

Yardstick Self Assessment Tool for Public Health Food Safety Testing

In April 2003, the Association of Public Health Laboratories (APHL) published the document, “A Recipe for Stronger Food Safety Testing Programs: Findings and Recommendations from the Association of Public Health Laboratories Food Safety Laboratory Capacity Assessment Project”. This document was intended to identify the essential elements necessary to improve national food safety testing capacity. Since its release, there have been requests to APHL to update foodborne illness testing recommendations outlined in the 2003 document and develop a tool to assess public health laboratories’ foodborne illness testing capabilities.- Sponsored by the Council to Improve Foodborne Outbreak Response (CIFOR) ,APHL convened a task force of subject matter experts in the field of foodborne illness testing. Task force members represented clinical, environmental and agriculture sectors of public health with expertise in microbiology, chemistry and administrative processes. The task force was given the charge to develop a foodborne illness testing self assessment tool for public health laboratories* (PHL) to utilize. The tool is intended to serve as a “gold standard”, or “Yardstick”, that laboratories can measure themselves against in order to identify potential areas for improvement. Recommendations for best practices described in this document are based upon subject matter expert opinion, published guidelines and the 2003 APHL document mentioned above. The Yardstick self assessment tool is now ready for use and is being made available to public health laboratories.

The format of the Yardstick assessment tool is multi-faceted. It outlines for PHL’s, through a series of recommendations, the best practices for all categories (foodborne pathogens, chemicals, toxins, or radiation) and areas (clinical, food, or environmental) of foodborne illness testing. Each recommendation is followed by a number of assessment questions intended for laboratorians to answer. PHL’s are encouraged to record their responses to the assessment questions and re-visit the assessment tool on an annual basis. PHL’s can then use the collective information to determine if they are meeting the best practices as they are written in this document and generate discussion within their laboratory and/or jurisdiction. The Yardstick task force and APHL realize that, in all likelihood, no one laboratory will meet all of the recommended gold standards that are outlined in the self assessment tool. It is also understood that many PHL’s may not be able to answer all of the assessment questions and may need to collaborate with, and to enlist the aid of, their partners in foodborne illness testing. It is hoped that this tool will help develop, foster and improve partnerships that will strengthen foodborne illness testing within your state or jurisdiction. On behalf of the Yardstick task force, and the Association of Public Health Laboratories, we encourage you to use this assessment tool in your laboratory. APHL is committed to revisiting this tool and updating it as necessary such that it will remain relevant over time and will be a re-useable resource for PHL’s. Please feel free to share your thoughts about this tool with APHL and provide suggestions for improvement. We thank you for your time and commitment to this assessment and for your continued dedication and contributions to foodborne illness testing and surveillance within your jurisdiction. Collectively, PHL contributions to foodborne illness detection and surveillance provide a stronger national food safety system and prevent an untold number of foodborne illnesses.

*For the purpose of this tool, the term “public health laboratory” will refer to any governmental laboratory that performs testing for foodborne pathogens, chemicals, toxins, or radiation in clinical, food, and/or environmental samples in support of public health.

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Is your laboratory a:

- ☐ State Public Health Laboratory
☐ Local Public Health Laboratory
☐ Agricultural Laboratory
☐ State Chemist Laboratory
☐ Other (please specify) _____

Laboratory Testing

Collection, Submission, and Storage of Specimens/Samples

1. The quality of the clinical specimen/food sample submitted for food safety testing is critical to providing meaningful laboratory data. Included in ensuring specimen quality are 1) selection of the appropriate specimen type and collection method, 2) complete and accurate identification and labeling, 3) appropriate preservation methods when required, and 4) adequate transport to the laboratory. Instructions for proper collection and handling of specimens/samples including specimen/sample requirements and rejection criteria must be available to laboratory personnel and anyone who collects and sends specimens/ samples to the laboratory.

- a. Does your laboratory have written policies and procedures regarding specimen/sample collection and transport?

- ☐ Yes
☐ No (If No, Skip to part b.)

If Yes, above...	
Are these written policies and procedures available to all laboratory personnel and clients who submit specimens/samples to the laboratory?	☐ Yes ☐ No
Are specimen/sample requirements and procedures for collection and transport embedded in each testing SOP?	☐ Yes ☐ No
Is there documentation of at least annual review by the laboratory director?	☐ Yes ☐ No
Does the laboratory director or designee approve all changes before implementation?	☐ Yes ☐ No

- b. Does the laboratory provide collection containers, transport packaging, collection instructions and test requisition forms upon request?

Requirements and Provisions	Yes/No
The appropriate specimen/sample for a given pathogen or analyte	☐ Yes ☐ No

Any preparation of the patient and/or sampling site prior to collection	☐ Yes ☐ No
Any special technique or timing for collection	☐ Yes ☐ No
The volume of specimen/sample required for testing	☐ Yes ☐ No
Choice of collection container to promote survival and/or detection of the suspected agent	☐ Yes ☐ No
Addition of preservatives, stabilizers, neutralizers, anticoagulants, etc. to promote survival and/or detection of the suspected agent	☐ Yes ☐ No
The laboratory's requirements for specimen/sample labeling	☐ Yes ☐ No
Handling and storage conditions between collection and delivery to the laboratory.	☐ Yes ☐ No
Packaging and shipping requirements	☐ Yes ☐ No
A clear listing of rejection criteria	☐ Yes ☐ No
Laboratory contact information for questions	☐ Yes ☐ No

c. Does your laboratory requisition form include the following elements?

Elements
- Patient/ sample identifier
- Patient sex (if applicable)
- Patient date of birth or age (if applicable)
- Patient contact information (if applicable)
- Name and address of the physician or person legally authorized to order the test
- The test(s) requested
- Date and time of specimen/sample collection
- Source of specimen/sample
- Additional information as required

The form includes:

- ☐ 7-8 of the above criteria
- ☐ 5-6 of the above criteria
- ☐ 3-4 of the above criteria
- ☐ <3 of the above criteria
- ☐ None of the above criteria
- ☐ Our laboratory does not have a requisition form

- d. Does your public health laboratory requisition form for chemical/radiation testing include the following elements?

Elements
- Patient/ sample identifier - Patient sex (if applicable) - Patient date of birth or age (if applicable) - Patient contact information (if applicable) - Specimen/Sample type (matrix) - Collection date - Description of specimen/ sample - Reason for collection - Analysis requested - Submitter name and contact information

The form includes:

- ☐ 5-7 of the above criteria
☐ 3-4 of the above criteria
☐ <of the above criteria
☐ None of the above criteria
☐ Our laboratory does not have a requisition form for chemistry/radiological testing

- e. Does the laboratory have a policy/procedure to (check all that apply):

- ☐ Address unlabeled or mislabeled specimens/samples
☐ Obtain missing information or resolve discrepancies in information
☐ Reject specimens/samples that do not meet criteria
☐ Record all actions taken when a specimen is deemed unacceptable (i.e., reason for rejection; final action; name, position, and contact information of the person notified)

- f. Does the laboratory track the absence of the following for QA purposes?

Absence of Required Information by Type	Yes/No	N/A
Patient / sample identification or DOB (if applicable)	☐ Yes ☐ No	☐
Specimen or sample type/source	☐ Yes ☐ No	☐
Collection date	☐ Yes ☐ No	☐
Submitter	☐ Yes ☐ No	☐

g. Does your laboratory do the following during the accessioning process?

Procedures	Yes/No
Record transport time (received date minus collected date)	☐ Yes ☐ No
Record date/time that specimen is received in the laboratory	☐ Yes ☐ No
Verify that identification information on the specimen matches information on the request form	☐ Yes ☐ No
Verify that the specimen/sample meets the laboratory's acceptance criteria	☐ Yes ☐ No
In the case that an unacceptable specimen/sample must be processed, include a qualifying comment on the final report	☐ Yes ☐ No

2. At least 95% of both clinical and/or food diagnostic samples should be received in the laboratory within 24 hours of collection. Unsatisfactory specimen/ sample transport times should be reported to the submitting agency.

a. What percent of foodborne illness specimens are received in the laboratory within 24 hours of collection?

- ☐ 90-100
- ☐ 80-90
- ☐ 51-80
- ☐ 0-50

b. What percent of food samples are received in the laboratory within 24 hours of collection?

- ☐ 90-100
- ☐ 80-90
- ☐ 51-80
- ☐ 0-50

c. Are unsatisfactory specimens/samples reported to the submitter within 24 hours of receipt?

- ☐ Yes
- ☐ No

3. Each PHL should have the means to ensure timely delivery of both routine and emergency specimens and samples to the laboratory for testing of foodborne pathogens, toxins, chemicals or radiation.

- a. Does your laboratory have a means to ensure timely delivery of specimens or samples for testing of foodborne pathogens, toxins, chemicals, or radiation?

Foodborne pathogens ☐ Yes ☐ No

Toxins ☐ Yes ☐ No

Chemicals ☐ Yes ☐ No

Radiation ☐ Yes ☐ No

- b. For specimens not received in a timely manner, does your laboratory have a mechanism in place to communicate with submitters to address this issue?

☐ Yes

☐ No

Please check from the list below how your laboratory receives **routine** specimens or samples for testing of foodborne pathogens, toxins, chemicals or radiation (check all that apply):

☐ US Mail

☐ Private courier

☐ In-house courier

☐ Hospital courier

☐ Other state agency

☐ Law enforcement

☐ Direct delivery by inspectors, sanitarians, and epidemiologists

☐ Other: _____

Please indicate how **emergency** specimens or samples are delivered to your lab (Check all that applies):

☐ US Mail

☐ Private courier

☐ In-house courier

☐ Hospital courier

☐ Other state agency

☐ Law enforcement

☐ Direct delivery by inspectors, sanitarians, and epidemiologists

☐ Other: _____

4. In an effort to measure food safety laboratory efficiency, laboratories should monitor their sample processing turnaround times. The PHL should be able to document the date of specimen/ sample receipt, the date of serotyping completion, the date of molecular subtyping (PFGE, MLVA, or other) completion, and the date that subtype clusters were identified.

Does your laboratory document:

- a. Specimen/ Sample receipt dates?

☐ Yes, 80-100% of the time

☐ Yes, 50-79% of the time

- ☐ Yes, less than 50% of the time
- ☐ No, we never document any of our sample receipt dates

b. Pathogen identification and confirmation dates?

- ☐ Yes, 80-100% of the time
- ☐ Yes, 50-79% of the time
- ☐ Yes, less than 50% of the time
- ☐ No, we never document any of our identification and confirmation dates

c. Serotyping completion dates?

- ☐ Yes, 80-100% of the time
- ☐ Yes, 80-100% of the time
- ☐ Yes, 50-79% of the time
- ☐ Yes, less than 50% of the time
- ☐ No, we never document any of our serotyping completion dates

d. Subtyping (PFGE, MLVA) completion date?

- ☐ Yes, 80-100% of the time
- ☐ Yes, 50-79% of the time
- ☐ Yes, less than 50% of the time
- ☐ No, we never document any of our subtyping completion dates

e. The date subtype patterns are uploaded?

- ☐ Yes, 80-100% of the time
- ☐ Yes, 50-79% of the time
- ☐ Yes, less than 50% of the time
- ☐ No, we never document any of our subtype pattern upload dates

f. The date PFGE and cluster information is shared with public health (i.e. epidemiologist)?

- ☐ Yes, 80-100% of the time
- ☐ Yes, 50-79% of the time
- ☐ Yes, less than 50% of the time
- ☐ No, we never document any of our PFGE and cluster information sharing dates

5. At a minimum, all public health laboratories should securely store clinical specimens, food and environmental samples, or isolates until the testing has been completed, the outbreak declared over or specific in house protocols have been met. Food samples should be frozen immediately if received frozen or at least 48 hours if

not tested at that time. PHLs should securely store all routine and/or foodborne outbreak isolates for a minimum of one year. Storage of isolates should be at -70°C or below and include at least two levels of security with the number of levels dependent upon the risk level of the organism being stored. Every PHL must understand the risk level for all isolates stored in their facility.

- a. Does your laboratory have adequate space to store all routine and/or foodborne outbreak specimens/samples as recommended above?

☐ Yes

☐ No

- b. Does your laboratory have adequate space to store all routine and/or foodborne outbreak isolates as recommended above??

☐ Yes

☐ No

- c. Does your laboratory have the following security measures in place to securely store the recommended foodborne isolates (check all that apply)?

Security Measure	
Locked laboratory door(s)	
Key card laboratory access	
Fingerprint access to the laboratory	
Restricted access to the laboratory (ID badges)	
Locked refrigerators/freezers	
Background checks of employees	
General signage, not indicating specific names and location of organisms, on the exterior of storage equipment	
Regular inspections of the security measures	
Isolate usage log	
Surveillance cameras	

- d. Does your PHL have a stored specimen inventory system or database for facilitating retrieval of stored isolates?

☐ Yes

☐ No

If you answered yes, does your destruction protocol for stored isolates include (check all that apply)?

Destruction Protocol Measure	
Safe disposal measures	
Documentation of removal from your inventory	

Documentation of the disposal date and person responsible for the disposal	
Other (List):	

- e. Does your laboratory have a protocol in place for the destruction of stored isolates when your facility either runs out of physical space for storage or your facility deems the isolates no longer significant to justify storage any longer?

☐ Yes
☐ No

- f. Does your laboratory store any isolates off-site?

☐ Yes
☐ No

If you answered yes, does your laboratory have a protocol for ensuring the security and integrity of isolates stored off-site?

☐ Yes
☐ No

Verification/Validation/Capability Studies

6. Standardized food testing methods, such as those defined by AOAC International, US Food and Drug Administration (FDA), US Department of Agriculture (USDA), Centers for Disease Control (CDC), Environmental Protection Agency (EPA), should be used where appropriate. Public health laboratories should be able to demonstrate verification, validation, and capability to meet performance standards for all applicable methods.

- a. Does your laboratory perform in-house verification, validation, or capability studies for new methods before using the methods?

☐ Yes
☐ No

7. Each public health laboratory should have written protocols defining how new food safety assays should be validated. Validation data should include limitations of applicability and procedures for quality control and calibration.

- a. Does your laboratory have the following? (check all that apply)

☐ Written validation criteria
☐ Validation limitations
☐ Procedure for QA/QC
☐ Procedure for assay calibration

8. Each PHL should be able to execute unvalidated methods within limits of SOPs and report results in emergency circumstances. However, laboratories should: a) perform all such testing using positive and negative controls, and b) attempt to confirm results whenever possible.

- a. Does/would your laboratory perform unvalidated methods, when necessary, to support foodborne outbreak investigations?
- ☐ Yes
☐ No (move to question 57)
- b. When necessary, does/would your laboratory report a result determined by the use of an unvalidated method?
- ☐ Yes
☐ No
- c. Are results obtained from the use of unvalidated method confirmed with another method whenever possible?
- ☐ Yes
☐ No
- d. Does your laboratory include a disclaimer on all results obtained using unvalidated methods?
- ☐ Yes
☐ No

Analytical Issues

Recommended Test Capabilities

9. Laboratory test methods and protocols should be controlled (master documents protected, changes made by only responsible official after staff discussion, annual documentation of staff review and acceptance, etc) and available electronically to all laboratory personnel performing the testing.
- a. Are your laboratory test methods and protocols controlled?
- ☐ Yes
☐ No
- b. Are your laboratory test methods and protocols available electronically?
- ☐ Yes
☐ No
10. Each jurisdiction should fund or have access to at least one governmental laboratory capable of testing for foodborne disease pathogens in clinical specimens as well as food and environmental samples. This testing should be performed in a timely manner for effective foodborne surveillance. Public health labs should be able to perform confirmatory testing of the following food borne illness agents or toxins or assure that they are confirmed at another laboratory: *Bacillus cereus*, *Clostridium botulinum*, *Campylobacter* sp., *Clostridium*

perfringens, *Cryptosporidium* sp., *Cyclospora* sp., *Giardia* sp., Hepatitis A, *Listeria monocytogenes*, Norovirus, *Salmonella* sp., Shiga toxin-producing *E. coli* (STEC), *Shigella* sp., *Staphylococcus aureus*, *Vibrio* sp. and *Yersinia enterocolitica*. Public health laboratories should perform serotyping and/ or subtyping, or assure that it is performed, on all foodborne pathogens such as *Salmonella* sp., shiga toxin-producing *E.coli*, *Shigella* sp. and *Listeria monocytogenes*. Other pathogens should be serotyped and/ or subtyped according to jurisdictional statute or health department protocol. In addition, all isolates of shiga toxin-producing *E. coli* should be tested for the distinct shiga toxins 1 and 2 and results reported to the primary physician as soon as possible.

- a. What percent of funding does your jurisdiction provide to your laboratory to test the following food safety specimens/ samples?

Type	☐ >50%	☐ <50%	☐ NA
Clinical Specimens	☐	☐	☐
Food Samples	☐	☐	☐
Environmental Samples	☐	☐	☐

- b. (Skip for Agricultural or Chemist Laboratories) Does your laboratory perform OR assure testing is performed for the following pathogens and/or toxins in CLINICAL specimens in your jurisdiction: (select ONLY one answer for each program)

Clinical Program	Perform	Assure	Neither
<i>Bacillus cereus</i> and/or toxins	☐	☐	☐
<i>Bacillus anthracis</i>	☐	☐	☐
<i>Brucella</i> sp.	☐	☐	☐
<i>Clostridium botulinum</i> and/or toxins	☐	☐	☐
<i>Clostridium perfringens</i> and/or toxins	☐	☐	☐
<i>Cryptosporidium</i> sp	☐	☐	☐
<i>Cyclospora</i> sp.	☐	☐	☐
<i>Campylobacter</i> sp.	☐	☐	☐
<i>Francisella tularensis</i>	☐	☐	☐
<i>Giardia</i> sp.	☐	☐	☐
Hepatitis A	☐	☐	☐
<i>Listeria monocytogenes</i>	☐	☐	☐
Norovirus	☐	☐	☐
<i>Salmonella</i> sp.	☐	☐	☐
Shiga toxin producing <i>E. coli</i>	☐	☐	☐
<i>Shigella</i> sp.	☐	☐	☐
<i>Staphylococcus aureus</i> and/or toxins	☐	☐	☐
<i>Vibrio</i> sp.	☐	☐	☐
<i>Yersinia enterocolitica</i>	☐	☐	☐
<i>Yersinia pestis</i>	☐	☐	☐

- c. Does your public health laboratory perform OR assure testing for the following pathogens in FOOD samples in your jurisdiction?

Clinical Program	Perform	Assure	Neither
<i>Bacillus cereus</i> and/or toxins	☐	☐	☐
<i>Bacillus anthracis</i>	☐	☐	☐
<i>Brucella</i> sp.	☐	☐	☐
<i>Clostridium botulinum</i> and/or toxins	☐	☐	☐
<i>Clostridium perfringens</i> and/or toxins	☐	☐	☐
<i>Cryptosporidium</i> sp	☐	☐	☐
<i>Cyclospora</i> sp.	☐	☐	☐
<i>Campylobacter</i> sp.	☐	☐	☐
<i>Francisella tularensis</i>	☐	☐	☐
<i>Giardia</i> sp.	☐	☐	☐
Hepatitis A	☐	☐	☐
<i>Listeria monocytogenes</i>	☐	☐	☐
Norovirus	☐	☐	☐
<i>Salmonella</i> sp.	☐	☐	☐
Shiga toxin producing <i>E. coli</i>	☐	☐	☐
<i>Shigella</i> sp.	☐	☐	☐
<i>Staphylococcus aureus</i> and/or toxins	☐	☐	☐
<i>Vibrio</i> sp.	☐	☐	☐
<i>Yersinia enterocolitica</i>	☐	☐	☐
<i>Yersinia pestis</i>	☐	☐	☐

- d. Does your public health laboratory perform OR assure testing for the following pathogens in ENVIRONMENTAL samples in your jurisdiction?

Clinical Program	Perform	Assure	Neither
<i>Bacillus cereus</i> and/or toxins	☐	☐	☐
<i>Bacillus anthracis</i>	☐	☐	☐
<i>Brucella</i> sp.	☐	☐	☐
<i>Clostridium botulinum</i> and/or toxins	☐	☐	☐
<i>Clostridium perfringens</i> and/or toxins	☐	☐	☐
<i>Cryptosporidium</i> sp.	☐	☐	☐
<i>Cyclospora</i> sp.	☐	☐	☐
<i>Campylobacter</i> sp.	☐	☐	☐
<i>Francisella tularensis</i>	☐	☐	☐
<i>Giardia</i> sp.	☐	☐	☐
Hepatitis A	☐	☐	☐
<i>Listeria monocytogenes</i>	☐	☐	☐
Norovirus	☐	☐	☐
<i>Salmonella</i> sp.	☐	☐	☐

Shiga toxin producing <i>E. coli</i>	☐	☐	☐
<i>Shigella</i> sp.	☐	☐	☐
<i>Staphylococcus aureus</i> and/or toxins	☐	☐	☐
<i>Vibrio</i> sp.	☐	☐	☐
<i>Yersinia enterocolitica</i>	☐	☐	☐
<i>Yersinia pestis</i>	☐	☐	☐

- e. If your laboratory performs or assures testing for *Salmonella* from clinical, food, or environmental sources, does your laboratory perform *Salmonella* serotyping, or assure it is performed, on all isolates?
- ☐ Perform on all
- ☐ Perform on some
- ☐ Assure it is performed on all
- ☐ Assure it is performed on some
- ☐ Neither perform nor assure serotyping on *Salmonella*
- f. If your laboratory performs or ensures testing for shiga toxin-producing *E. coli* from clinical, food, or environmental sources, does your laboratory perform serotyping, or ensure it is performed, on all STEC isolates?
- ☐ Perform on all
- ☐ Perform on some
- ☐ Assure it is performed on all
- ☐ Assure it is performed on some
- ☐ Neither perform nor assure serotyping on STEC
- g. If your laboratory performs or ensures testing for shiga toxin-producing *E. coli* from clinical, food, or environmental sources, does your laboratory perform shiga toxin 1 and 2 testing, or assure it is performed, on all STEC isolates?
- ☐ Perform on all
- ☐ Perform on some
- ☐ Assure it is performed on all
- ☐ Assure it is performed on some
- ☐ Neither perform nor assure shiga toxin testing on STEC
- h. If your laboratory performs or assures testing for *Shigella* sp. from clinical, food, water or environmental sources, does your laboratory perform serogrouping, or ensure it is performed, on all *Shigella* sp. isolates?
- ☐ Perform on all
- ☐ Perform on some
- ☐ Assure it is performed on all
- ☐ Assure it is performed on some

☐ Neither perform nor assure serotyping on *Shigella*

11. All public health laboratories should either have the capability to perform food chemistry tests for foodborne illness agents of public health significance, such as environmental contaminants, natural toxins, chemical agents, and radiation, or should have access to another laboratory with such capability to assure this testing can be done.

- a. Does your laboratory perform or assure the following tests are performed on food or environmental samples?

Test	Food	Environment
Allergens	☐	☐
Cyanide	☐	☐
Filth	☐	☐
Heavy metals	☐	☐
Histamines	☐	☐
Pesticides/Residues	☐	☐
Sulfites/Sulfates/Nitrites	☐	☐
Volatile organic compounds	☐	☐
Semi-volatile organic compounds	☐	☐
Gross alpha/beta	☐	☐
Tritium	☐	☐
Gamma emitters	☐	☐

12. Whenever possible, any public health laboratory that uses rapid tests to detect foodborne pathogens should also perform culture to isolate those pathogens for further characterization and subtyping.

- a. For those PHLs that perform rapid testing, do you confirm positive results from the following tests with culture and identification?

Rapid Test	Perform?	Confirm positive results?
Automated bacterial detection system*	☐ Yes ☐ No	☐ Yes ☐ No
DNA-based detection**	☐ Yes ☐ No	☐ Yes ☐ No
Antigen/antibody-based detection***	☐ Yes ☐ No	☐ Yes ☐ No
*Automated Bacterial detection systems include Faurier Transform Infrared Spectroscopy (FTIR), PLEX-ID[®], MALDI-TOF Biotyper[®], Ibis T5000[®] among others **DNA based assays include DNA hybridization techniques, PCR, Phage typing, and DNA sequencing ***Antigen-antibody based assays include Latex agglutination (LA) test, Reverse passive LA, Immunodiffusion test, Enzyme-linked immunosorbent assay (ELISA), Immunomagnetic Separation, Immunoprecipitation /Immunochromatography		

13. Each public health laboratory should have the capability to prepare necessary media and reagents in-house or have access to necessary media, if it cannot be acquired commercially during foodborne

disease outbreaks. Media and reagents must be labeled and tested for quality according to applicable regulations

Commercially prepared media and reagent records should include the following:

- name or description
- manufacturer's lot number
- date received
- date opened
- date prepared for QC
- manufacturer's expiration date
- discard date
- initials of the recipient

In-house media and reagents should be labeled with an identification scheme consistent with the laboratory QA program and include the following:

- name or description - batch number
- date of preparation
- date approved or rejected with the initials of person who approved/rejected the media/ reagent

Does your laboratory perform QA/QC testing on? (Check all that apply)

- ☐ commercially prepared media
- ☐ in-house media
- ☐ commercially purchased reagents
- ☐ in-house reagents

14. If the PHL performs serotyping of foodborne pathogens, the turnaround time (TAT) from either the receipt of a culture isolate, or isolation of the pathogen in the laboratory, to the serotyping result should be "real-time" and not exceed the recommended number of business days.

a. Within the past year, what % of isolates that were serotyped in your laboratory were done so within the real-time framework?

Pathogen	Percent	Recommended serotyping TAT for "real-time" pathogen detection (business days)	Do not perform serotyping on this pathogen
<i>Salmonella</i> sp.	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	4	☐ N/A
<i>E. coli</i> O157	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	4	☐ N/A
Non-O157 STECs	☐ 90-100% ☐ 70-89%	4	☐ N/A

	☐ 50-69% ☐ <50%		
<i>Shigella</i> sp.	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	3	☐ N/A

- b. What barriers prevent you from meeting the recommended serotyping TATs for surveillance cultures: (check all that apply)

- | | |
|--|--|
| ☐ Funding | ☐ Equipment/Reagents |
| ☐ Staffing | ☐ Serotyping methodology |
| ☐ Training | ☐ Testing is referred to another laboratory |
| ☐ Physical/Facility | ☐ Other _____ |

15. SKIP IF NOT A STATE OR LOCAL PUBLIC HEALTH LABORATORY

If the laboratory receives clinical specimens (stool or other) during an outbreak, the turn- around time from receipt of specimen to final test result should follow the recommended number of business days.

- a. Within the past year, what percent of clinical specimens were tested within these timeframes (days from receipt of clinical specimens to obtaining final test results):

Pathogen	Percent	Recommended TAT for final test result (business days)	Do not perform testing for this pathogen
<i>Cryptosporidium</i> sp.	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	2	☐ NA
<i>Cyclospora</i> sp.	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	2	☐ NA
<i>Giardia</i> sp.	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	2	☐ NA
Hepatitis A	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	2	☐ NA
Norovirus/Calicivirus	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	2	☐ NA
<i>Bacillus cereus</i>	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	4	☐ NA

<i>Clostridium botulinum</i>	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	5	☐ NA
<i>Clostridium perfringens</i>	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	7	☐ NA
<i>Campylobacter</i> sp.	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	5	☐ NA
<i>Listeria monocytogenes</i>	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	5	☐ NA
<i>Salmonella</i> sp.	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	5	☐ NA
Shiga toxin-producing <i>E. coli</i>	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	5	☐ NA
<i>Shigella</i> sp.	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	5	☐ NA
<i>Staphylococcus aureus</i>	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	5	☐ NA
<i>Vibrio</i> sp.	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	5	☐ NA
<i>Yersinia enterocolitica</i>	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	5	☐ NA

b. What barriers prevent you from meeting the recommended testing TATs for outbreak specimens: (check all that apply)

- | | |
|--|--|
| ☐ Funding | ☐ Equipment/Reagents |
| ☐ Staffing | ☐ Testing methodology |
| ☐ Training | ☐ Testing is referred to another laboratory |
| ☐ Physical/Facility | ☐ Other _____ |

PulseNet Activities SKIP IF NOT A PULSENET LABORATORY

16. Each PulseNet Laboratory should confirm the identification to species level for isolates that are subtyped.

- a. Does your laboratory confirm the identification of isolates to species level for those that are subtyped?

☐ Yes

☐ No

17. PulseNet laboratories should perform routine, molecular subtyping of STEC, *Salmonella* serotypes, *Shigella* species, and *Listeria monocytogenes* isolates. In addition, all PulseNet laboratories should be capable of subtyping or ensuring the subtyping of, all *Campylobacter*, *Bacillus cereus*, *Staphylococcus aureus*, *Vibrio* species, and *Yersinia enterocolitica* upon request.

- a. Does your laboratory perform PFGE subtyping on the following organisms? (check all that apply)

Organism	Yes/No
<i>E. coli</i> O157:H7	☐ Yes ☐ No
Non-O157 Shiga-toxin positive <i>E. coli</i>	☐ Yes ☐ No
<i>Listeria monocytogenes</i>	☐ Yes ☐ No
<i>Shigella</i> spp.	☐ Yes ☐ No
<i>Salmonella</i> spp.	☐ Yes ☐ No
<i>Campylobacter</i> spp.	☐ Yes ☐ No
<i>Bacillus cereus</i>	☐ Yes ☐ No
<i>Staphylococcus aureus</i>	☐ Yes ☐ No
<i>Vibrio</i> spp.	☐ Yes ☐ No

<i>Yersinia</i> spp.	☐ Yes ☐ No
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- b. Does your laboratory perform PFGE subtyping on 100% of the following isolates received in the laboratory?

Organism	☐ Yes/No
<i>E. coli</i> O157:H7	☐ Yes ☐ No
Non-O157 Shiga-toxin positive <i>E. coli</i>	☐ Yes ☐ No
<i>Listeria monocytogenes</i>	☐ Yes ☐ No
<i>Shigella</i> spp.	☐ Yes ☐ No
<i>Salmonella</i> spp.	☐ Yes ☐ No

- c. If not, what are the barriers? (check all that apply)

- ☐ Cost/funding
☐ Staffing
☐ Equipment
☐ Training
☐ Other, please specify _____

- d. Does your laboratory electronically upload the PulseNet patterns for the following organisms for which you are certified? check all that apply)

- ☐ *E. coli* O157:H7
☐ Non-O157 Shiga-toxin positive *E. coli*
☐ *Listeria monocytogenes*
☐ *Shigella* spp.
☐ *Salmonella* spp.
☐ *Vibrio* spp.
☐ *Campylobacter*

18. To more rapidly detect foodborne illness clusters and outbreaks, PFGE patterns and case information should be uploaded to PulseNet within 24 hours of subtyping.
- a. Does your laboratory submit all PFGE patterns to the PulseNet national database within 24 hours of subtyping?
- ☐ Yes
☐ No
- b. If not, why?
- ☐ We did not know all patterns should be submitted
☐ Inadequate staffing
☐ Inadequate computer equipment/license strings
☐ Only subsets of isolates from large outbreaks were submitted
☐ Non-PulseNet laboratory testing took priority
☐ Frequent poor quality gels
☐ Other, please specify: _____
19. All PulseNet laboratories should have access to and regularly utilize the PulseNet web board (SharePoint) in order to quickly identify and respond to multi-state clusters of foodborne pathogens. All pertinent information should be shared with state epidemiologists for further investigation. Each PulseNet laboratory should respond to PulseNet postings on CDC Team within 24 hours with recent matching patterns
- a. Does your laboratory have access to the CDC Team web board?
- ☐ Yes
☐ No, please skip to Question 61.
- b. How often does your laboratory staff review and/or respond to CDC Team postings?
- ☐ Daily
☐ 1-3 times/week
☐ Weekly
☐ Occasionally
- c. How often does your laboratory staff forward CDC Team posting information to Epidemiologists?
- ☐ Daily
☐ Weekly
☐ Only as clusters are identified
☐ Not routinely communicated

☐ Not applicable

20. All PulseNet laboratories should have representation at the Annual PulseNet Update Meeting and should participate in sufficient training to be able to meet the expectations of a PulseNet laboratory (PFGE subtyping laboratory training and BioNumerics software training).

a. Does your laboratory send a representative to the Annual PulseNet Update Meeting each year?

☐ Yes

☐ No

b. Has your laboratory ever received formal PFGE training by the CDC or a PulseNet Area Laboratory?

☐ Yes

☐ No

c. Has your laboratory ever received formal BioNumerics Analysis Training by the CDC or a PulseNet Area Laboratory?

☐ Yes

☐ No

21. All PulseNet laboratories should have adequate facilities, staff, equipment and technology to perform the recommended, PulseNet-standardized PFGE testing. Access to BSL-3 laboratory facilities might be necessary if your laboratory is PulseNet-certified for *Y. pestis* or desired if certified for *V. cholerae* or other highly infectious agents.

a. Does your laboratory have access to a BSL-3 and/or select agent facility for PFGE testing if required?

☐ Yes

☐ No

b. Is the number of PFGE electrophoresis units in your laboratory sufficient for routine subtyping of foodborne pathogens in your jurisdiction?

☐ Yes

☐ No

If yes, how many PFGE electrophoresis units do you have?

If no, how many additional units are needed?

- c. Does your laboratory use the minimum version of BioNumerics software recommended by PulseNet to analyze your data (i.e. Is your laboratory able to purchase BioNumerics software version updates as they are approved by PulseNet)?

- ☐ Yes
☐ No

- d. Does your laboratory have a sufficient number of certified staff to both perform PFGE subtyping and efficiently upload subtyping data to PulseNet within 24 hours of completion?

- ☐ Yes
☐ No

22. All PulseNet laboratories should have personnel certified for PFGE subtyping procedures (gels and tiff images for PFGE) and analysis for all geographically important agents in their jurisdiction. Implementation of second generation subtyping using Multi Locus Enzyme Variable Number Tandem Repeat (MLVA) analysis is encouraged by PulseNet. If MLVA analysis is not performed by your laboratory, your laboratory must ensure isolates are referred to a PulseNet-certified laboratory when requested.

- a. Do your laboratory personnel possess PulseNet certifications for the subtyping and analysis of the following agents?

Organism	PFGE Subtyping (Gel/TIFF Creation)	PFGE Analysis	MLVA Subtyping (PCR/ Sequencing)	MLVA Analysis
<i>E.coli</i> O157:H7	☐	☐	☐	☐
Non-O157 STEC	☐	☐	NA	NA
<i>Listeria monocytogenes</i>	☐	☐	☐	☐
<i>Shigella</i> spp.	☐	☐	NA	NA
<i>Salmonella</i> spp.	☐	☐	☐	☐
<i>Campylobacter</i> spp.	☐	☐	NA	NA
<i>Vibrio</i> spp.	☐	☐	NA	NA

- b. How many current staff members either hold certifications, or have PulseNet certifications pending, for the following organisms? (Insert number of certifications held or submitted at this time).

Organism	Gel/TIFF	Analysis	MLVA	MLVA Analysis
<i>E.coli</i> O157:H7	☐	☐	☐	☐
Non-O157 STEC	☐	☐	NA	NA
<i>Listeria monocytogenes</i>	☐	☐	☐	☐

<i>Shigella</i> spp.	☐	☐	NA	NA
<i>Salmonella</i> spp.	☐	☐	☐	☐
<i>Campylobacter</i> spp.	☐	☐	NA	NA
<i>Vibrio</i> spp.	☐	☐	NA	NA

c. Did your laboratory participate in and pass the most recent PulseNet Proficiency Testing Challenge?

☐ Yes

☐ No

23. All isolates of *E. coli* O157:H7 and *Listeria monocytogenes* should be subtyped in real time. Real time is defined as the time between arrival of pure culture in the PFGE laboratory to upload to the respective PulseNet databases. The standard PulseNet real time turnaround time is 4 business days. PulseNet laboratories should have the ability to meet the PulseNet turnaround time standards for all pathogens for 90% or more of their isolates, especially during an outbreak.

a. How does your laboratory manage the following organisms received for PFGE in the laboratory? (check all that apply)

Organism	Real-time	Batch	Upon Request	Not Tested
<i>E. coli</i> O157:H7	☐	☐	☐	☐
Non-O157 Shigatoxin-producing <i>E. coli</i>	☐	☐	☐	☐
<i>Listeria monocytogenes</i>	☐	☐	☐	☐
<i>Salmonella</i> spp.	☐	☐	☐	☐
<i>Shigella</i> spp.	☐	☐	☐	☐
<i>Campylobacter</i> spp.	☐	☐	☐	☐
<i>Bacillus cereus</i>	☐	☐	☐	☐
<i>Clostridium</i> spp.	☐	☐	☐	☐
<i>Staphylococcus aureus</i>	☐	☐	☐	☐
<i>Vibrio</i> spp.	☐	☐	☐	☐
<i>Yersinia</i> spp.	☐	☐	☐	☐

b. Please list the percent of isolates that are subtyped within the real-time framework:

Pathogen	Laboratory TAT for PFGE subtyping (business days)	Recommended real-time PFGE subtyping TAT for pathogen (business days)
<i>E. coli</i> O157:H7	☐ 90-100%	4

	☐ 70-89% ☐ 50-69% ☐ <50%	
Non-O157 Shiga-toxin positive <i>E. coli</i>	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	4
<i>Listeria monocytogenes</i>	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	4
<i>Salmonella</i>	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	4
<i>Shigella</i>	☐ 90-100% ☐ 70-89% ☐ 50-69% ☐ <50%	4

c. What barriers prevent you from meeting the PulseNet recommended TATs? (check all that apply)

- | | |
|--|--|
| ☐ Funding | ☐ Equipment/Reagents |
| ☐ Staffing | ☐ Serotyping methodology |
| ☐ Training | ☐ Testing is referred to another laboratory |
| ☐ Physical/Facility | ☐ Other _____ |

24. Each PulseNet laboratory should routinely perform second enzyme testing on *L. monocytogenes*, *E. coli* O157:H7, and Non-O157 Shiga-toxin positive *E. coli*, and have the ability to perform second enzyme subtyping on other organisms identified in clusters or outbreaks, if requested by PulseNet.

a. On which of the following organisms do you perform second enzyme PFGE subtyping and when is second enzyme subtyping performed in your laboratory?

Organism	2° enzyme concurrent with 1° enzyme	2° enzyme after 1° is indistinguishable, highly related or similar (voluntary lab/epi decision)	Never use 2° enzyme on this organism	2° enzyme only if requested by PulseNet
<i>E. coli</i> O157:H7	☐	☐	☐	☐
Non-O157 Shiga-toxin positive <i>E. coli</i>	☐	☐	☐	☐
<i>Listeria monocytogenes</i>	☐	☐	☐	☐
<i>Salmonella</i> spp.	☐	☐	☐	☐

<i>Shigella</i> species	☐	☐	☐	☐
<i>Campylobacter</i> spp.	☐	☐	☐	☐

Data Management

Information Management Systems

25. Every PHL should have a laboratory information management system (LIMS) for food safety data that complies with Public Health Information Network (PHIN) communication standards and certification guidelines.

a. Does your laboratory have a single or multiple LIMS that addresses all functional areas of food safety in your laboratory (e.g. foodborne illness (clinical), environmental, food, etc)?

- ☐ a single LIMS
☐ multiple LIMS that are integrated
☐ multiple LIMS that are not integrated
☐ No

If no, what are you using?

- ☐ Paper (hard copy)
☐ Microsoft Access
☐ Microsoft Excel
☐ Other: _____

b. Does your LIMS system comply with PHIN communication standards and certification guidelines?

- ☐ Yes
☐ No

26. Every LIMS should have the ability to collect, maintain, disseminate, and accept verified laboratory data using currently accepted data formats, (e.g. HL7, LOINC and SNOMED). This includes but is not limited to the following cases:

- a. Laboratory data essential for public health epidemiological and environmental health analysis and decision-making at the local, state
- b. Laboratory test orders and results with private clinical partners (if applicable)
- c. Laboratory test orders and results to other local, state or federal laboratories in support of surge capacity, reference and confirmation testing

Does your LIMS have all the above capabilities?

- ☐ Yes
☐ No

27. Every LIMS should be able to manage the multi-directional dissemination of verified laboratory data and information to assist in the detection of, rapid response to, and management of potentially catastrophic public health food safety emergencies and events.
- a. Does your LIMS have the capability to electronically receive and report information (e.g., PHL to physician, Hospital Lab to PHL, PHL to Epidemiology,)?
- ☐ Yes; bidirectional capability
 - ☐ Receive only
 - ☐ Report only
 - ☐ No electronic messaging capability
- b. If you have had a food safety emergency event, has your LIMS performed adequately during emergency events?
- ☐ Yes
 - ☐ No
 - ☐ Not Applicable?

Data Accuracy and Security

28. The accuracy of data entry as well as all food safety test results should be verified
- a. Do you regularly verify the accuracy of your data entry?
- ☐ Yes
 - ☐ No
- b. Do you regularly verify the accuracy of your food safety test results?
- ☐ Yes
 - ☐ No
- c. Does the laboratory perform quality assurance assessment (verification) of the food safety testing data transmitted?
- ☐ Yes
 - ☐ No
29. All public health laboratories should ensure that all food safety testing data transmitted electronically is secure and accurate. Data security measures should include locked files password, limited access, and other safeguards depending on the type of media (paper file, electronic file, etc.).
- a. Does your lab have an effective way of securely transferring food safety testing data?
- ☐ Yes

☐ No

- b. When reporting test results, is there a mechanism in place for confirming whether results were received? (check all that apply)

☐ Return email receipt
☐ Confirmation fax received
☐ Other (specify)

☐ No

- c. Does your laboratory contain locked storage for classified or sensitive food safety testing files or paperwork?

☐ Yes
☐ No

- d. Are sensitive electronic files and/or websites password protected?

☐ Yes
☐ No

- e. Does your laboratory have a secure IT area?

☐ Yes
☐ No

If yes, what measures are in place to protect the secure laboratory areas? (Check all that apply)

☐ Key/Locks
☐ Alarm Systems
☐ Video cameras/Surveillance
☐ Electronic access with tracking of entry/access

- f. Does your laboratory have a policy for food safety testing data security?

☐ Yes
☐ No

- g. Does your laboratory provide security training to staff (e.g. HIPAA regulations)?

☐ Yes

☐ No

Data Analysis and Reporting

30. Each PHL should electronically upload test results into PHLIS, or a similar electronic reporting platform at CDC, at least weekly..

a. Does your laboratory electronically report food safety test results to PHLIS?

☐ Yes

☐ No

b. How frequently are results reported to PHLIS?

☐ Daily

☐ Weekly

☐ Bi-Weekly

☐ Monthly

☐ Quarterly

c. What organisms are included in the report to PHLIS? (check all that apply)

☐ *Salmonella*

☐ *Shigella*

☐ *Campylobacter*

☐ *E. coli* O157:H7

☐ Non-O157 STEC

31. Foodborne disease organisms found in non-clinical (e.g., food) samples should be reported in a common database such as the Electronic Laboratory Exchange Network (eLEXNET).

a. Does your laboratory have access to eLEXNET?

☐ Yes

☐ No

b. Does your laboratory routinely report to eLEXNET?

☐ Yes

☐ No

c. How frequently are results reported to eLEXNET?

- ☐ Immediately
- ☐ Daily
- ☐ Weekly
- ☐ Monthly
- ☐ Other

d. What results are reported to eLEXNET? (check all that apply)

- ☐ All food results
- ☐ Outbreak food testing results
- ☐ Food surveillance testing results
- ☐ Proficiency testing results

32. Public health laboratories participating in the Laboratory Response Network (LRN) and/or Food Emergency Response Network (FERN) should report results of food testing for potential bioterrorism agents.

a. Does your laboratory report results of food testing for potential bioterrorism agents to the LRN/FERN?

- ☐ Yes
- ☐ No

b. How are results reported to LRN/FERN?

- ☐ LRN messenger
- ☐ eLEXNET
- ☐ Telephone
- ☐ Other, please specify _____

33. Testing methods used in studies for which Institutional Review Board approval is required must receive IRB review as part of the approval. Test results should be reported in the manner specified in the IRB approval document.

a. Is your laboratory aware of what food safety testing needs IRB approval?

- ☐ Yes
- ☐ No

b. If your laboratory does food safety testing for studies requiring IRB review or approval, do you have an approval protocol in place?

- ☐ Yes

- ☐ No
- ☐ Not applicable

c. Are food safety testing methods in which IRB approval is required reviewed as part of the approval process?

- ☐ Yes
- ☐ No
- ☐ Not applicable

d. Do you report food safety results as specified in the IRB-approved document?

- ☐ Yes
- ☐ No
- ☐ Not applicable

34. Public health laboratories performing foodborne disease testing for other states should send test reports and/or isolates back to that state (if the two are different)

a. Does your laboratory perform testing for other states in the following capacities? (check all that apply)

- ☐ During suspected outbreaks
- ☐ At the request of Epidemiology
- ☐ Surge capacity testing
- ☐ PulseNet Area Lab responsibility
- ☐ CaliciNet Outbreak Support Center
- ☐ MOA (Memo of Agreement)
- ☐ National testing laboratory within state boundaries (i.e. ARUP, Quest)
- ☐ Routinely if out-of-state patient isolate is received at your laboratory
- ☐ Other (specify): _____

b. If your laboratory performs foodborne disease testing on samples/specimens from other states, are the results and/or isolates returned to that state upon completion?

- ☐ Results reported
- ☐ Isolates sent
- ☐ Both results and isolates sent
- ☐ Neither results nor isolate sent
- ☐ Not applicable

Communication and Coordination with Partners

The organization of public health laboratories is not as significant as their ability to communicate, coordinate funding, and share resources. Working relationships among state public health partners should be well established before a crisis occurs.

35. Does your laboratory have routine working relationships with all of the following: Office of Foodborne Epidemiology, Food Protection Program, Department of Agriculture, Office of State Chemist (if applicable) and Environmental Health Department?

- ☐ Yes
☐ No

- a. What barriers prevent the sharing of resources?

- ☐ State law prohibits
☐ Agency policy/culture prohibits
☐ Not enough resources to share
☐ Other, specify: _____

36. Public health laboratories should establish partnerships with federal network programs, such as the Food Emergency Response Network (FERN) and the Laboratory Response Network (LRN) that address testing food samples for significant contaminants and potential agents of bioterrorism.

- a. Is your laboratory, or a laboratory within your food safety system, a member of FERN?

- ☐ Yes
☐ No

- b. Is your laboratory, or a laboratory within your food safety system, a member of LRN?

- ☐ Yes
☐ No

37. SKIP IF NOT A LOCAL or STATE PUBLIC HEALTH LABORATORY

Ideally, the Public Health Laboratory and office of foodborne epidemiology should be located in the same facility. But regardless of location, sufficient communication and interaction must take place for effective routine foodborne illness surveillance.

- a. Is your laboratory located in the same facility as the office of foodborne epidemiology?

- ☐ Yes
☐ No

- b. If your public health laboratory and office of foodborne epidemiology are not located in the same facility, does it hinder your ability to interact in matters of food safety?

- ☐ Hinder
☐ Does not hinder

c. What is the frequency of routine communication between the public health laboratory, office of foodborne epidemiology, and other agencies?

Agency	Frequency of Communication			
	Weekly Meetings/Emails/Phone Calls	Monthly	Quarterly	Less Than Quarterly
Foodborne Epidemiology				
Dept of Agriculture				
Environmental Health Dept				
State Chemist				
Food Protection Program				
Emergency Management				
Other: _____				

38. SKIP IF NOT A LOCAL or STATE PUBLIC HEALTH LABORATORY

State or local public health officials should ensure that discussions involving laboratory and epidemiology cluster data are made by teams that include staff from the State or Local Public Health Laboratory and other appropriate state or local programs and/or agencies.

a. Does your laboratory participate in discussions involving laboratory and epidemiological cluster data?

- ☐ Yes
☐ No

b. How would you assess the effectiveness of discussions between laboratories and epidemiology departments?

- ☐ Effective
☐ Not Effective

39. SKIP IF NOT A LOCAL or STATE PUBLIC HEALTH LABORATORY

Communication should exist between state or local public health laboratories and clinical laboratories. Important information and requests should be easily accessible and communicated to clinical laboratories in a timely manner.

a. Does your laboratory have an effective method of communication with clinical labs in your jurisdiction?

- ☐ Yes
☐ No

- b. Does your laboratory have the means to efficiently, and in a timely manner, obtain specimens from clinical laboratories in support of suspected or confirmed foodborne outbreak events?

☐ Yes
☐ No

Outbreak Planning

40. Each public health laboratory should have a food emergency response plan that can be implemented in the event of a foodborne disease outbreak or other food emergency. The plan should be developed in cooperation with the state public health laboratory, state office of foodborne epidemiology, the state food protection program, state department of agriculture and other relevant state and federal agencies and should outline the roles and responsibilities of each of these entities. The plan should also contain an agreement with other laboratories to provide testing assistance, exchange of laboratory data, and provisions for adequate staff in the event of a foodborne disease outbreak or other food emergency. Working relationships among state and local public health partners should be formally defined in a written communication plan before a crisis occurs.

- a. Does your laboratory have a food emergency response plan developed in cooperation with the aforementioned entities that outlines their roles and responsibilities?

☐ Yes
☐ No (skip to part d.)

- b. Is the foodborne emergency response plan updated on a regular basis?

☐ Yes
☐ No

- c. Are your staff (lab, support, IT, administration) trained in their respective responsibilities according to the laboratory foodborne emergency response plan?

☐ Yes
☐ No

- d. Does your foodborne emergency response plan include a list of key personnel and contacts that is updated at least annually?

☐ Yes
☐ No

- e. Please indicate the type of relationship that is defined with each entity in your state's foodborne emergency response plan (check all that apply):

Agency	Coordination	Communication	Sharing of Resources
Foodborne Epidemiology	☐	☐	☐
Dept of Agriculture	☐	☐	☐
Environmental Health Dept	☐	☐	☐
Industry	☐	☐	☐
Academia	☐	☐	☐
State Chemist	☐	☐	☐
Food Protection Program	☐	☐	☐
Emergency Management	☐	☐	☐
Other: _____	☐	☐	☐

f. What barriers prevent the sharing of resources?

- ☐ Federal/State law prohibits
- ☐ Agency policy/culture prohibits
- ☐ Not enough resources to share
- ☐ Other, specify: _____

g. What is the frequency of communication during a foodborne outbreak investigation or food emergency between the state public health laboratory and state office of foodborne epidemiology?

- ☐ Daily meetings/emails/phone calls
- ☐ Weekly meetings/emails/phone call
- ☐ Less than weekly or not at all

h. What is the frequency of communication during a foodborne outbreak investigation or food emergency between the state public health laboratory and other relevant stakeholders including State Food Protection, Department of Agriculture and Environmental Health?

- ☐ Daily meetings/emails/phone calls
- ☐ Weekly meetings/emails/phone calls
- ☐ Less than weekly or not at all
- ☐ _____

41. Every public health laboratory should have available computer support personnel capable of responding to emergencies within 2 hours and within 2 days for routine concerns. PHL's should also have the capability to efficiently and promptly transmit food safety test results and data to necessary agencies (epidemiology, agriculture laboratories, public health agencies, etc).

a. Does your laboratory have a resident IT department and/or staff able to respond during emergency situations?

- ☐ Yes
- ☐ No

b. What is the average response time to emergency situations?

- ☐ less than or equal to 2 hours
- ☐ more than 2 hours
- ☐ we do not have an IT department able to respond during emergency situations
- ☐ we have not experienced an emergency situation that required the notification of IT personnel

c. Can your laboratory adequately transmit food safety test data in routine or emergency situations?

- ☐ Yes
- ☐ No

42. Public health laboratories should report outbreak testing results on a daily basis to relevant stakeholders (e.g., CDC, local health department, etc).

a. Does your laboratory report outbreak testing results on a daily basis to relevant stakeholders?

- ☐ Yes
- ☐ No

43. In the event of a public health emergency (e.g. pandemic influenza), can your laboratory continue food safety testing?

- ☐ Yes
- ☐ No

44. Does your laboratory have adequate space for surge capacity food safety testing in the event of a foodborne disease outbreak?

- ☐ Yes
- ☐ No SKIP IF NOT A LOCAL/STATE PUBLIC HEALTH LABORATORY

45. Each Local/State Public Health Laboratory should initiate an agreement with their office of foodborne epidemiology to provide feedback (after action reports, conference calls, written reports, etc.) to the laboratory on the outcome of a foodborne outbreak investigation or a food emergency investigation. If epidemiology fails to provide this feedback, the laboratory should proactively follow up with epidemiology.

a. Please indicate the percent of investigations in which epidemiology provides feedback to your laboratory.

- ☐ 100%
- ☐ 50-75%
- ☐ 25-50%
- ☐ Less than 25%

☐ Never

If less than 100% please specify the barriers to epidemiology providing feedback:

b. Please indicate the percent of investigations in which your laboratory provides feedback to the epidemiology program.

- ☐ 100%
☐ 50-75%
☐ 25-50%
☐ Less than 25%
☐ Never

If less than 100%, please specify the barriers to providing feedback to epidemiology:

c. Does your laboratory have a mechanism for follow up with the epidemiology program when feedback is not provided?

- ☐ N/A
☐ Yes
☐ No

d. Following a foodborne outbreak or emergency response, does your laboratory participate in an after action review?

- ☐ Yes
☐ No

e. Following a foodborne outbreak or emergency response, does your laboratory contribute to or review any final report(s) for accuracy of any laboratory –based findings and/or recommendations?

- ☐ Yes
☐ No

f. Following a foodborne outbreak or emergency response, does your laboratory incorporate lessons learned into the food emergency response plan?

- ☐ Yes
☐ No

- g. Does your laboratory conduct drills or exercises to test communication capabilities to prepare for foodborne emergency events?

- ☐ Yes
☐ No

Administration Organization

Laboratory Website

46. Each Public Health Laboratory should have a functional website that provides useful, accurate and up-to-date information for its users. This website should be a user-friendly tool for the acquisition of food safety testing information, emergency response materials and links to other pertinent websites.

- a. Does your PHL currently have a functional website?

- ☐ Yes
☐ A website is currently under development
☐ No

Only answer the next 6 questions if your laboratory currently has a functional website:

- b. Does your PHL website have hyperlinks to the following useful food safety-related sites (check all that apply)?

- ☐ US Department of Agriculture
☐ US Centers for Disease Control
☐ Association of Public Health Laboratories
☐ Health Alert Network
☐ State Health Department (EpiS)
☐ Local Health Departments
☐ Agricultural and/or State Chemist Laboratory
☐ The American Society for Microbiology
☐ National Laboratory Training Network
☐ US Food and Drug Administration
☐ Veterinary Diagnostic Laboratory
☐ World Health Organization
☐ Council to Improve Foodborne Outbreak Response
☐ Council of State and Territorial Epidemiologists
☐ Food Emergency Response Network
☐ US Environmental Protection Agency

- c. Does your PHL website contain or link to food safety emergency response contact information for the following (Check all that apply)?

- ☐ Foodborne illnesses

- ☐ Bioterrorism/Select agents
- ☐ Radiation illness
- ☐ Chemical illness
- ☐ Catastrophic event
- ☐ There is no emergency contact information

d. How routinely is the website updated?

- ☐ It is updated routinely and immediately with breaking news and other items of interest
- ☐ It is routinely updated (on schedule)
- ☐ It is updated only when events occur
- ☐ It is not routinely updated

e. Does your website have adequate collection and submission information and documents such as (Check all that apply):?

- ☐ Access to your laboratory test reference manual
- ☐ Requisition forms
- ☐ Requirements for tests offered
- ☐ Shipping and handling information

f. Does your laboratory website currently offer or link to the following information (check all that apply):?

- ☐ Outbreaks/clusters of illness
- ☐ Product recall notices
- ☐ Antimicrobial resistance
- ☐ Environmental health concerns
- ☐ Foodborne Disease fact sheets
- ☐ MSDS information for foodborne pathogens
- ☐ Audio conferences/teleconferences
- ☐ Newsletters

Legal Issues

47. Each public health laboratory should have a clear legal authority to conduct all types of testing in support of outbreak or food contamination investigations.

a. Do legal authorities exist that allow you to perform lab testing in an outbreak situation?

- ☐ Yes

☐ No

b. Is a laboratory point of contact identified for support of foodborne outbreak investigations?

☐ Yes

☐ No

48. State law should mandate that hospitals and clinical laboratories that receive specimens associated with foodborne illnesses refer positive test results and isolates to the patient's state and/or local public health department.

a. Does your state require reporting of the following organisms?

Pathogen	Required Reporting
<i>Bacillus anthracis</i>	☐ Yes ☐ No
<i>Bacillus cereus</i>	☐ Yes ☐ No
<i>Brucella</i> sp.	☐ Yes ☐ No
<i>Campylobacter</i> sp.	☐ Yes ☐ No
<i>Clostridium botulinum</i>	☐ Yes ☐ No
<i>Clostridium perfringens</i>	☐ Yes ☐ No
<i>Cryptosporidium</i> sp.	☐ Yes ☐ No
<i>Cyclospora</i> sp.	☐ Yes ☐ No
<i>Francisella tularensis</i>	☐ Yes ☐ No
<i>Giardia</i> sp.	☐ Yes ☐ No
Hepatitis A	☐ Yes ☐ No
<i>Listeria monocytogenes</i>	☐ Yes ☐ No
Norovirus	☐ Yes ☐ No
<i>Salmonella</i> sp.	☐ Yes ☐ No
Shiga-toxin producing <i>Escherichia coli</i> O157 (STEC O157)	☐ Yes ☐ No
non-O157 STEC	☐ Yes ☐ No
<i>Shigella</i> sp.	☐ Yes ☐ No

<i>Staphylococcus aureus</i>	☐ Yes ☐ No
<i>Staphylococcus enterotoxin B</i>	☐ Yes ☐ No
<i>Vibrio</i> sp.	☐ Yes ☐ No
<i>Yersinia enterocolitica</i>	☐ Yes ☐ No
<i>Yersinia pestis</i>	☐ Yes ☐ No

- b. Does your state require submission of isolates or clinical material containing the following organisms?

Pathogen	Required Reporting
<i>Bacillus anthracis</i>	☐ Yes ☐ No
<i>Bacillus cereus</i>	☐ Yes ☐ No
<i>Brucella</i> sp.	☐ Yes ☐ No
<i>Campylobacter</i> sp.	☐ Yes ☐ No
<i>Clostridium botulinum</i>	☐ Yes ☐ No
<i>Clostridium perfringens</i>	☐ Yes ☐ No
<i>Cryptosporidium</i> sp.	☐ Yes ☐ No
<i>Cyclospora</i> sp.	☐ Yes ☐ No
<i>Francisella tularensis</i>	☐ Yes ☐ No
<i>Giardia</i> sp.	☐ Yes ☐ No
Hepatitis A	☐ Yes ☐ No
<i>Listeria monocytogenes</i>	☐ Yes ☐ No
Norovirus	☐ Yes ☐ No
<i>Salmonella</i> sp.	☐ Yes ☐ No
O157STEC	☐ Yes ☐ No
non-O157STEC	☐ Yes ☐ No
<i>Shigella</i> sp.	☐ Yes ☐ No

<i>Staphylococcus aureus</i>	☐ Yes ☐ No
<i>Staphylococcus enterotoxin B</i>	☐ Yes ☐ No
<i>Vibrio</i> sp.	☐ Yes ☐ No
<i>Yersinia enterocolitica</i>	☐ Yes ☐ No
<i>Yersinia pestis</i>	☐ Yes ☐ No

- c. Public health laboratories testing specimens for legal or regulatory purposes must have chain-of-custody procedures in place.

Is there a chain-of-custody procedure in place in your laboratory?

- ☐ Yes
☐ No

Laboratory Certifications and Accreditations (other than PulseNet)

49. Every public health laboratory should be accredited for its scope of testing (clinical, food, and environmental) by a recognized accrediting authority using internationally recognized criteria (e.g. CLIA, CAP, ISO).

- a. Is your laboratory accredited for your scope of testing?

- ☐ Yes
☐ No

**Check the scope of testing and list all accrediting bodies that apply:

<i>Discipline</i>	<i>Scope of Testing</i>	<i>Accrediting Body</i>	<i>Date of Last Accreditation</i>
Clinical	☐	_____	_____
Food	☐	_____	_____
Environmental	☐	_____	_____

- b. Any public health laboratory working with select agents must be registered with the CDC select agent program.

- c. Is your lab registered with CDC select agent program?

- ☐ Yes
☐ No, but we have other reporting and referral policies related to select agents
☐ No, we have no select agents on hand

Budget

50. The public health laboratory budget should be based on defined, optimal capacity and capability. The budget should include a fund to support laboratory activities during routine testing and during food emergencies.

a. Does your laboratory have adequate funding to support the following during routine food and foodborne illness surveillance? (check all that apply)

- ☐ Personnel
- ☐ Equipment
- ☐ Supplies

b. Does your laboratory have access to emergency funding to support the following in the event of a food emergency? (check all that apply)

- ☐ Personnel
- ☐ Equipment
- ☐ Supplies

c. Federal public health agencies contribute funding to build and maintain state and local public health laboratory infrastructure. Public health laboratories should proactively attempt to secure federal funding (e.g. Emergency Laboratory Capacity, FERN Co-Ag lab, etc.) to support their foodborne illness surveillance activities.

Does your laboratory apply for federal funding?

- ☐ Yes
- ☐ No

Facilities

51. Each public health laboratory should have dedicated areas for both foodborne illness specimens (clinical) and food testing

a. Does your laboratory have dedicated areas for the following:

<i>Foodborne Illness (Clinical)</i>	<i>Yes/No</i>	<i>Food Testing</i>	<i>Yes/No</i>
Bench	☐ Yes ☐ No	Bench	☐ Yes ☐ No
Office	☐ Yes ☐ No	Office	☐ Yes ☐ No
Storage of specimens	☐ Yes ☐ No	Storage of samples	☐ Yes ☐ No

Surge Capacity	☐ Yes ☐ No	Surge Capacity	☐ Yes ☐ No
Receiving and Accessioning	☐ Yes ☐ No	Receiving and Accessioning	☐ Yes ☐ No

b. Is there a triage area for receipt of select agents or BT/CT/RT specimens and/or food samples related to foodborne disease outbreaks?

- ☐ Yes
☐ No

c. Are the receiving and processing areas secure?

- ☐ Yes
☐ No

52. Each public health laboratory should have at least one biological safety level-3 (BSL-3) isolation room readily available if needed for food safety testing of BSL-3 agents.

a. Does your laboratory have a BSL-3 isolation room available for food safety testing of BSL-3 agents?

- ☐ Yes
☐ No

b. Is there a back-up BSL-3 isolation room available for food safety testing?

- ☐ Yes
☐ No

c. Does your laboratory have the BSL-3 -isolation room(s) certified annually?

- ☐ Yes
☐ No

53. Each public health laboratory performing bioassays for detection of foodborne illness in humans (e.g. botulism) should have access to an animal facility in compliance with the Institutional Animal Care and Use Committee (IACUC) and Biosafety in Microbiological and Biomedical Laboratories (BMBL) standards .

a. Does your laboratory have access to an in-house or offsite animal facility in compliance with the IACUC and BMBL?

- ☐ Yes

- ☐ No
☐ Bioassays performed off-site

54. Each public health laboratory facility should have a back-up power supply and surge protection for critical food safety testing equipment (e.g., incubators, refrigerators, freezers, analyzers).

a. Does your laboratory have a back-up power supply sufficient to operate existing food safety testing equipment?

- ☐ Yes
☐ No

b. Does your facility have surge protection/UPS available for critical food safety testing equipment?

- ☐ Yes
☐ No

Equipment

Testing/Safety Equipment

55. Each public health laboratory should have equipment available to perform all necessary culture and identification testing, rapid diagnostics, and characterization of isolates for investigation of foodborne disease pathogens. In addition to the equipment needed for traditional food microbiology testing, each public health laboratory system should have the molecular diagnostic equipment listed below and trained staff to operate them.

a. Does your laboratory have the following molecular diagnostic equipment?

<i>Equipment</i>	<i>Yes/No</i>
Thermal Cycler	☐ Yes ☐ No
PFGE equipment and software	☐ Yes ☐ No
DNA sequencer	☐ Yes ☐ No
Real-time PCR instrument	☐ Yes ☐ No
Microplate Reader	☐ Yes ☐ No
Microplate Washer	☐ Yes ☐ No
Reagent Grade Water Purification System	☐ Yes ☐ No
Spectrophotometer	☐ Yes ☐ No

Fluorometer (TRF)	☐ Yes ☐ No
Bead-based multiplex detection system	☐ Yes ☐ No
ELISA-based systems	☐ Yes ☐ No

b. Are staff adequately trained to use existing food safety testing equipment above?

- ☐ Yes
☐ No

56. Each state laboratory should have at least one biological safety cabinet (BSC), readily available for food safety and foodborne illness testing. All biological safety cabinets should be certified annually to ensure proper operation.

a. How many biological safety cabinets do you have that can be used for food or foodborne disease testing?

- ☐ >1
☐ 1
☐ (0)

b. Does the laboratory have all BSC's certified annually?

- ☐ Yes
☐ No

57. Each food safety system should have access to at least one radiation detector and X-ray equipment to screen food emergency specimens and/or samples upon arrival at the laboratory, or ensure that specimens and/or samples are screened prior to receipt at the laboratory.

a. Does your laboratory have access to a radiation detection device for screening specimens and/or samples or ensure that they are screened prior to receipt?

- ☐ Yes
☐ No

b. If yes, what type of radiation can be detected or what type of radiations is detected by outside agencies?

- ☐ Alpha
☐ Beta

☐ Gamma

c. Does your laboratory have access to X-ray equipment for screening food emergency samples or ensure they are screened prior to receipt?

☐ Yes

☐ No

58. Each public health laboratory should have the equipment and expertise to perform organic and inorganic analyses to detect, separate, and quantify chemical contaminants in clinical specimens and food. At a minimum, public health laboratories should have each piece of equipment listed below.

a. Does your laboratory have the following Food Chemistry equipment?

Sample Preparation Equipment	Yes/No
Soxlet extractors	☐ Yes ☐ No
Solid-Phase micro extractors (SPME)	☐ Yes ☐ No
Microwave oven	☐ Yes ☐ No

Analytical Equipment	Yes/No
High-Performance Liquid Chromatography (HPLC)	☐ Yes ☐ No
LC-MS/MS	☐ Yes ☐ No
Gas Chromatography (GC)	☐ Yes ☐ No
Gas Chromatography-Mass Spectrometry (GC-MS)	☐ Yes ☐ No
Fourier Transform Infrared Spectroscopy (FTIR)	☐ Yes ☐ No
Inductively Coupled Plasma (ICP)	☐ Yes ☐ No
Inductively Coupled Plasma- Mass Spectrometry (ICP-MS)	☐ Yes ☐ No

- b. Does your laboratory have the following Clinical Chemistry equipment?

Sample Preparation Equipment	Yes/No
Soxlet extractors	☐ Yes ☐ No
Solid-Phase micro extractors (SPME)	☐ Yes ☐ No
Microwave oven	☐ Yes ☐ No

Analytical Equipment	Yes/No
High-Performance Liquid Chromatography (HPLC)	☐ Yes ☐ No
LC-MS/MS	☐ Yes ☐ No
Gas Chromatography (GC)	☐ Yes ☐ No
Gas Chromatography-Mass Spectrometry (GC-MS)	☐ Yes ☐ No
Fourier Transform Infrared Spectroscopy (FTIR)	☐ Yes ☐ No
Inductively Coupled Plasma (ICP)	☐ Yes ☐ No
Inductively Coupled Plasma- Mass Spectrometry (ICP-MS)	☐ Yes ☐ No

59. Each public health laboratory should have the equipment and expertise to perform radiation chemistry analyses to detect, separate, and quantify chemical contaminants in clinical specimens and food. At a minimum, state laboratories should have each piece of equipment listed below.

Analytical Equipment	Yes/No
Liquid Scintillation Counter	☐ Yes ☐ No

Gamma Spectroscopy System	☐ Yes ☐ No
Alpha Spectroscopy System	☐ Yes ☐ No
Gross Alpha/Beta Counting System	☐ Yes ☐ No

Communications Equipment

60. SKIP IF NOT A LOCAL/STATE PUBLIC HEALTH LABORATORY

All state and local public health laboratories should have telediagnostic equipment available on-site. Telediagnosis can expedite disease or infectious agent diagnoses, especially in the diagnoses of foodborne parasites and bacteria (e.g. CDC DPDx program).

- a. Does your laboratory have all of the following telediagnosis equipment: Digital camera, camera adapters, trinocular microscope, computer and peripherals with modem connection?

☐ Yes
☐ No

61. To ensure adequate communication with critical partners in emergency situations, each public health laboratory should possess, at a minimum, mobile phones for essential staff and a satellite phone.

- a. Which of the following equipment do you have for emergency communication? Check all that apply.

☐ Cell phone
☐ Blackberry
☐ Satellite phone
☐ None

Personnel

62. Every food safety system, regardless of jurisdiction population size, should have sufficient public health laboratory staff trained in quality assurance, molecular microbiology, conventional food and/or clinical microbiology, chemistry, radiological methods, virology and parasitology. In addition, every PHL must have clerical and support staff in sufficient numbers to serve the needs of the jurisdiction population.

- a. Does your laboratory have sufficient numbers of trained staff for each discipline listed?

Discipline	Yes/No	How many additional personnel would
------------	--------	-------------------------------------

		you need?
Conventional Microbiology	☐ Yes ☐ No	
Virology	☐ Yes ☐ No	
Parasitology	☐ Yes ☐ No	
Food Chemistry	☐ Yes ☐ No	
Molecular Biology	☐ Yes ☐ No	
Radiological	☐ Yes ☐ No	
Quality Assurance staff	☐ Yes ☐ No	
Clerical staff	☐ Yes ☐ No	

63. Each food safety system should have public health laboratories with staff with doctoral-level expertise in food chemistry and food and clinical microbiology.

a. Does your laboratory have doctoral-level staff with expertise in food chemistry?

- ☐ Yes
☐ No

b. Does your laboratory have doctoral-level staff with expertise in food microbiology?

- ☐ Yes
☐ No

c. Does your laboratory have doctoral-level staff with expertise in clinical microbiology?

- ☐ Yes
☐ No

64. Each public health laboratory should have an on-call schedule for foodborne illness/food testing staff, with support available 24 hour a day seven days a week and have a mechanism in place to compensate staff for overtime in the event of foodborne disease emergency.

a. Does your laboratory have on-call staff available during a foodborne disease emergency?

- ☐ Yes

☐ No

- b. Does your laboratory have a mechanism by which on-call staff or staff brought in for a weekend foodborne disease emergency could be compensated for overtime?

☐ Yes

☐ No

65. Staff salaries should be based upon training and experience, with experienced staff compensated at a rate above the standard entry-level salary for their position. In addition, public health laboratories should provide a clear career development path for laboratorians to advance professionally through the organization.

- a. Do salaries of your foodborne testing staff at your laboratory adequately reflect years of experience and qualifications?

☐ Yes

☐ No

- b. Does your current hiring process allow you to effectively recruit competitive food and/ or clinical microbiologists and food chemists?

☐ Yes

☐ No

- c. Does your laboratory provide a clear path for promotional opportunities from entry-level through laboratory program supervisor in the food safety program (or other pertinent program) area?

☐ Yes

☐ No

66. Public health laboratories should offer competitive compensation packages (including benefits and local cost-of-living adjustments) to hire and retain qualified personnel. In addition, each public health laboratory should cross-train employees within and between food and clinical laboratories (if applicable), with career advancement and/or tuition reimbursement or certifications as an incentive for cross-training.

- a. Public health laboratories should have a method in place to assess the fair market salaries of their employees and provide commensurate compensation when necessary.

Does your laboratory have a mechanism like the one described above?

☐ Yes

☐ No

- b. Does your laboratory offer competitive compensation packages in the food safety program (or other pertinent program) area of the laboratory (including benefits and local cost of living adjustments)?
- ☐ Yes
☐ No
- c. Does your laboratory provide educational incentives as part of compensation?
- ☐ Yes
☐ No
- d. If applicable, does your laboratory cross-train employees within and between food sample testing and clinical laboratories?
- ☐ Yes
☐ No
☐ Not applicable
- e. Does your laboratory offer career advancement and/or advanced degree compensation as an incentive for cross-training?
- ☐ Yes
☐ No

Training and Continuing Education

67. Food chemists and food and clinical microbiologists should be offered opportunities for participation in continuing education (CE) programs. All CE training should be documented in personnel files.
- a. Does your laboratory provide food and/ or foodborne illness testing CE opportunities for staff?
- ☐ Yes
☐ No
- b. Does your laboratory document all CE training in staff personnel files?
- ☐ Yes
☐ No
68. Analysts should be provided with hands-on and web-based training opportunities specific to food safety testing and sample collection, as appropriate to each foodborne testing staff's subject area. Appropriate federal, state and/or local agencies should provide the infrastructure for this training at federal, state, and/or local facilities. Laboratories should have a designated training coordinator that maintains a resource file and publicizes food

safety training opportunities.

- a. Does your laboratory provide opportunities for staff to participate in hands-on or web-based food safety training specific to their subject areas?

☐ Yes
☐ No

- b. Do you maintain or have access to a resource file with food safety training opportunities?

☐ Yes
☐ No

- c. What barriers hinder your laboratory's ability to provide food safety training opportunities to staff?

☐ Inadequate funding
☐ Travel restrictions
☐ Unavailability of food safety/food defense courses
☐ Insufficient staff (to cover for those participating in training)
☐ Other (please list): _____

- d. Does your laboratory have a designated training coordinator?

☐ Yes
☐ No

- e. Can your laboratory conduct food safety training on site?

☐ Yes
☐ No

69. Each state or local food safety system should actively participate in training in the use of the CIFOR Toolkit and strive to implement its recommended practices to improve their overall food safety program preparedness. All partners in the food safety system, including but not limited to laboratory, epidemiology, regulatory and clinical/infection control practitioners should be involved in the training and implementation process. Ideally, all levels of the system, such as federal, state, regional, local and private will be actively involved in the CIFOR toolkit implementation as well.

- a. Has your food safety system completed or planned to complete the CIFOR Toolkit?

☐ Yes, completed
☐ Plan to complete
☐ No (IF NO, MOVE TO QUESTION 36.)

b. If you have completed or plan to complete the CIFOR Toolkit, were all partners in your food safety system present for the training or will you invite all levels of partners to the training?

- ☐ Yes, all partners present/invited
- ☐ No, not all partners present or invited
- ☐ Yes, plan to invite all partners in your food safety program

c. If you have completed the CIFOR Toolkit , have you identified areas for improvement?

- ☐ Yes
- ☐ No

If yes, have you implemented changes to your food safety program as a result?

- ☐ Yes
- ☐ No

Laboratory Safety 70. Each PHL must adequately ensure the safety of all staff exposed to foodborne pathogens. Adequate staff safety may be attained by, but is not limited to, the regular use of training programs, the provision of personal protection equipment, the provision of applicable vaccines and the implementation of staff illness surveillance and monitoring programs within the laboratory..

a. Does your laboratory provide safety training at least annually for all staff?

- ☐ Yes
- ☐ No

b. Does your laboratory provide adequate personal protective equipment (lab coats, gloves, goggles/safety glasses, face shields) for all staff exposed to foodborne pathogens?

- ☐ Yes
- ☐ No

c. Are foodborne pathogen vaccinations (*Salmonella* Typhi) available to food safety staff when warranted and desired by staff?

- ☐ Yes
- ☐ No

d. Does your laboratory have a staff illness surveillance and monitoring system in place that would adequately detect a cluster of illness among laboratory staff due to exposure to or manipulation of foodborne pathogens?

- ☐ Yes
- ☐ No

Yardstick Self Assessment Tool- Glossary of Terms*

***Terms below have been defined as they apply to this self assessment tool. These terms may be defined in a different manner when applied in another context. This glossary of terms is meant to aid those food safety staff utilizing the Yardstick Assessment Tool.**

Accreditation- process whereby a professional association or nongovernmental agency grants recognition to a public health laboratory for demonstrated ability to meet predetermined criteria for established food safety testing standards

APHL- Association of Public Health Laboratories; association of public health, environmental and agriculture laboratories that work together to shape national and global health objectives with the participation of federal agencies, non-profit organizations, corporations and invested individuals; APHL Food Safety Committee is the sponsor of the Yardstick Self Assessment Tool

Certification- process by which a public health laboratory is evaluated and recognized as meeting certain predetermined criteria and standards

Cluster (of foodborne illness)- confirmed cases of a foodborne disease that occur in close proximity to one another within a specified time or space. Number of cases and scope of cluster defined by the foodborne disease agent

Chain of Custody- documentation of receipt of a particular piece of evidence; documentation that a piece of evidence is what it reports to be; documentation of continuous possession of the piece of evidence; documentation by the person in possession of the piece of evidence that the piece of evidence remains in the same condition as when that person gained possession of it.

Council to Improve Foodborne Outbreak Response (CIFOR)- Local, state and federal partners collaborating effectively to reduce the burden of foodborne illness in the United States by improving methods at the local, state, and federal levels to detect, investigate, control, and prevent foodborne disease outbreaks.

Foodborne Illness- Of or relating to a clinical illness in a patient as a result of consumption or exposure to a food or food product that is contaminated by pathogenic organisms, chemicals or radiation
Foodborne Outbreak (FBO)- A rise in the rate of disease as a result of exposure to food vehicle; two or more cases of foodborne illness shown by epidemiological investigation to result from a common source; cluster of foodborne illness cases with a clear association among cases; scope of outbreak may be defined by the foodborne disease agent

Food Emergency Response Network (FERN)- network of food-testing laboratories at local, state, and federal levels that is able to respond to emergencies involving biological, chemical, or radiological contamination of food; ensures federal and state inter-agency participation and cooperation in the formation, development, and operation of the network

Food Safety- Principles and practices that preserve the quality and safety of food and prevent foodborne illnesses

Food Safety System- Within a state or jurisdiction; collective agencies that collaborate to ensure the safety of food or food products; often include, but is not limited to: state and local public health laboratories, state agriculture laboratories, state chemist office, state and local epidemiology officials, state and local environmental officials, and food regulatory agencies

Isolate- single population of bacteria recovered from a food or food product; pure strain

Laboratory Response Network (LRN)- integrated national and international network of state, local, federal, military, veterinary, environmental and food laboratories equipped to respond quickly to acts of chemical or biological terrorism, emerging infectious diseases, and other public health threats and emergencies; addresses preparedness for and potential response to acts of food terrorism

Local Public Health Laboratory (LPHL)- Local laboratory that performs laboratory testing on clinical specimens of public health significance in agreement with state or local mandate and state or local division of public health epidemiology offices; may also perform laboratory testing on food samples of public health significance

Public Health Information Network (PHIN)- CDC initiative to improve the capacity of public health entities to use and exchange information electronically; promotes the use of standards and defines functional and technical requirements; improve public health nationally through best practices related to efficient, effective, and interoperable public health information systems

Public Health Laboratory (PHL)- A state, regional, or local public health laboratory or state agriculture or chemist laboratory that performs testing in support of public health authorities (state division of public health or state department of agriculture) in their jurisdiction

PulseNet- Network of public health laboratories that perform standardized PFGE testing of foodborne bacterial pathogens and submit the band patterns to a national database for comparison purposes (identification of clusters of illness).

Pulsed-Field Gel Electrophoresis (PFGE)- production of DNA band patterns (or “DNA fingerprint”) as a result of restriction enzyme-cleaving of bacterial DNA, followed by separation by electrophoresis using shifting (in direction and duration) current; primary molecular subtyping method utilized by PulseNet

Sample- portion, piece or segment representative of a whole food or food product; non-clinical origin

Specimen- stool, blood, urine, etc. that is collected for diagnostic purposes; clinical origin

State Agriculture Laboratory- State or regional laboratory that does not perform testing on clinical specimens; generally performs testing on food and environmental samples which may be of public health significance in agreement with the state department of agriculture in their jurisdiction

State Public Health Laboratory (SPHL)- State or regional laboratory that performs laboratory testing on clinical specimens of public health significance in agreement with state mandate and state division of public health epidemiology offices; may also perform laboratory testing on food samples of public health significance

Surge Capacity- ability to obtain adequate staff, supplies equipment, structures and systems to provide adequate services or testing during a foodborne illness emergency or event

Yardstick- A self-assessment tool to be used by public health laboratories; standard of food safety recommendations and best practices against which public health laboratories may “measure” their effectiveness and preparedness, thereby focusing resources on any needed improvements.

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