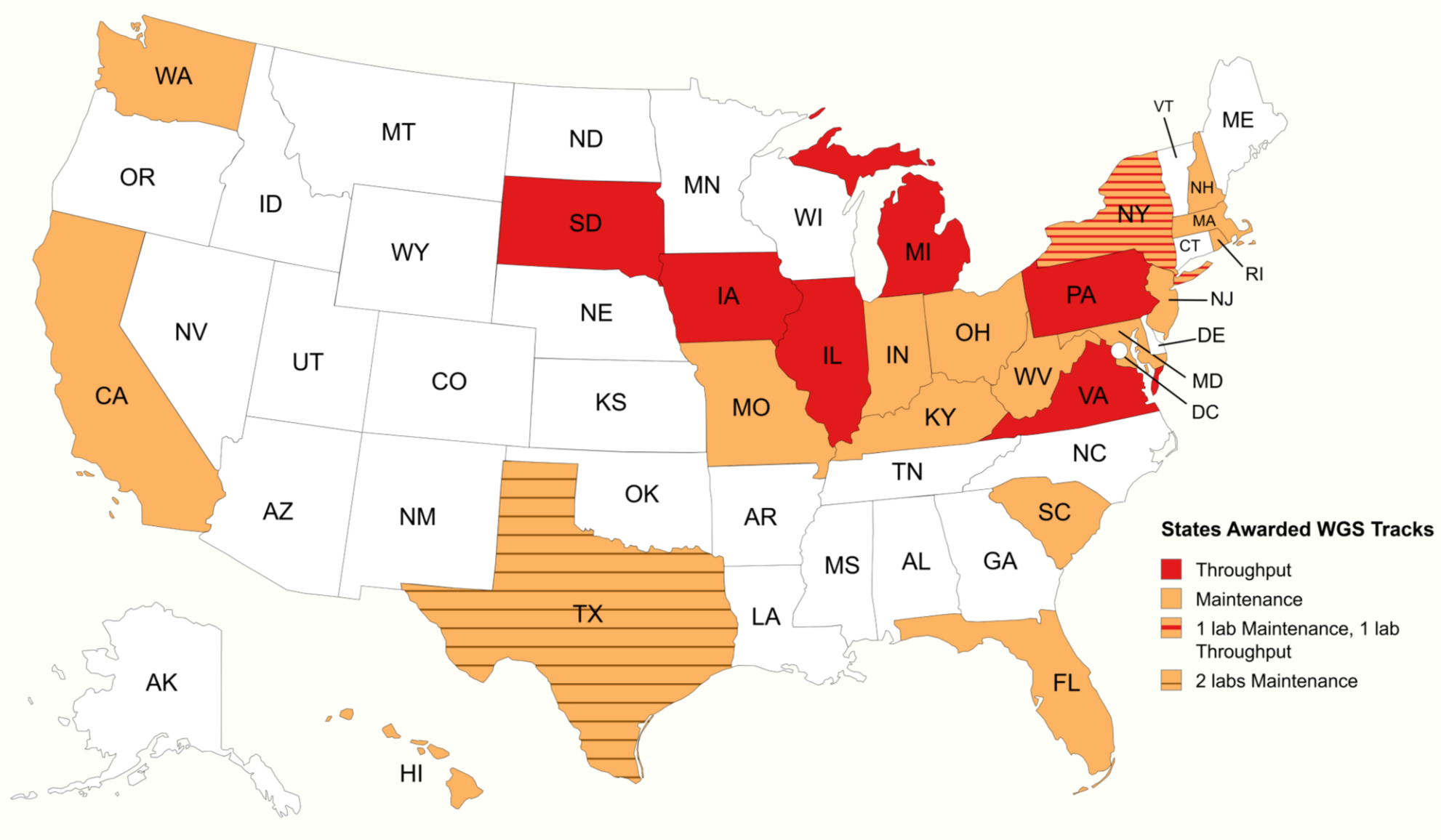
16 WGS Tracks labs were also in M-HAF tracks

- YR2: 121 isolates from M-HAF surveillance
- YR3: 111 isolates from M-HAF surveillance
- YR4: 107 isolates from M-HAF surveillance
- YR5: 155 isolates from M-HAF surveillance

Shout out to labs who assisted with sequencing isolates from M-HAF labs who lack sequencing capabilities (MI Dept of Health, VA Division of Consolidated Lab Services!!)

**EPA/NARMS isolates received double analysis count due to the micro bench work needed*

LFFM (2025 -2030) WGS Tracks by State



Current WGS Track Awardees

Maintenance (18)

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
FLORIDA STATE DEPT OF AGRIC/CONSUM SRVCS
HAWAII STATE DEPARTMENT OF HEALTH
INDIANA STATE DEPARTMENT OF HEALTH
KENTUCKY ST CABINET/HEALTH/FAMILY SERVICES
MARYLAND STATE DEPARTMENT OF HEALTH
MASSACHUSETTS STATE DEPT OF PUB HEALTH
MISSOURI STATE DEPT/ HEALTH & SENIOR SRV
NEW JERSEY STATE DEPARTMENTR/AGRICULTURE
NEW HAMPSHIRE STATE DEPT/HLTH STATISTICS/DATA MGMT
NEW YORK STATE DEPT OF AGRICULTURE/ MARKETS
OHIO STATE DEPARTMENT OF AGRICULTURE
RHODE ISLAND STATE DEPT OF HEALTH
SOUTH CAROLINA DEPARTMENT OF PUBLIC HEALTH
TEXAS A&M AGRILIFE RESEARCH
TEXAS STATE DEPT OF HEALTH SERVICES
WASHINGTON STATE DEPARTMENT OF AGRICULTURE
WEST VIRGINIA STATE DEPT OF AGRICULTURE

Throughput (7)

ILLINOIS INSTITUTE OF TECHNOLOGY
IOWA - UNIVERSITY OF IOWA
MICHIGAN STATE DEPT OF AGRICULTURE
NEW YORK WADSWORTH CENTER
PENNSYLVANIA STATE UNIVERSITY
SOUTH DAKOTA STATE UNIVERSITY
VIRGINIA DIVISION/CONSOLIDATED LAB SRVS

WGS Maintenance Track

- WGS support for labs in M-HAF or M-NARMS Track
- Sequence isolates from LFFM surveillance and outbreak samples
  - M-HAF: Salmonella, L. mono, STEC
  - NARMS: Salmonella, Campylobacter, E. coli, Vibrio
  - YR6: 29 M-HAF isolates (4 sequenced by WGS Throughput labs), 160 NARMS isolates
- Upload WGS data to NCBI
  - Follow GenomeTrakr protocols
  - Consistent completion of metadata fields
  - Submit within 7 days of isolate confirmation (goal)
- Participate in GenomeTrakr PT
- Participate in GenomeTrakr Meeting

WGS Impact on Surveillance Samples – Year 6

- WGS distinguished between a concurrent Salmonella LFFM sprout sample and positive SSIW surveillance sample (same firm) linked to clinicals
  - Demonstrated the firm had multiple strains of Salmonella in their facility and guided investigation
- WGS established a link between a positive STEC LFFM surveillance sample in raw milk cheese and recent clinical isolates
  - Provided a regulatory sample to confirm outbreak vehicle
- WGS continues to build a body of evidence that enoki mushrooms from multiple firms and countries of origin contain closely related L. mono strains
  - Guides long-term investigation re: shared source(s)
- We continue to see occasional LFFM sample isolates closely related to clinical isolates, yet lacking epi and/or the clinicals are not recent
  - While WGS does not conclusively demonstrate a link, these isolates continue to build the library for that strain and impact future investigations

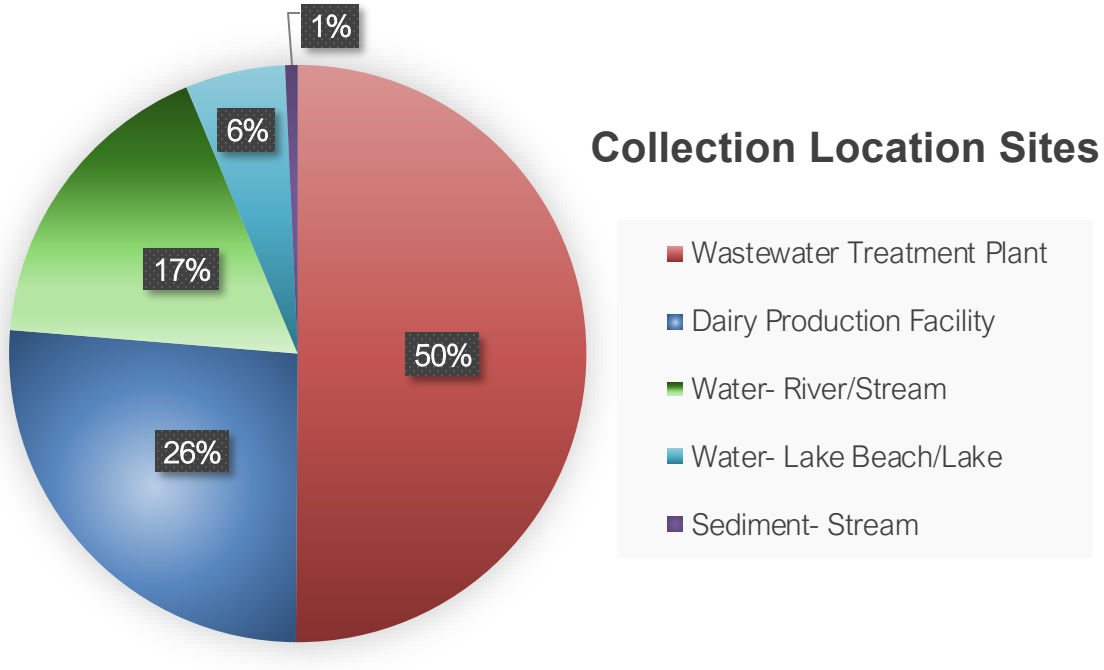
WGS Throughput Track

- Sequence enteric pathogens from environmental, food, and animal samples
  - Historical isolate sequencing collaborations
  - Collection of non-regulatory environmental samples for microbiological analysis and sequencing of enteric pathogens
- Support sequencing of isolates from M-HAF labs who lack capability
  - Shout-out to VA DCLS, NY Wadsworth, UIowa!
  - 4 samples from YR6, 4 samples from YR7 (year in progress)
- Upload WGS data to NCBI
  - Follow GenomeTrakr protocols
  - Consistent completion of metadata fields
  - Submit within 7 days of isolate confirmation (goal)
- Participate in GenomeTrakr PT
- Participate in GenomeTrakr Meeting

WGS Throughput Track – Year 6 Activities

- Historical isolates from collaborators
  - STEC and Salmonella from misc. sources (Academia)
  - Clostridium spp. from dairy facility (Academia)
  - Salmonella from Wastewater (Academia)
  - Salmonella, Listeria, E. coli from water sources and wild birds (Academia)
  - Cronobacter from rural/urban/natural environments (Academia)
- Environmental Samples
  - 6 labs collected 285 samples

Pathogen	# Samples	# Positive
Salmonella	285	64
L. mono	240	97
STEC	34	1
Campylobacter	22	2
Cronobacter	75	0
Cyclospora	17	0



WGS Throughput Track – Year 6 Activities

- Environmental Samples (continued)

Positivity rate of samples by sample type

Sample Type	Campylobacter	Cronobacter	Salmonella	Cyclospora	L. mono	EHEC/STEC
Water- DEUF	4.3% (23)	-	23.5% (34)	0% (17)	26.5% (34)	2.9% (34)
Wastewater	-	-	35.4% (144)	-	67.2% (131)	-
Sediment	-	-	15.6% (32)	-	-	-
Soil	-	-	-	-	-	-
Manure	-	-	-	-	-	-
Facility	-	0% (75)	0% (75)	-	0% (75)	-

WGS related MDV and C/C projects

- Year 1: 6 labs developed WGS capabilities under M-C/C Track
  - 5 of 6 labs rolled over to WGS Track and sequenced 1,137 isolates in YR2-5.
  - 4 of 6 labs are participating in WGS-Maintenance in current award, sequenced 13 M-HAF and 28 M-NARMS isolates in YR6 (41 isolates total).
- Year 4-5: Multi-lab project to implement portable Oxford Nanopore Technology (ONT) for real-time sequencing of foodborne bacterial pathogens
  - 9 labs participated
  - Labs purchased bespoke GridION bundle
  - Labs participated in training during 2024 GenomeTrakr meeting
  - PT samples were sent out after the meeting – all labs successfully demonstrated competency
  - Labs are able to use GridION at their discretion; on deck for MLV down the road
    - One lab reports using GridION to profile E. coli strains from false-positive STEC reactions
- Year 7: Genomic surveillance (Salmonella/Cronobacter) and Metagenomics-Based Authentication of Edible Insect Products in the Marketplace
  - 1 lab is working with FDA
  - Purchasing RTE insect products online for gDNA extraction and testing using two kits and protocols
  - Project in-progress

Publications Supported in part by LFFM

Publication	Year	Lab(s)
Clustering and Source Association of Clinical and Nonclinical Listeria monocytogenes Isolates, New York, USA, 2000-20211.	2026	NYSDOH, NYAGM
Genomic and clinical determinants of extraintestinal Clostridium perfringens infections in immunocompromised patients.	2026	NYSDOH
Genomic Evidence of Multidrug-Resistant Salmonella in Wild Waterbirds from High-Andean Lakes of Ecuador.	2026	NYAGM
Prevalence and Antimicrobial Resistance of Nontyphoidal Salmonella in Retail Meat in Puerto Rico: A Two-Year Study (2022–2023) – PMC	2026	PSU
Antimicrobial resistance profiles of Campylobacter spp. isolated from retail meat in Puerto Rico - PMC	2025	PSU
Genetic exchange networks bridge mobile DNA vehicles in the bacterial pathogen Listeria monocytogenes.	2025	NYSDOH
Genomic Diversity and Potential Transmission and Persistence of Salmonella in the Cambodian Vegetable Supply Chain - PubMed	2025	PSU
High prevalence of multidrug-resistant Salmonella enterica in Thailand food markets: insights from complete genome and phenotypic characterization of ESBL-producing strains.	2025	NYSDOH
Retrospective Analysis of Historical Listeria monocytogenes Clinical Isolates, New York, USA, 2000-20211.	2025	NYSDOH, NYAGM
Salmonella isolated from street foods and environment of an urban park: A whole genome sequencing approach	2025	NYAGM
Whole-genome sequence of 19 Listeria monocytogenes, isolated from municipal wastewater in State College, Pennsylvania - PMC	2025	PSU

Publications Supported in part by LFFM

Publication	Year	Lab(s)
A Retrospective Analysis of Salmonella Isolates across 11 Animal Species (1982–1999) Led to the First Identification of Chromosomally Encoded blaSCO-1 in the USA – PMC	2024	SDSU
Fluoroquinolone-resistant Campylobacter in backyard and commercial broiler production systems in the United States – PMC	2024	NCSU
Genomic characterization of Listeria monocytogenes and Listeria innocua isolated from milk and dairy samples in Ethiopia - PMC	2024	PSU, MDARD
Host species shapes genotype, antimicrobial resistance, and virulence profiles of enterotoxigenic Escherichia coli (ETEC) from livestock in the United States - PubMed	2024	PSU
Implementation of a high-throughput whole genome sequencing approach with the goal of maximizing efficiency and cost effectiveness to improve public health.	2024	NYSDOH
Investigating the adherence factors of Escherichia coli at the bovine recto-anal junction - PMC	2024	PSU
Megaplasmid Dissemination in Multidrug-Resistant Salmonella Serotypes from Backyard and Commercial Broiler Production Systems in the Southeastern United States.	2024	NCSU
Outbreak-associated Salmonella Baildon found in wastewater demonstrates how sewage monitoring can supplement traditional disease surveillance - PMC	2024	PSU
Salmonella sp. Tied to Multistate Outbreak Isolated from Wastewater, United States, 2022 - PMC	2024	PSU
Widespread prevalence of plasmid-mediated blaCTX-M type extended-spectrum beta-lactamase Escherichia coli in backyard broiler production systems in the United States – PMC	2024	NCSU

Publications Supported in part by LFFM

Publication	Year	Lab(s)
Challenges Associated with Investigating Salmonella Enteritidis with Low Genomic Diversity in New York State: The Impact of Adjusting Analytical Methods and Correlation with Epidemiological Data.	2023	NYSDOH
Exploring Antimicrobial Resistance Profiles of E. coli Isolates in Dairy Cattle: A Baseline Study across Dairy Farms with Varied Husbandry Practices in Puerto Rico - PMC	2023	PSU
High resistance of fluoroquinolone and macrolide reported in avian pathogenic Escherichia coli isolates from the humid subtropical regions of Pakistan - PubMed	2023	PSU
Whole-Genome Subtyping Reveals Population Structure and Host Adaptation of Salmonella Typhimurium from Wild Birds - PMC	2023	PSU
Comparative Genomic Analysis of Salmonella enterica Serovar Typhimurium Isolates from Passerines Reveals Two Lineages Circulating in Europe, New Zealand, and the United States – PubMed	2022	PSU
Evidence for common ancestry and microevolution of passerine-adapted Salmonella enterica serovar Typhimurium in the UK and USA – PMC	2022	PSU
Genomic analysis of Salmonella Typhimurium from humans and food sources accurately predicts phenotypic multi-drug resistance - PubMed	2022	PSU
Low occurrence of multi-antimicrobial and heavy metal resistance in Salmonella enterica from wild birds in the United States – PubMed	2022	PSU
Salmonella enterica Serovar Typhimurium Isolates from Wild Birds in the United States Represent Distinct Lineages Defined by Bird Type - PubMed	2022	PSU
Virulence Potential of Escherichia coli Isolates from a Beef Farm in Puerto Rico - PMC	2022	PSU

Questions?

We welcome feedback: ODP.Feedback@fda.hhs.gov


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