Food Safety Surveillance and Testing Practices

2019 Survey Report

MARCH 2022

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

CONTENTS

INTRODUCTION

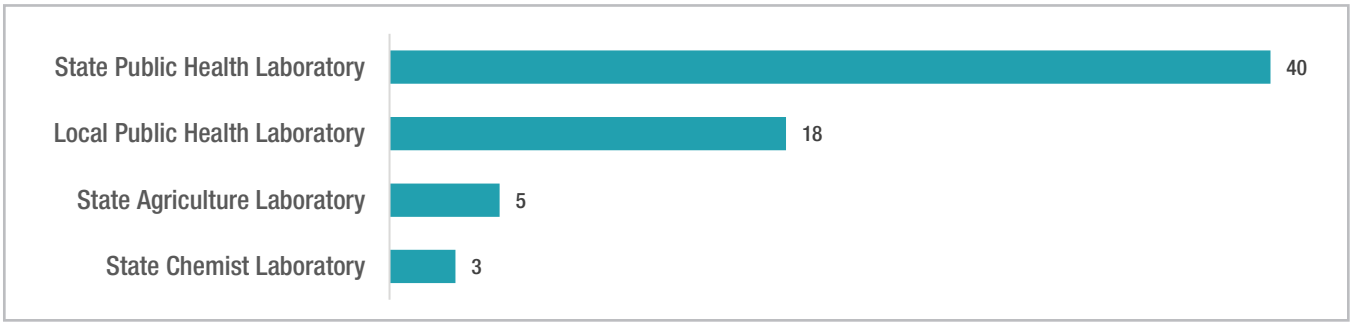
The food safety surveillance and testing practices survey was distributed to state, local and associate institutional laboratory members in fall 2019. The purpose of the survey was to gather information on members' food safety testing practices covering areas such as PulseNet performance, whole genome sequencing implementation, bioinformatics capability, recommendations of the Council to Improve Foodborne Outbreak Response (CIFOR), general foodborne pathogen and food contaminant testing, and ISO accreditation. The information obtained from this survey offers APHL's Food Safety Committee the ability to assess member practices and processes, consider available support as well as gaps, and build plans for food safety testing improvements nationally.

RESPONDING INSTITUTIONS

A total of 64 respondents completed the survey. Respondents were asked to classify their laboratory as state public health, local public health, state agriculture and/or state chemist. Three respondents selected multiple classifications given that their laboratories serve multiple roles (**Figure 1**).

Question 1. ***Please classify your laboratory. Check all that apply.***

Figure 1. Respondents by type of laboratory (n=64)



PULSENET AND BIOINFORMATICS

A few months prior to the launch of this survey, the PulseNet network fully converted to whole genome sequencing (WGS) as its primary method for molecular characterization of enteric pathogens. Survey data was collected to assess WGS turnaround time (TAT) and factors leading to delays in sequencing for PulseNet participating laboratories (n=48). The survey then asked all respondents who currently performed WGS for foodborne pathogens (clinical or food isolates) about their technical proficiency, bioinformatics resources and challenges to WGS analysis (n=50).

PulseNet TAT

PulseNet recommends that enteric pathogens be sequenced and uploaded to the national database within seven days of receipt at the public health laboratory. Respondents from PulseNet laboratories (n=48) were asked to answer question two:

Question 2. ***PulseNet has recommended performing mixed pathogen WGS runs to improve TAT. With a mixed run option, what is your anticipated TAT in days for WGS analysis for enterics?***

With a mixed run option, 21 respondents (44%) reported that they meet the recommended TAT (**Figure 2**).

The 27 respondents whose laboratories did not meet the PulseNet TAT recommendation were asked to identify factors responsible for the delay (**Figure 3**). Primary drivers included low specimen volume, staffing issues, funding, IT constraints and instrumentation limitations; "other" factors included calculation engine time, seasonal/high volume demands, validation delays and having to repeat specimens. They were then asked how they plan to address these issues (**Figure 4**).

Figure 2. Time to Sequence Enteric Pathogens and Upload to the National Database (n=48)

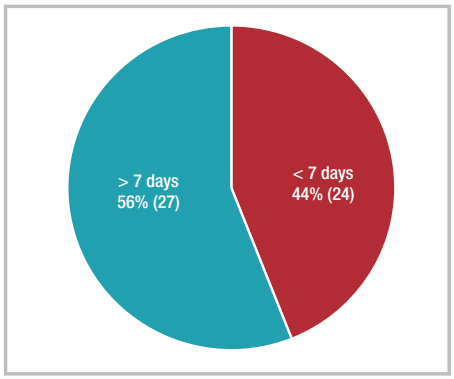


Figure 3. Factors Responsible for Delayed TAT (n=27)

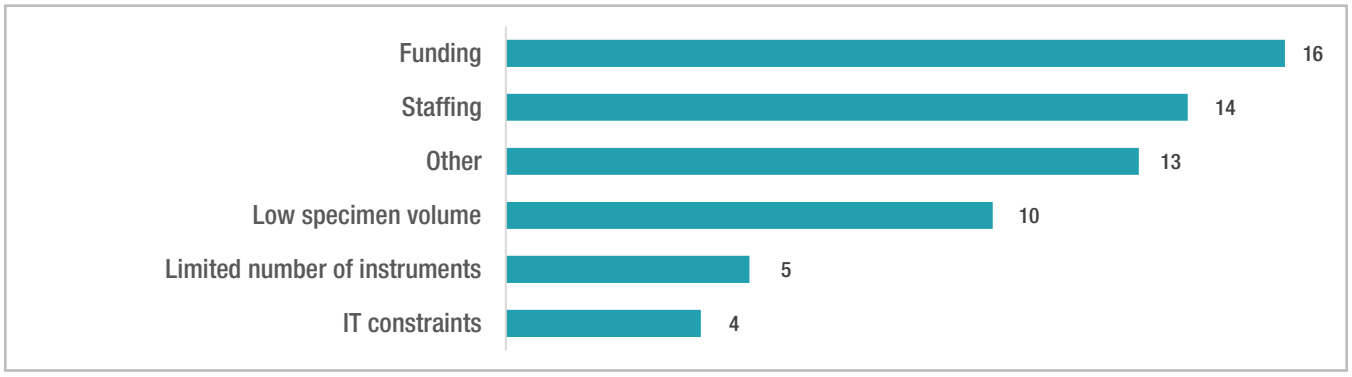
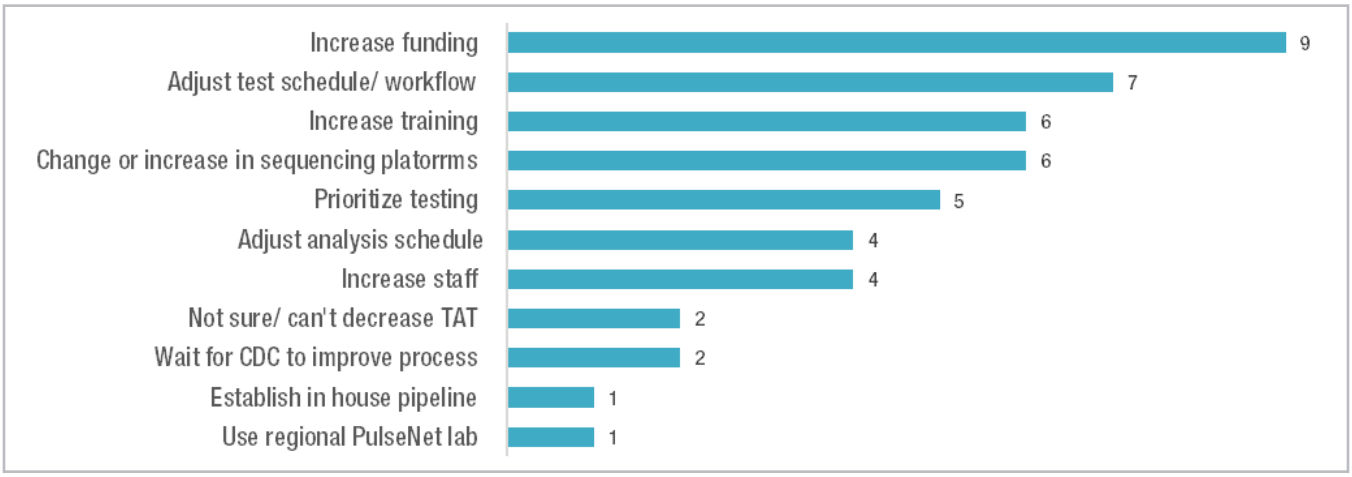


Figure 4. Plans to Decrease WGS TAT (n=27)



WGS and Bioinformatics

Respondents whose laboratories sequence enteric bacteria (n=50) were asked to respond to questions three through six. Two of these respondents are not PulseNet participants.

Re-sequencing of WGS Specimens

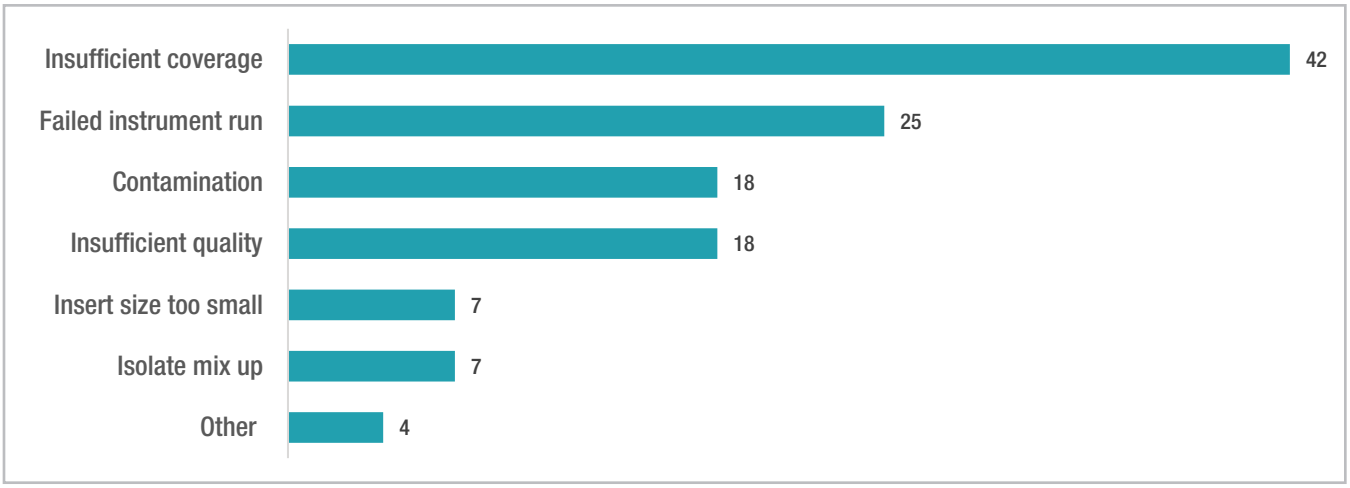
Question 3. ***What percentage of isolates sequenced in your laboratory have to be re-sequenced?***

Table 1. Percentage of Isolates that Require Re-sequencing (n=50)

	%	Count
< 0.5%	14%	7
0.5% to < 1.5%	26%	13
1.5% to < 2.5%	16%	8
2.5% to < 5%	20%	10
≥ 5%	24%	12

Question 3a. ***In your laboratory's experience, what are the key reason(s) why your isolates fail and need to be re-sequenced?***

Figure 5. Factors Impacting Need to Re-sequence Isolates (n=50)



Question 4. ***How has your laboratory responded to the workforce needs of implementing WGS? Please check all that apply.***

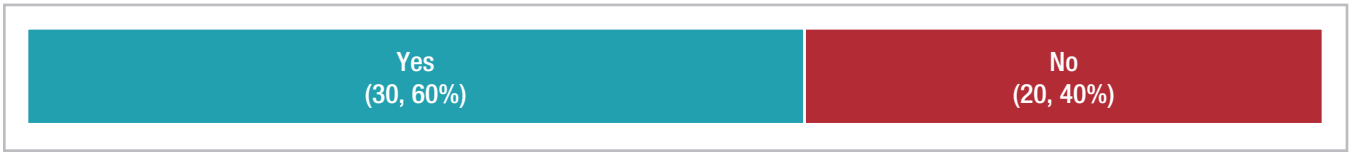
Table 2. Responses to Workforce Needs of Implementing WGS (n=50)

	Changes made in 2018 or before		Anticipated action in 2019		No changes needed	
	%	#	%	#	%	#
Retrain existing staff for positions in WGS	80%	40	20%	10	8%	4
Cross train existing staff to assist in WGS	58%	29	62%	31	6%	3
Hire new staff for WGS	34%	17	38%	19	32%	16
Other - please specify	2%	1	8%	4	90%	45

"Other" responses included: automation, bioinformatics training, keeping up with software changes and hiring a bioinformatician.

Question 5. ***Outside of BioNumerics, do you have the ability to perform analysis of your WGS data internally? (Figure 6)***

Figure 6. Ability to Analyze WGS Data Internally, Outside BioNumerics (n=50)



Those respondents with in-house WGS data analysis capability (n=30) were asked to check all resources available in their laboratories with regard to staff, equipment and software (**Figure 7**). "Other" responses included: Google VM; EID bioinformatics fellow/ bioinformatics regional resource; staph-B pipelines using Google cloud services; CI and UT pipelines; HPC on-prem; state-specific data sharing portal SFTP; Amazon web services cloud; local Linux workstations; Bionformatics Core; Galaxy Trakr; Basespace and SeqSero (*Salmonella)*.

Respondents who indicated they did not have the ability to perform WGS analysis internally (N=20) were asked where they are receiving bioinformatics support (**Figure 8**).

Figure 7. Resources Available in Laboratories with In-house WGS Data Analysis Capabilities (n=30)

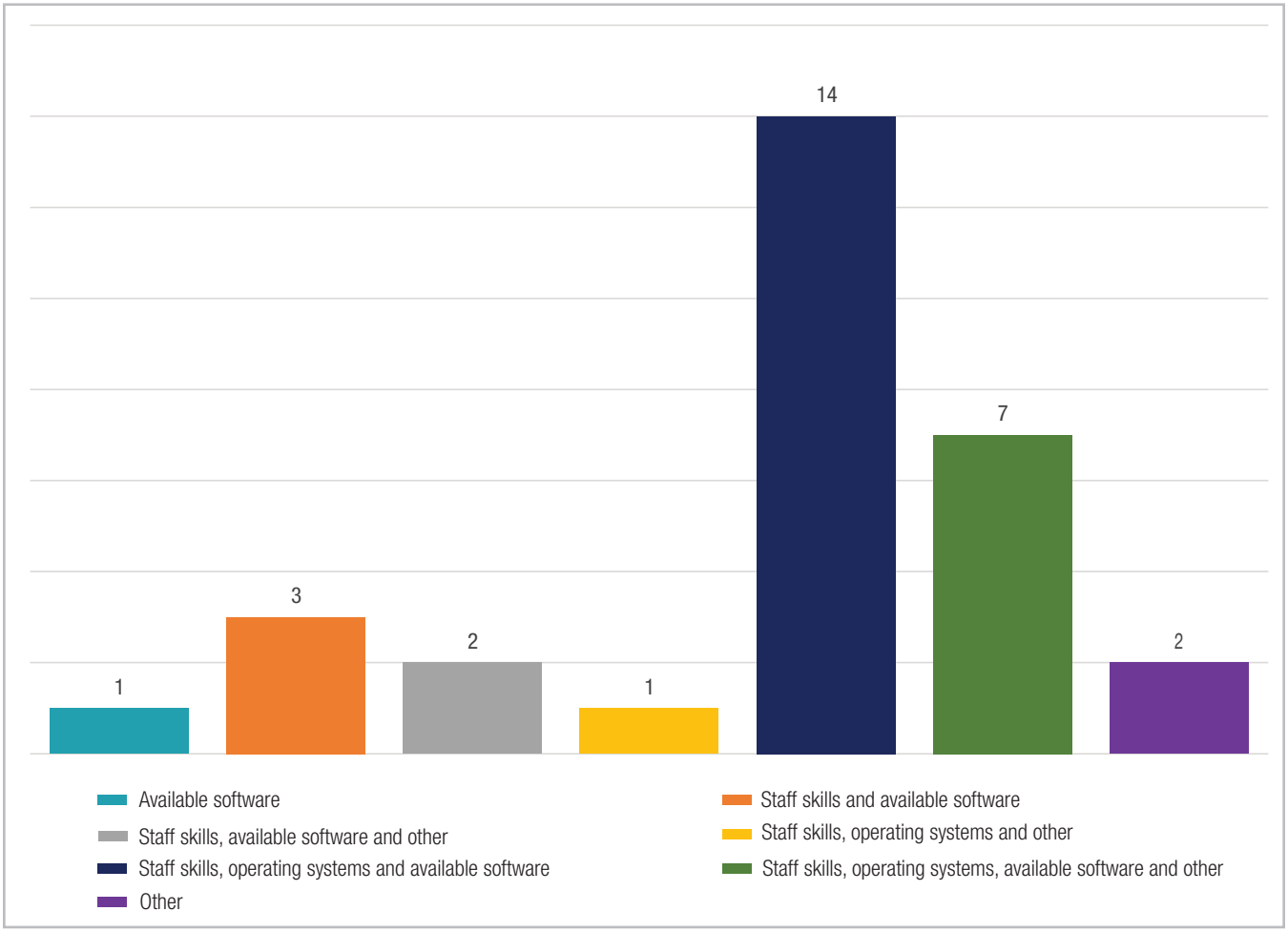
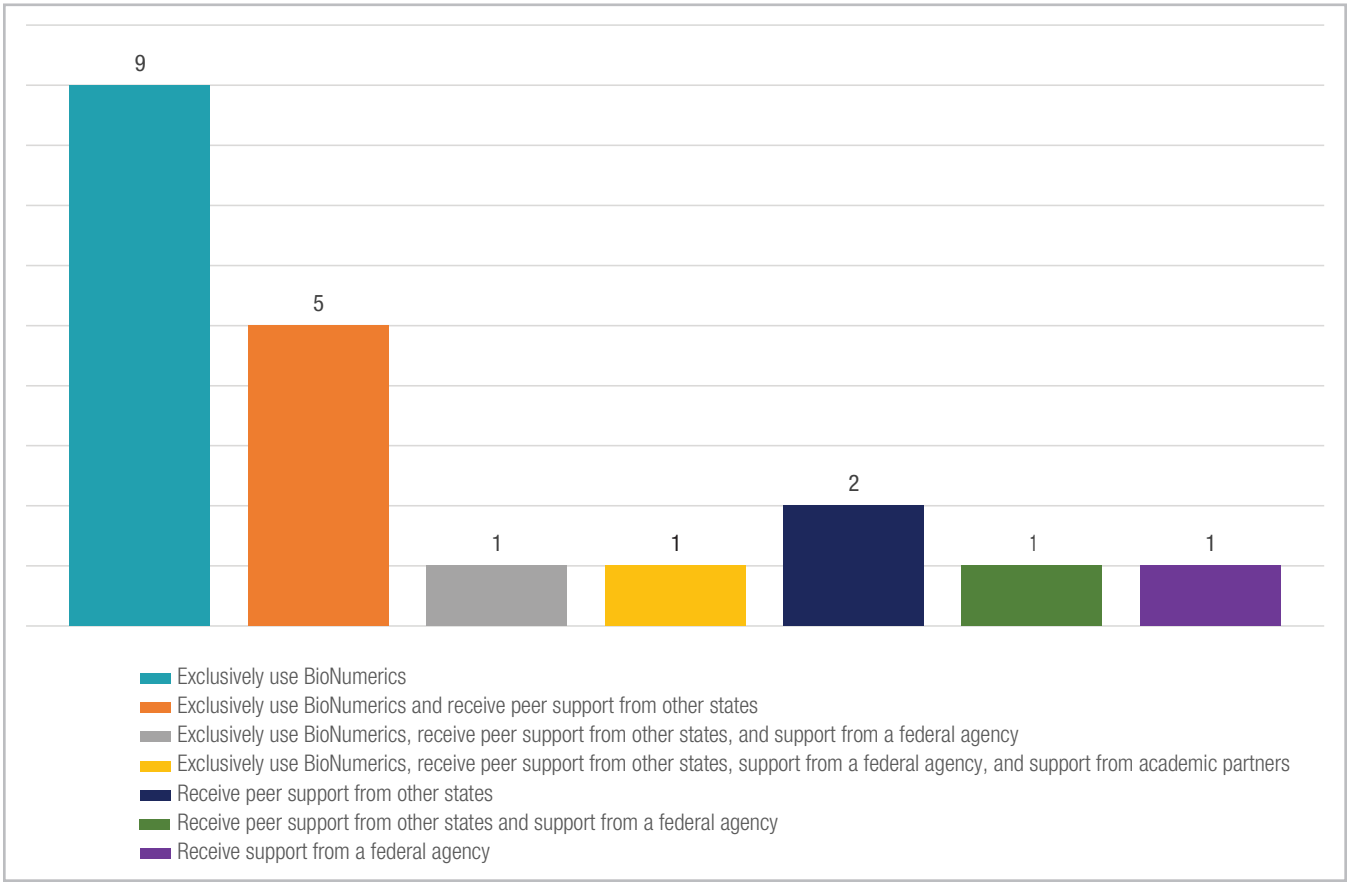


Figure 8. Sources of External Bioinformatics Support (n=20)



Question 6. ***What WGS-based applications have you or do you plan to validate for reporting? (e.g., identification, subtyping, virulence gene characterization)***

Table 3. Validation Status of WGS-based Applications

	Currently validated		Planning for validation in the future		We do not plan to validate		Total Responses	
	%	#	%	#	%	#	%	#
ANI	8%	4	55%	26	36%	17	100%	47
Seq Sero	29%	14	57%	28	14%	7	100%	49
Serotype finder	6%	3	55%	26	38%	18	100%	47
ResFinder	4%	2	39%	18	57%	26	100%	46
Other - please specify	7%	2	30%	9	63%	19	100%	30

"Other" responses included: WG MLST, Geneious, Assembly and LYVE-set; CLC work station; strep pneumoniae typing; long read sequencing; viral ID; virulence finder.

CIFOR

The Council to Improve Foodborne Outbreak Response (CIFOR) is a multidisciplinary collaboration of local, state and federal agencies representing epidemiologists, environmental health practitioners and public health laboratorians. CIFOR works to improve methods to detect, investigate, control and prevent foodborne disease outbreaks.

CIFOR Tools & Resources

CIFOR has published several tools and resources since its inception in 2006. The most notable tool, the CIFOR Guidelines for Foodborne Disease Outbreak Response are a comprehensive source of information on foodborne disease investigation and control for local, state and federal health agencies.

Question 7. ***Has your laboratory used any CIFOR tools or resources specifically for the purpose of improving processes or procedures in place in your laboratory? (Figure 9)***

Respondents (n=25) who indicated that they use CIFOR tools to improve processes and procedures were asked which tools they have used in their laboratory (**Figure 10**). Respondents (N=39) who indicated that they have not used CIFOR tools and resources were asked to provide reasons for non-use (**Table 4**).

Figure 9. Use of CIFOR Tools or Resources for Improving Laboratory Processes or Procedures

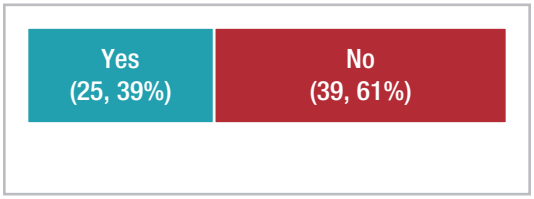


Figure 10. CIFOR Tools or Resources Used for Improving Laboratory Processes or Procedures

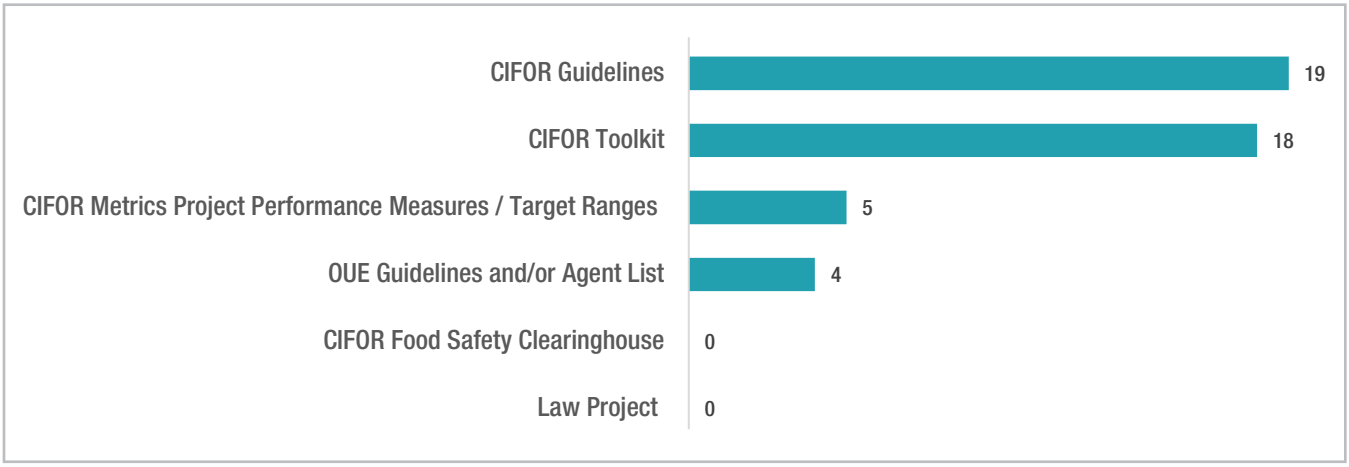


Table 4. Reasons for Not Using CIFOR Tools or Resources for Improving Laboratory Processes or Procedures

	%	#
Not familiar with CIFOR	48.7%	19
Not sure where to find CIFOR tools and resources	10.2%	4
Not applicable to us	23%	9
No resources to implement needed changes	12.8%	5
We're already in line with CIFOR recommendations	10.2%	4
Other - please specify	23%	9

"Other" responses included: Our decision is based on epi-needs; CIFOR recommendations and tools are being reviewed; we have concentrated on requirements in FoodCORE and PulseNet; did not know there was laboratory specific guidance; plan to review the tool kit and determine if any changes are needed in our laboratory; these activities belong to another state agency; as an agriculture laboratory, we adapt CIFOR tools and resources that fit us.

CIFOR Laboratory-specific Recommendations

Questions 8-12 are based on laboratory-specific recommendations listed in the Second Edition of the CIFOR Toolkit, Focus Area 9- Laboratory Investigations.

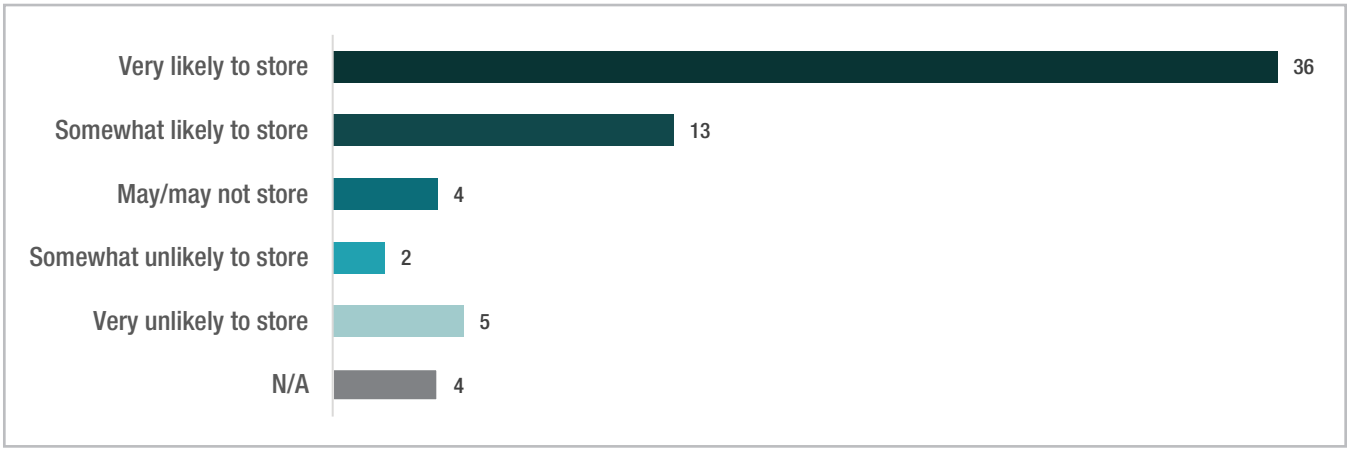
Question 8. ***When specimens are collected as part of a foodborne investigation, how often are the epidemiology and/or environmental health investigators in your jurisdiction able to properly collect, store and transport specimens/samples for a foodborne investigation?***

Table 5. Ability of Jurisdictional Epidemiology/Environmental Health Investigators to Properly Collect, Store and Transport Specimens/ Samples for Foodborne Investigations

	Epi and EH staff do not collect/ store/transport		< 50% of the time		50-90% of the time		> 90% of the time		Total Responses	
	%	#	%	#	%	#	%	#	%	#
Clinical specimens	11.1%	6	11.1%	6	12.9%	7	64.8%	35	100%	54
Food samples	3.6%	2	20%	11	18.1%	10	58.1%	32	100%	55
Environmental samples	6.6%	3	22.2%	10	13.3%	6	57.7%	26	100%	45

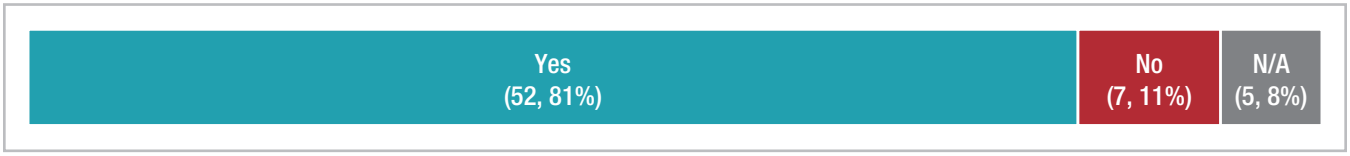
Question 9. ***How likely would you be to store outbreak specimens that test negative for routine foodborne pathogens if another laboratory offered testing for additional pathogens?***

Figure 11. Likeliness to store Outbreak Specimens That Test Negative for Routine Foodborne Pathogens if Another Laboratory Offered Testing for Additional Pathogens (n=64)



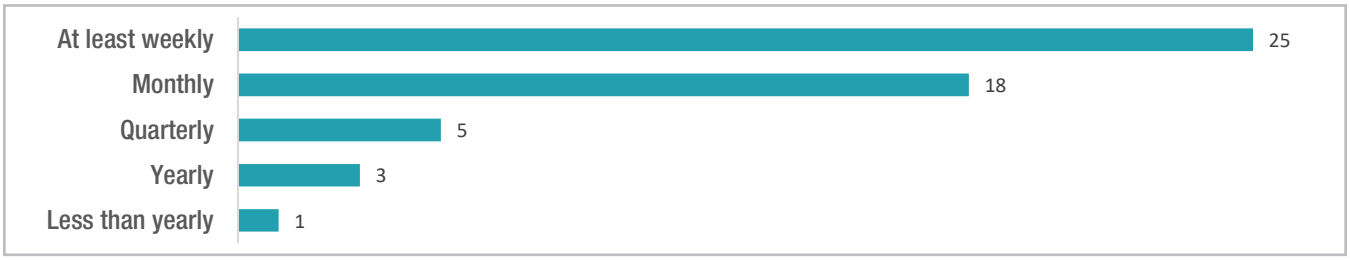
Question 10. ***Has your laboratory established routine procedures for communicating with outbreak response team members before an outbreak occurs?***

Figure 12. Establishment of Routine Communication Procedures with Outbreak Response Team Before Outbreak Occurs (n=64)



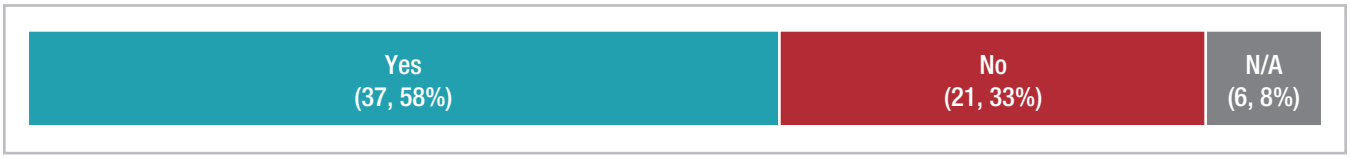
Respondents who answered 'Yes' to having established routine communication procedures (n=52) were asked how often the communication procedures are implemented (**Figure 13**).

Figure 13. Frequency of Implementation of Routine Communication Procedures (n=52)



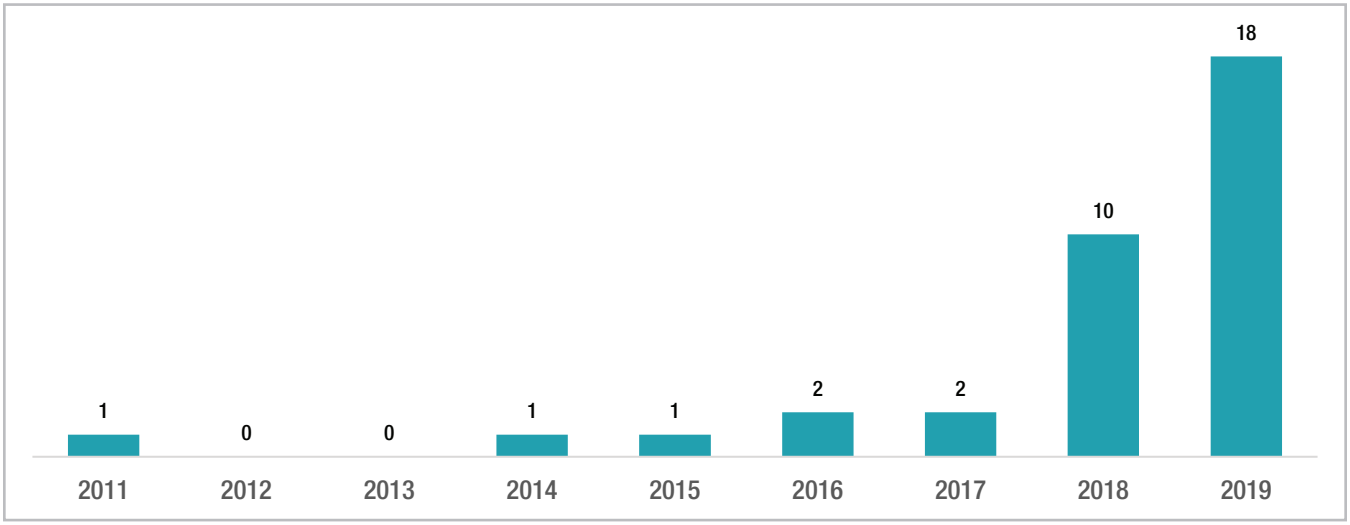
Question 11. ***Has your laboratory ever participated in joint outbreak response team exercises to ensure that each team member understands and can perform his/her role?***

Figure 14. Participation in Joint Outbreak Response Team Exercises (n=64)



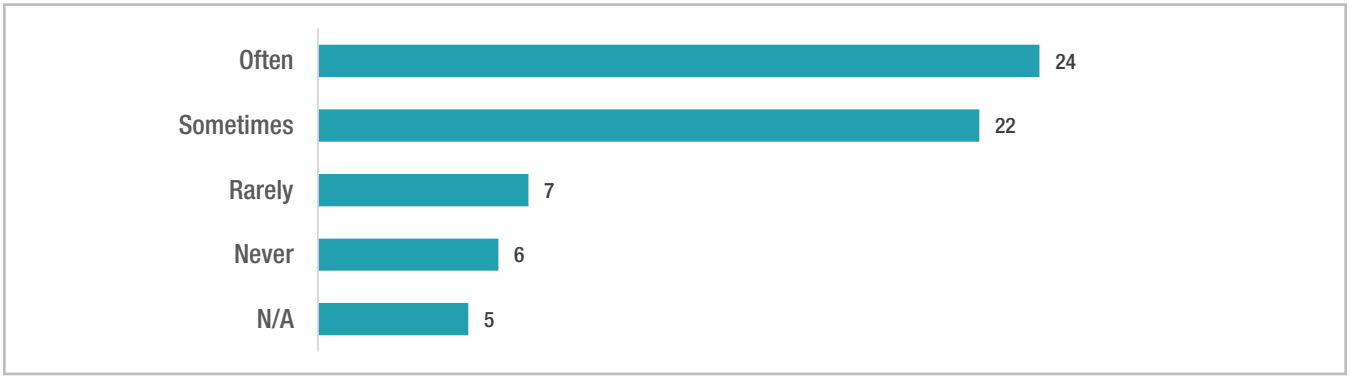
Respondents who indicated that they have participated in joint outbreak response team exercises (n=37) were asked to list the most recent joint exercise (**Figure 15**).

Figure 15. Most Recent Joint Outbreak Response Team Exercise (n=37)



Question 12. After a foodborne investigation has concluded, does your laboratory participate in debriefings with members of your jurisdiction's outbreak response team to identify lessons learned and compare notes on ultimate findings?

Figure 16. Participation in Debriefings After Foodborne Investigations (n=64)



Those respondents who indicated that they often, sometimes or rarely participate in foodborne investigation debriefings (n=53) were asked what changes their laboratory/jurisdiction made based on those debrief meetings (**Table 6**).

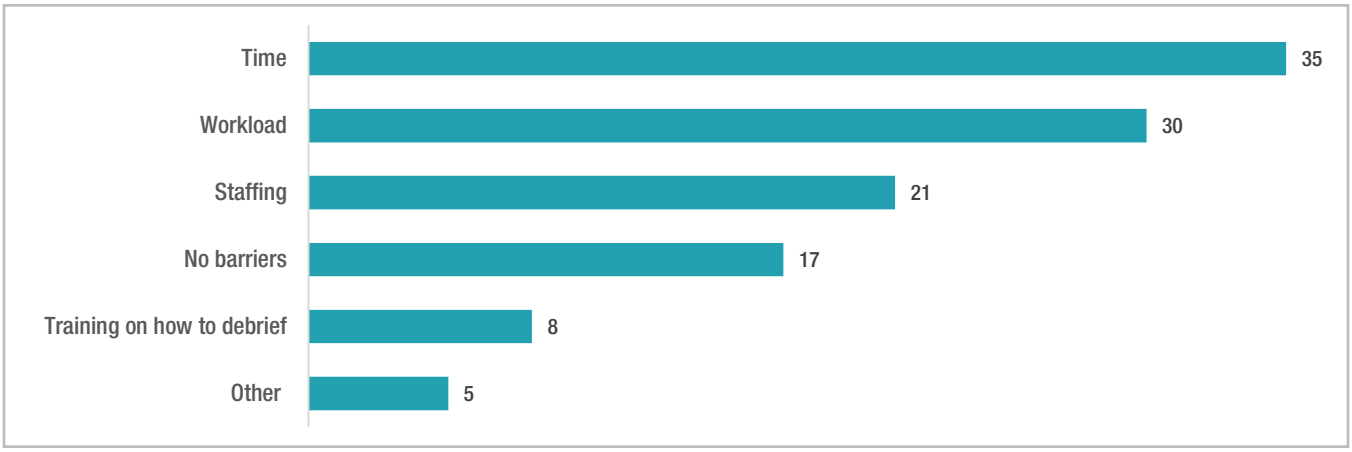
Table 6. Changes Made Within Laboratory or Jurisdiction Based on Foodborne Investigation Debrief (n=53)

	%	#
Identified areas for operational improvement	26	14
Identified communications gaps	81	43
Clarified changes to procedures	51	27
Identified needed resources	66	35
Identified training needs	43	23
Offered needed training	23	12
Adjusted agency or response team structure to optimize future investigations	19	10
Other - please specify	6	3

"Other" responses included: team effort is solid; meetings tend to focus on outbreak prevention and not the response.

All laboratories surveyed (n=64) were asked what barriers exist, if any, to debriefing your jurisdiction's outbreak response (**Figure 17**). "Other" responses included: communication; [debriefing] not always included; procedure to do so not in place; different departments (i.e., health vs agriculture).

Figure 17. Barriers to Conducting Foodborne Investigation Debrief (n=64)



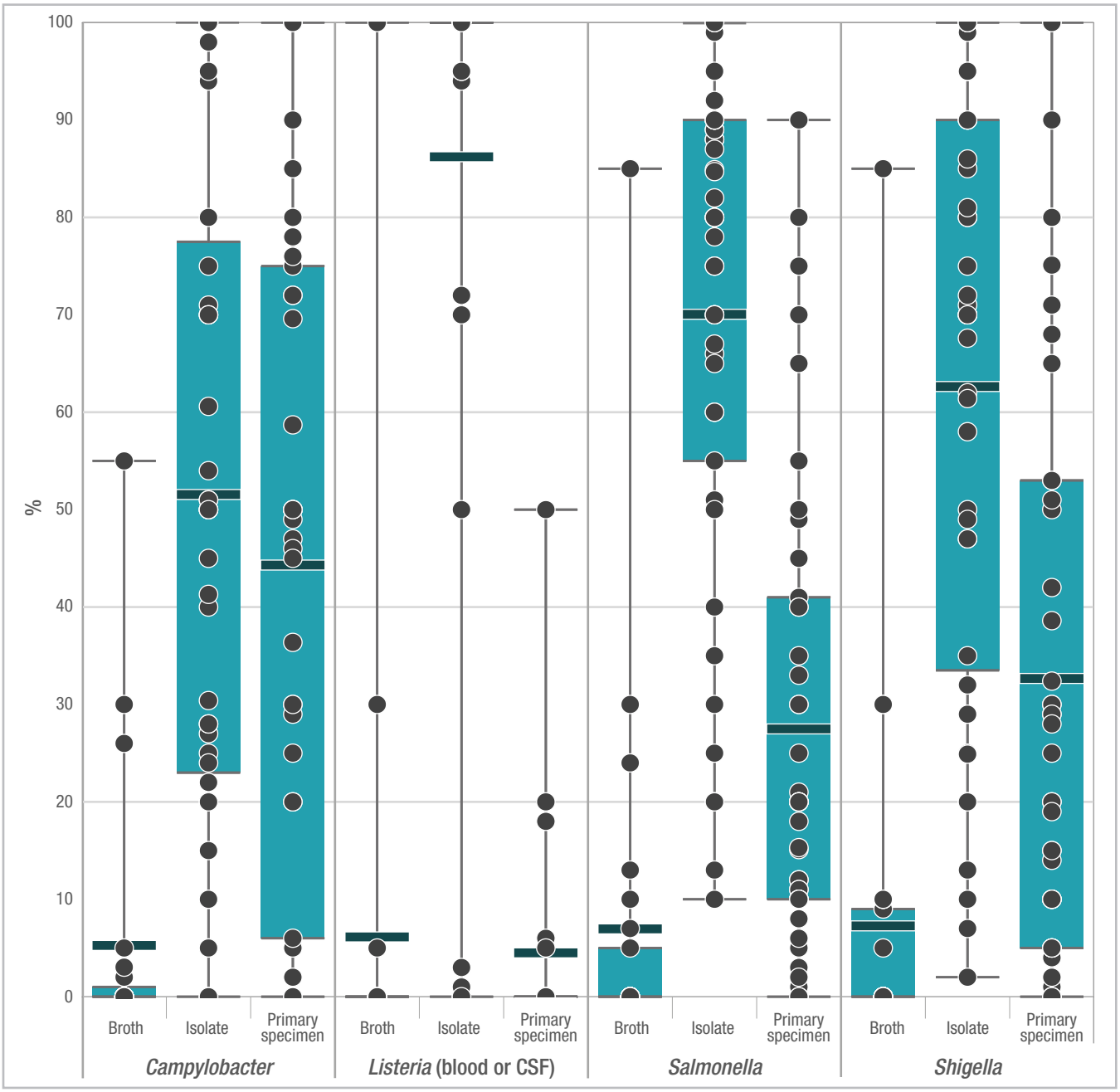
FOOD SAFETY TESTING

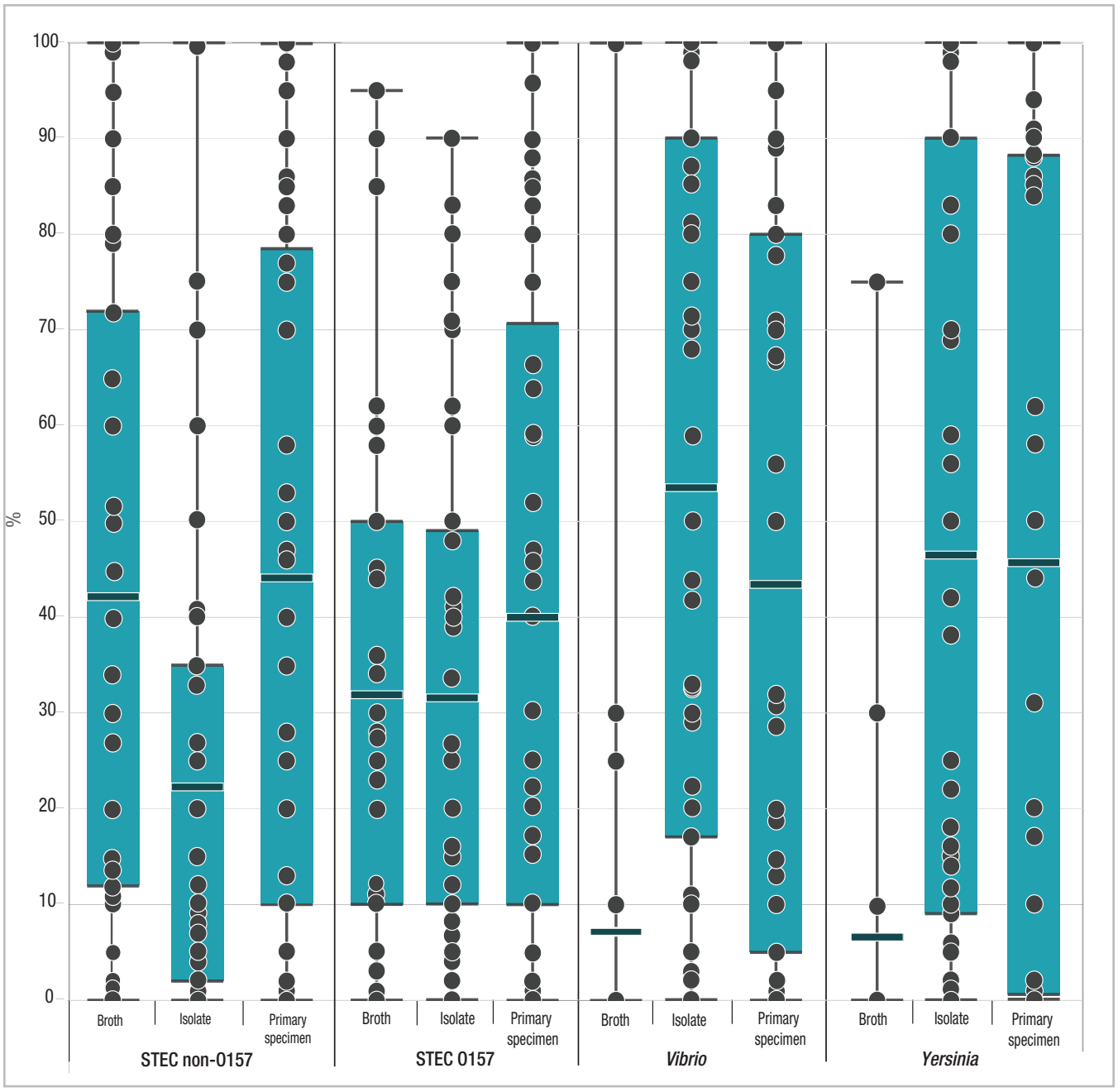
For calendar year 2018, respondents were asked to estimate their testing volume for key pathogens and from multiple specimen types. Additional questions asked about available testing for key targets in clinical specimens and in food and water samples, as well as further characterization capabilities now and in the future.

Question 13. ***For calendar year 2018, please estimate the percentage of specimen types (isolate, broth or primary specimen) received from the clinical laboratories for each of the following pathogens:*** **Campylobacter, Listeria *(blood or CSF)*, Salmonella, Shigella, *STEC non-0157*, *STEC 0157*, Vibrio *and* Yersinia.**

For each pathogen, the mean, minimum and maximum percentages are provided in **Figure 18** for each specimen type (primary, broth and isolate) and the dark gray circles represent individual responses. As expected, the types of specimens received for each pathogen varied greatly and were likely largely dependent on available CIDTs at the time of the survey.

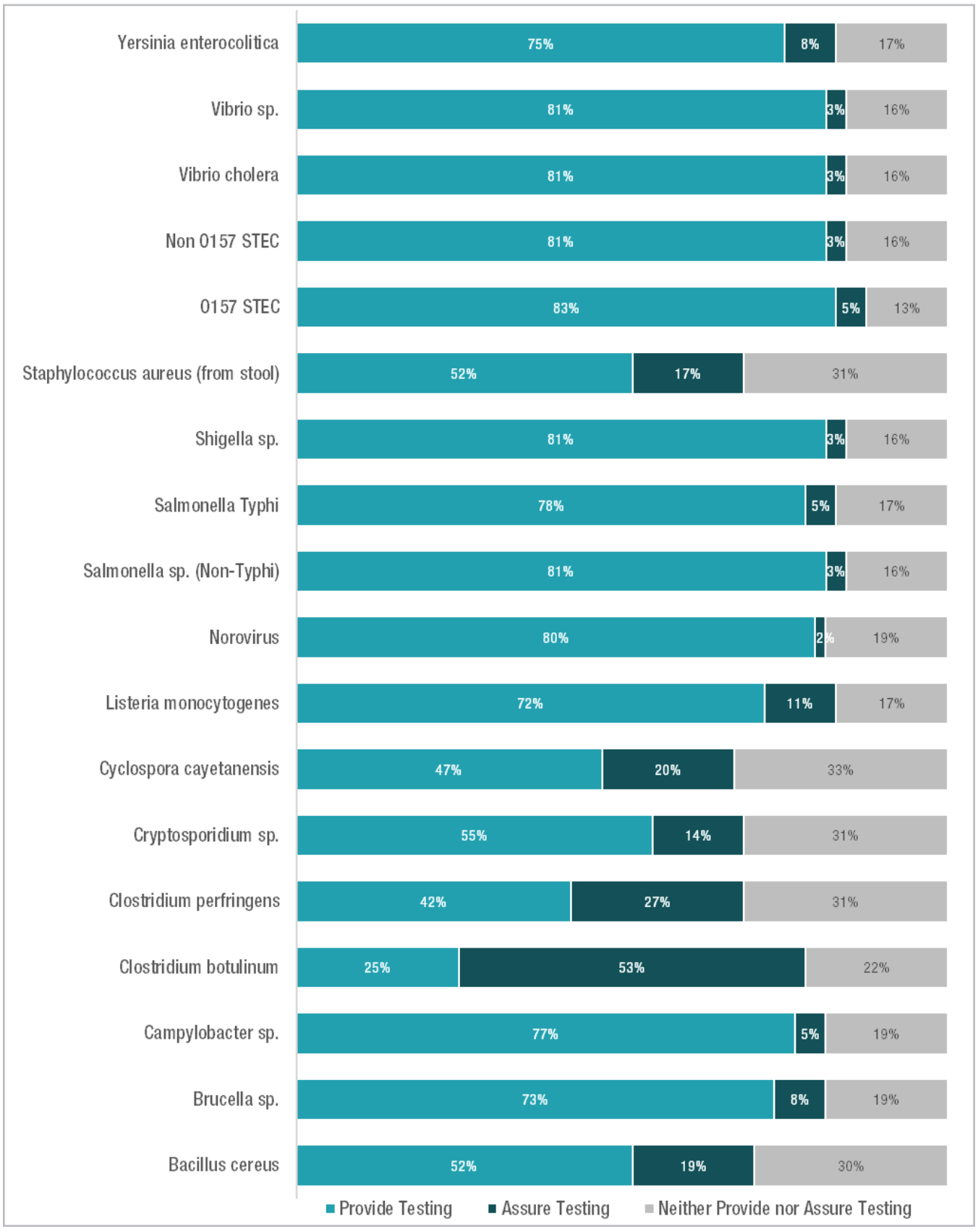
Figure 18. Percentage of Specimen Types Received from Clinical Laboratories, by Pathogen (n=64)




100
90
80
70
60
50
40
30
20
10
0
%
Broth
Isolate
Primary specimen
STEC non-O157
Broth
Isolate
Primary specimen
STEC O157
Broth
Isolate
Primary specimen
Vibrio
Broth
Isolate
Primary specimen
Yersinia

Question 14. For which of the following organisms or their toxins, does your laboratory provide or assure testing for clinical specimens to assist with foodborne disease outbreak investigations?

Figure 19. Provision or Assurance of Testing for Clinical Specimens, by Organism/Toxin



Question 14a. ***Which organisms does your laboratory further characterize by traditional methods (such as molecular subtype or perform AST) and/or further characterize by sequencing for routine clinical testing?***

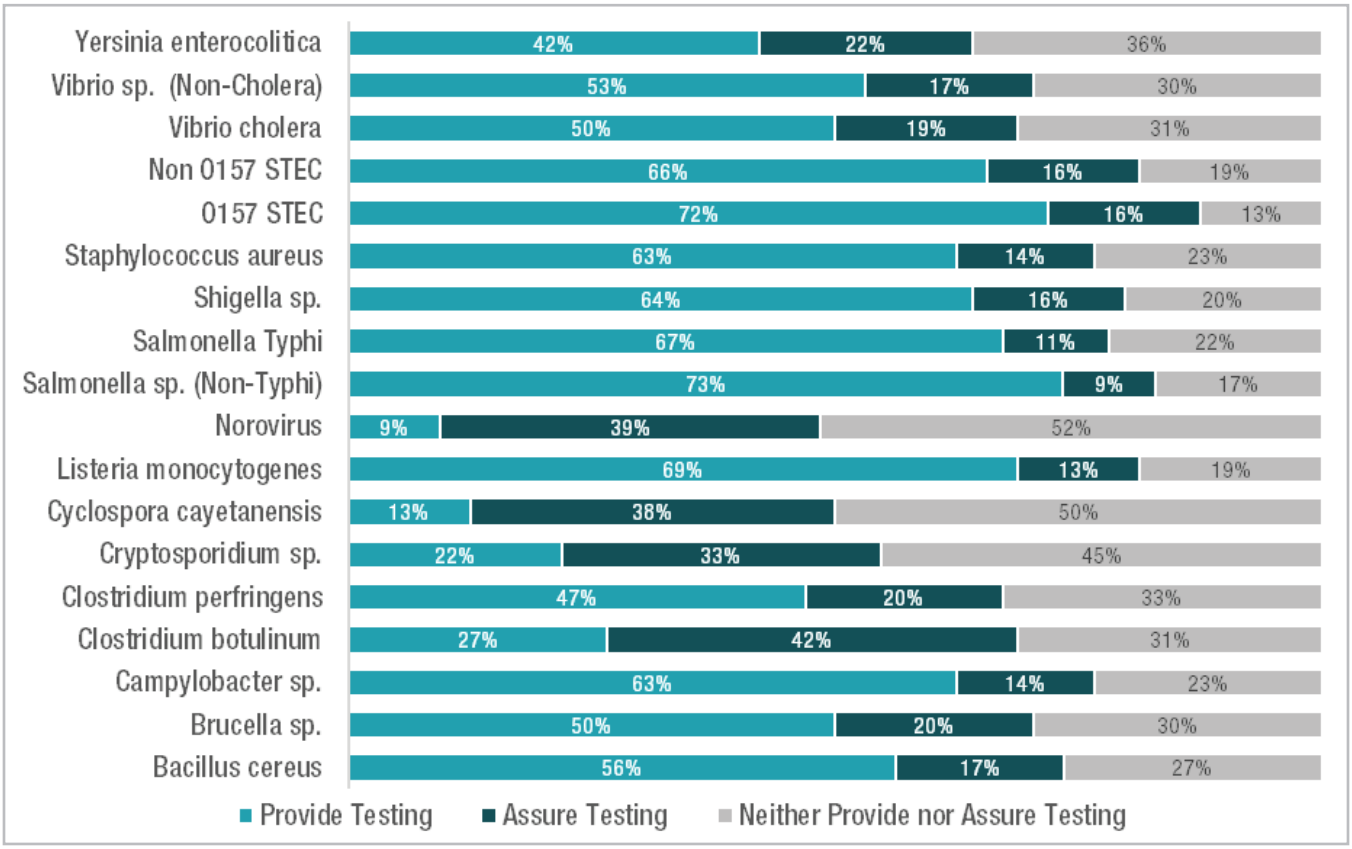
Respondents that indicated they provide testing for any of the organisms listed in question 14 were asked to provide the characterization method used in their laboratory for the respective organism.

Table 7. Characterization Method for Testing Clinical Specimens, by Organism/Toxin

	Further characterize by traditional methods now		Plan to further characterize by traditional methods in 2020		Further Characterize by sequencing (Sanger or WGS) now		Further Characterize by sequencing (Sanger or WGS) in 2020		Total Responses
	%	#	%	#	%	#	%	#	
Bacillus cereus	48.5%	16	9.1%	3	15.2%	5	27.3%	9	33
Brucella spp.	59.6%	28	10.6%	5	10.6%	5	19.1%	9	47
Campylobacter spp.	20.4%	10	0%	0	71.4%	35	8.2%	4	49
Clostridium botulinum	75.0%	12	0%	0	18.8%	3	6.3%	1	16
Clostridium perfringens	48.1%	13	3.7%	1	14.8%	4	33.3%	9	27
Cryptosporidium spp.	48.6%	17	14.3%	5	11.4%	4	25.7%	9	35
Cyclospora cayetanensis	36.7%	11	16.7%	5	10.0%	3	36.7%	11	30
Listeria monocytogenes	13.0%	6	0%	0	80.4%	37	6.5%	3	46
Norovirus	31.4%	16	3.9%	2	43.1%	22	21.6%	11	51
Salmonella spp. (Non-Typhi)	17.0%	9	0%	0	81.1%	43	1.9%	1	52
Salmonella typhi	14.0%	7	0%	0	84.0%	42	2.0%	1	50
Shigella spp.	19.2%	10	0%	0	73.1%	38	7.7%	4	52
Staphylococcus aureus (from stool)	48.5%	16	9.1%	3	9.1%	3	33.3%	11	33
O157 STEC	15.1%	8	0%	0	81.1%	43	3.8%	2	53
Non O157 STEC	15.4%	8	0%	0	80.8%	42	3.8%	2	52
Vibrio cholera	26.9%	14	5.8%	3	51.9%	27	15.4%	8	52
Vibrio spp.	25.0%	13	3.8%	2	57.7%	30	13.5%	7	52
Yersinia enterocolitica	43.8%	21	8.3%	4	18.8%	9	29.2%	14	48

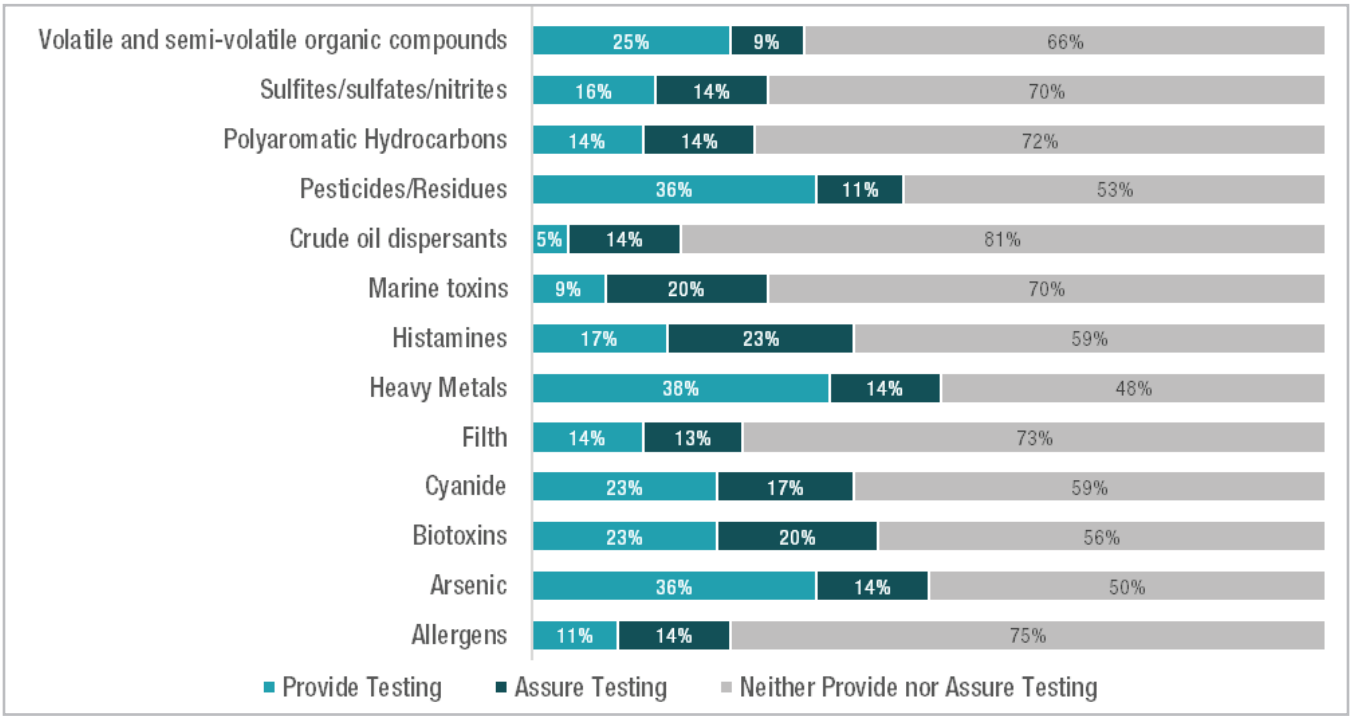
Question 15. ***For which of the following organisms or their toxins does your laboratory provide or assure testing for food and or water samples to assist with foodborne disease outbreak investigations?***

Figure 20. Provision or Assurance of Testing for Food and Water Samples, by Organism



Question 16. ***Does your laboratory provide or assure for the following tests in food samples?***

Figure 21. Provision or Assurance of Testing for Food Samples, by Test



ACCREDITATION

FDA has made a significant investment in state governmental human and animal food laboratory accreditation. Accreditation to the ISO/IEC 17025 standard helps ensure that a laboratory's data is high-quality and defensible and can be utilized for food safety enforcement actions. Through a cooperative agreement with FDA, APHL has been assisting in this effort.

Question 17. Is your lab accredited to ISO/IEC 17025?

Figure 22. ISO/IEC 17025 Accreditation Status

Respondents that indicated their laboratories were accredited (n=25) were asked to provide the types of samples and number of methods for which they're accredited.

Table 8. Accreditation Status, by Type of Samples and Methods (n=25)

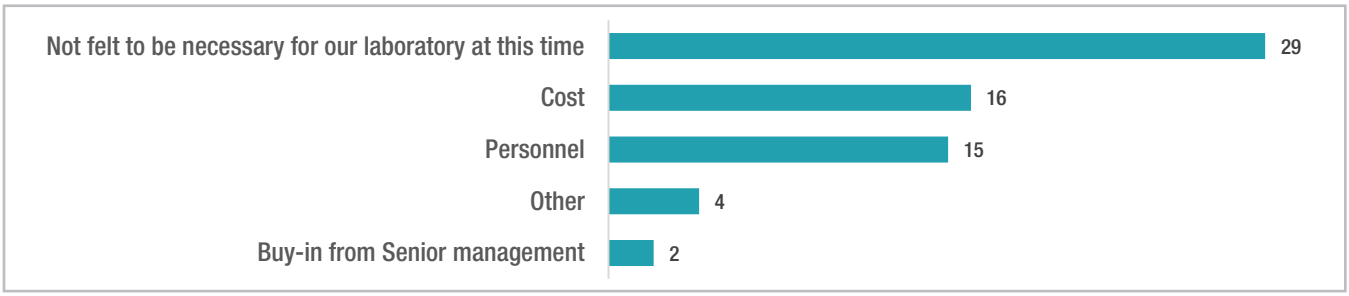
Number of Methods	Number of Accredited Laboratories		
	Food Samples	Feed Samples	Environmental Samples
0 – 5	4	2	6
6 – 10	11	1	1
11 – 15	3	1	3
16 – 20	2	0	2
21+	2	0	2

Of the 39 respondents who indicated their laboratories were not accredited at the time of the survey, seven (18%) reported that they were actively seeking accreditation.

Figure 23. Status of Non-accredited Laboratories Seeking Accreditation

Respondents (N=32) whose laboratories were neither accredited nor seeking accreditation at the time of the survey were asked about their reasons for not becoming accredited to the ISO 17025 standard (**Figure 24**).

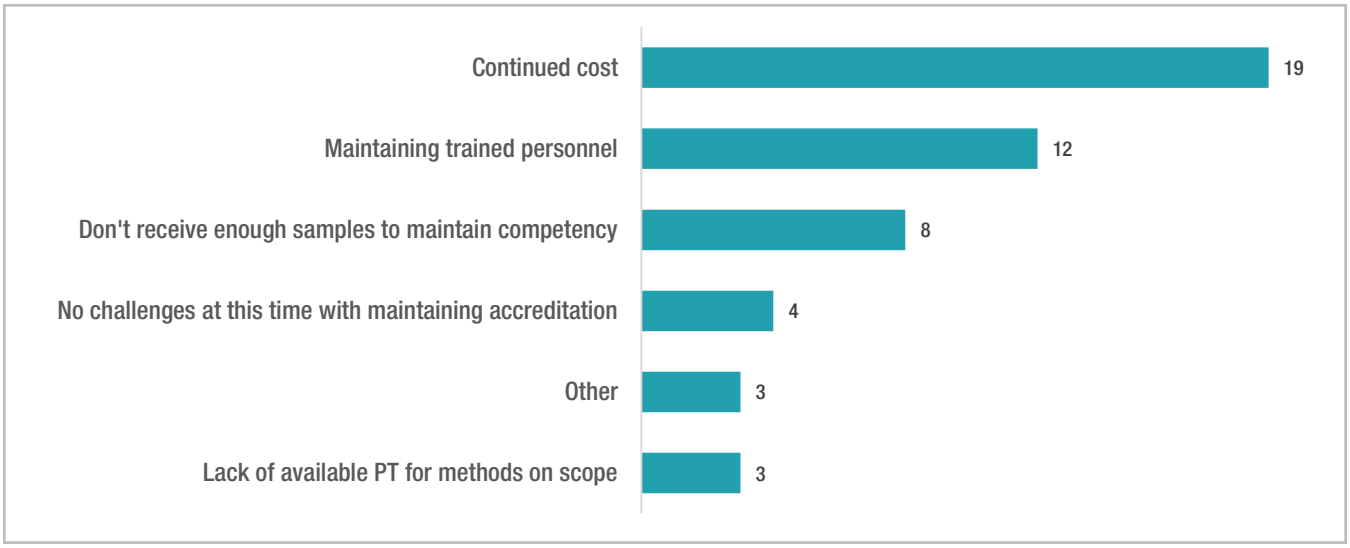
Figure 24. Reasons for Not Seeking Accreditation (n=32)



"Other" responses included: product testing is performed at the Department of Agriculture that is ISO accredited; testing capability was lost when the state removed the testing from our laboratory; staff turnover in key positions (QA and Chemistry Program Managers); PHL is accredited by CAP and CLIA; defer food and water testing to another state laboratory.

Question 18. ***What challenges are you facing (if any) with maintaining accreditation? Select all that apply.***

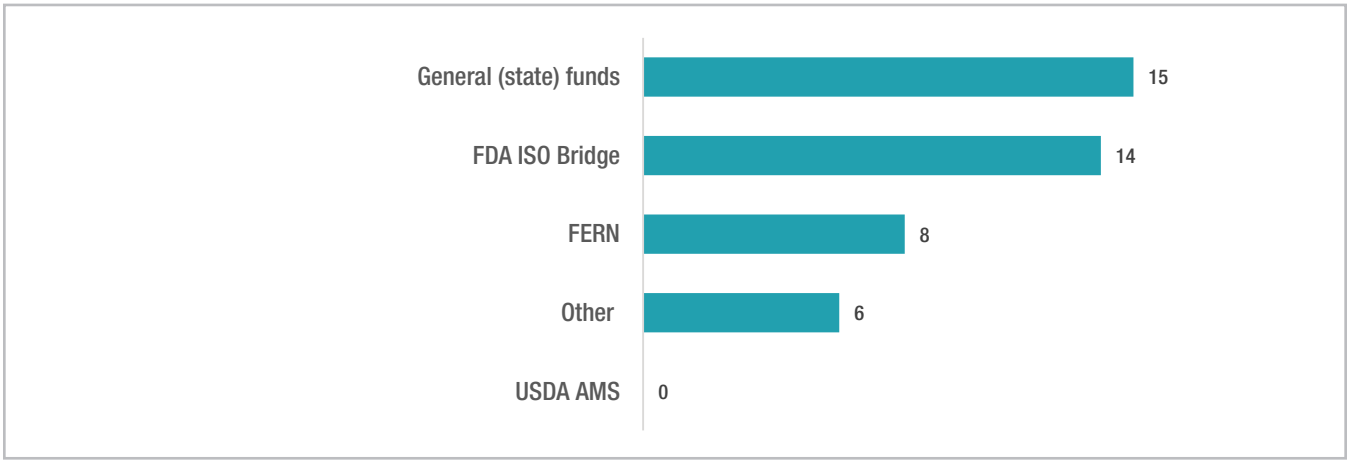
Figure 25. Challenges to Maintaining Accreditation



"Other" responses included: staffing, sustainability as FDA collaborative agreements transition to the LFFM, time commitment of staff for PTs, records.

Question 19. ***What funding is your laboratory using for ISO accreditation?***

Figure 26. Sources of ISO Accreditation Funding



"Other" responses included: fees for providing support to programs within department; grant funding; AFRPS CAP; FDA AFRPS; FDA ISO Attain and Maintain ISO accreditation CAP; NAHLN Level 3 Agreement.

CONCLUSION

Food safety testing practices continue to evolve. With widespread implementation of next generation sequencing methods in 2019 and metagenomics on the horizon, it will be increasingly important to ensure that public health and agriculture laboratories have the training, instrumentation, staffing and other resources they need to implement effective testing practices.

Surveys such as the one conducted in fall 2019 give APHL's Food Safety Program and Food Safety Committee the ability to assess practices, processes, and available resources to better support member laboratories and target programming to address any identified gaps. Key survey findings (de-identified, aggregate) are also shared with federal partners who manage and provide funding for important food safety programs and activities.

Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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