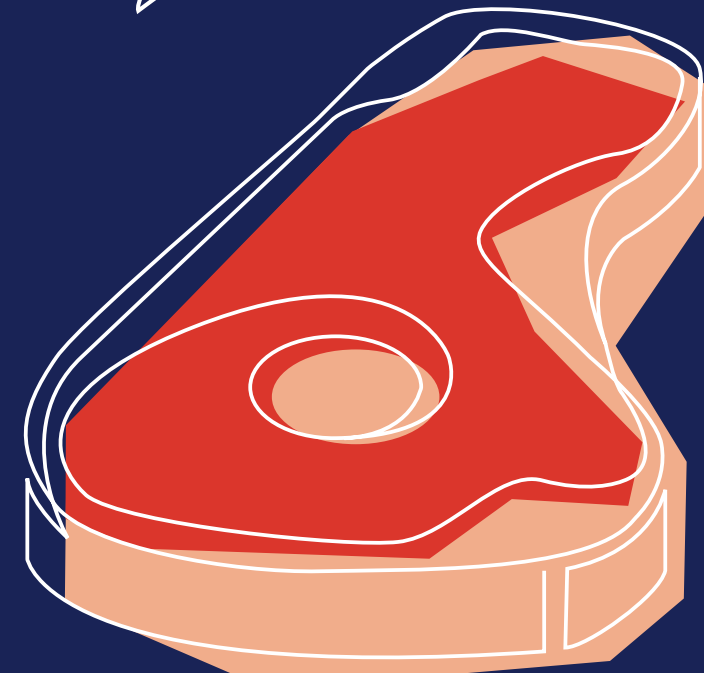


*A Recipe for*  
**STRONGER FOOD SAFETY  
TESTING PROGRAMS**



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*Findings and Recommendations  
from the* **ASSOCIATION OF  
PUBLIC HEALTH LABORATORIES**  
*Food Safety Laboratory Capacity  
Assessment Project*

april 2003

## WHO WE ARE

The Association of Public Health Laboratories (APHL) works to safeguard the public's health by strengthening public health laboratories in the United States and across the world. In collaboration with members, APHL advances laboratory systems and practices, and promotes policies that support healthy communities. The association's founding members are directors of state public health laboratories. Others include state laboratory staff, city and county laboratory directors, and international representatives. APHL is a non-profit, 501(c)(3) organization.

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**APHL Food Safety Laboratory Capacity Assessment Project**

**April 2003**



**Association of Public Health Laboratories**

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## EXECUTIVE SUMMARY

**The Centers for Disease Control and Prevention (CDC) estimates that 76 million illnesses, 300,000 hospitalizations, and 5,000 deaths in the United States each year are caused by foodborne illnesses.** Moreover, the agency predicts that the incidence of investigated foodborne outbreaks affecting at least ten individuals will more than double in coming years. CDC's report of foodborne illness in the U.S. in 2002 notes that while illnesses from *Campylobacter* and *Listeria* showed a sustained decline, those caused by *E. coli* O157:H7 and *Salmonella* did not, indicating that increased efforts are needed to reduce further the incidence of foodborne illnesses. The threat is twofold: researchers are identifying new foodborne pathogens and toxins (including antimicrobial resistant bacteria), and the changing nature of food production and commerce facilitates the widespread distribution of tainted food products. Since the terrorist attacks of the fall of 2001, the possibility of a deliberate attack on the food supply has become more tangible as well.

**Foodborne illness detection may begin when hospital and other clinical and public health laboratories screen specimens from patients being treated for suspected foodborne illness.** With few exceptions, state and local public health laboratories (SPHLs) are the primary facilities responsible for confirming the presence of foodborne microbes and toxins in clinical specimens, and for characterizing these agents in support of epidemiologic investigations. Despite the importance of public health laboratories in reducing the incidence of foodborne illness, there has been little work to date to define optimal laboratory capability and capacity for this important public health activity. Without objective benchmarks, deficiencies in staffing, training, or physical plant may go unrecognized and degrade laboratories' response capabilities, with potentially serious consequences. Moreover, any coherent action plan for food safety response must be predicated upon a set of minimal, common response capabilities across jurisdictions, with well-documented mechanisms for coordination with higher-level laboratories, state epidemiologists, and other responders.

The APHL Food Safety Project began before the terrorist attacks of the fall of 2001. Survey results reflect pre-September 11<sup>th</sup> capacities.

Recommendations pre-date a number of laws and regulations designed to increase security in laboratories handling potential agents of bioterrorism. In addition, funding levels to state food safety laboratory programs may have undergone substantial changes, often with increases in federal support for bioterrorism preparedness, and concurrent decreases in state support.

**The APHL Food Safety Laboratory Capacity Assessment Project is the first attempt to quantify both current and ideal laboratory capacity in a comprehensive fashion.**

Project findings are based on two sources of information. First, in August 2001, survey data were collected from 51 state and territorial public health laboratories to document current capability. Second, optimal public health laboratory capacity was defined by more than 70 laboratory experts at a consensus conference sponsored by APHL in January 2002. Their benchmarks for food safety testing capacity are presented as a series of recommendations herein.

**Although project findings primarily address state public health laboratory needs, they also apply to large local public health laboratories, particularly those in populous metropolitan areas or in geographically remote locations.** Project findings will also be of interest to health officials, food and drug officials, legislators, and other decision makers at the state and national levels who are responsible for allocating public health funds, setting policy, and/or coordinating the response to foodborne disease outbreaks.

The APHL Food Safety Laboratory Capacity Assessment Project was developed in cooperation with the CDC National Center for Infectious Diseases and is part of a larger effort, the National Food Safety Initiative, a multi-agency effort begun in 1997 to reduce the incidence of foodborne illness in the United States.

### ***Important Project Findings***

- **State public health laboratories are faced with a shortage of doctoral-level food safety microbiologists and chemists to conduct food safety testing.** This challenge is at least in part attributable to non-competitive public sector salaries. Building and sustaining an adequate public health laboratory workforce will require a long-term national strategy.
- **A complex mix of entities and jurisdictions are involved in the response to foodborne illnesses.** Depending on the health threat and the specific make-up of food safety services in each state, the response may require coordination among clinical, public health, veterinary, agriculture and other laboratories, and may involve laboratorians, epidemiologists, food and drug officials, and others. In addition, federal partner agencies - including CDC, the Food Safety and Inspection Service of the U.S. Department of Agriculture, (FSIS/USDA) and the U.S. Food and Drug Administration (FDA) - may be involved.
- **Gaps in emergency preparedness may hamper state public health laboratory readiness for major foodborne disease outbreaks and food-related terrorist incidents.** At least a third of responding laboratories indicated that they lack adequate space, staff, and/or equipment to handle a foodborne disease emergency. Many reported that they have inadequate communication tools (wireless phones, pagers, etc.) for use in an emergency.
- **State public health laboratories may face a “chemistry gap.”** While capability for food safety microbiology is present in all SPHLs, only half report having basic food chemistry capability. When laboratories are unable to explore a variety of etiologies, public health efforts to respond to increases in acute and chronic disease prevalence may be hampered.
- **Policymakers play a pivotal role in assuring that laboratories have adequate funding, legal authority and infrastructure to respond to food safety emergencies.** Chronic funding shortfalls and incomplete reporting and referral of samples from clinical laboratories are persistent challenges for state and local public health laboratories responding to food safety concerns.

**Through the Food Safety Laboratory Capacity Assessment Project, APHL has identified the essential elements to achieve optimal food safety testing capacity for our nation.**

**With sufficient commitment and resources, policymakers, health officials, and laboratorians can work together to make them a reality.**



## LISTING OF PROJECT RECOMMENDATIONS

(Recommendations and supporting information are explained in detail in the full project report.)

### LABORATORY INFRASTRUCTURE

#### Administration/Organization

##### *Legal Issues*

1. Each state public health laboratory (SPHL) should have clear legal authority to conduct outbreak investigations, even if this authority does not rest directly with the laboratory.
2. State law should mandate that hospital 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 laboratory.
3. SPHLs testing specimens for legal or regulatory purposes must have chain-of-custody procedures in place.
4. Each SPHL should have a policy clearly defining entities to which public health laboratories have the authority to ship isolates (e.g., universities, CDC, other federal agencies, other public health laboratories). The policy must conform to state and federal regulations.
5. States should verify compliance with all relevant state and federal laws and regulations regarding licensure agreements with commercial companies for the use of proprietary technologies, supplies or reagents.

##### *Laboratory Certifications*

6. Every SPHL should be accredited for its scope of testing by a recognized accrediting authority using internationally recognized criteria.
7. All SPHLs should complete PulseNet certifications for *E. coli* O157:H7, *Listeria monocytogenes*, *Salmonella* Typhimurium, and *Shigella sonnei*.
8. CDC officials should communicate PulseNet certification and proficiency test results in written format to all submitters within 60 calendar days.

##### *Coordination with Partners*

9. The organization of laboratories is not as significant as their ability to communicate, coordinate funding, and share resources. Working relationships among state public health programs should be formally defined in a written communication plan *before a crisis arises*.
10. Ideally, the SPHL, state office of epidemiology, and state food protection program should be located in the same building, but regardless of location, communication and interaction must take place.
11. Each public health laboratory should initiate an agreement with the state epidemiology office whereby the epidemiology program routinely provides feedback to the laboratory on the status of outbreak investigations and on disease clusters identified by the laboratory. If the epidemiology program fails to provide this feedback, the laboratory should proactively follow up with epidemiology.
12. State public health officials should ensure that decisions involving laboratory and epidemiologic data be made by teams that include staff from the SPHL and other appropriate state programs and/or agencies.
13. Each SPHL should have formal access to a laboratory testing *all* known foodborne pathogens in clinical specimens and food, and water samples.

***Crisis Planning***

14. Each SPHL should have a written plan - developed in cooperation with the state office of epidemiology, the state food protection program, state department of agriculture, and other relevant agencies - outlining the roles and responsibilities of each entity in the event of a foodborne disease outbreak.
15. Emergency plans should include provisions to secure adequate laboratory space for surge capacity through agreements with local or regional facilities.
16. Each SPHL should have a plan for rapid delivery of samples/specimens to the laboratory during an emergency.

***Budget***

17. The SPHL budget should be based on defined optimal capacity and capability. The budget should include a fund to support enhanced laboratory activities during a public health emergency and a fund to support continuing education activities.
18. Federal public health agencies should contribute funding to build and maintain state and local public health laboratory infrastructure. SPHLs should proactively participate in requests for federal funding.

**Facilities**

19. Each SPHL should have physical space sufficient to accommodate bench testing, equipment storage, office and administrative support functions, and surge capacity. Every SPHL should have lockable evidence space.
20. Each SPHL should have a secure area - with appropriate environmental controls - for receipt and storage of samples and specimens.
21. Each SPHL should have access to an animal facility in which to perform bioassays for detection of foodborne illness in humans.
22. Each SPHL should have access to a satellite downlink system and other appropriate distance-learning equipment within the building housing the laboratory.
23. Each SPHL should have a back-up power supply.

**Equipment*****Testing/Safety Equipment***

24. Each SPHL should have equipment available to perform all necessary culture and identification testing, rapid diagnostics, and characterization of isolates for investigation of foodborne disease pathogens. (See pathogens/toxins listed in Table 11 of the full report.) In addition to the equipment needed for traditional food microbiology testing, *at a minimum* each SPHL should have the molecular diagnostic equipment listed in Table 6 of the full report.
25. Each SPHL should have at least one biological safety cabinet, readily available for food safety testing.
26. Each SPHL should have at least one Biological Safety Level-3 (BSL-3) isolation room readily available for food safety testing, with one reserved as back-up for emergency use.
27. Each SPHL should have at least one radiation detector to screen samples upon arrival at the laboratory.
28. Each SPHL should have the equipment to perform organic and inorganic analyses to detect, separate, and quantify chemical contaminants in food. *At a minimum*, SPHLs should have each piece of equipment listed in Table 7 of the full report.

29. Each SPHL should have access to specialized equipment, such as a DNA Sequencer.

### ***Communications Equipment***

30. All SPHLs should have a complete set of telediagnostic equipment available on-site.
31. To ensure communication with critical partners in emergency situations, each SPHL should possess, *at a minimum*, pagers or mobile phones for essential staff and a two-way radio for the laboratory.
32. Every SPHL should have an adequate number of computers with sufficient capability - including Web-based reporting - to carry out the work of the lab.

### **Personnel**

#### ***Staffing***

33. Every state, regardless of population, should have laboratory staff trained in a) quality assurance, b) molecular microbiology, c) food microbiology, and d) analytical chemistry. In addition, every SPHL must have clerical and support staff in sufficient numbers to serve the needs of the state population.
34. SPHLs should have staff with doctoral-level expertise in both microbiology and chemistry.
35. Each SPHL should have a preplanned on-call schedule, with support available 24 hours a day, 7 days a week.
36. Every SPHL should have dedicated computer support personnel.

#### ***Compensation***

37. Staff salaries should be based upon training and experience, with experienced new staff compensated at a rate above the standard entry-level salary for their position. In addition, SPHLs should provide a clear career development path for laboratorians to advance professionally through the organization.
38. SPHLs should offer competitive compensation packages (including benefits and local cost-of-living adjustments) to hire and retain qualified personnel.
39. The salary ranges for professional laboratory staff within a state (e.g., microbiologists, chemists, forensic analysts) should be comparable, although individual pay may vary based on education and experience.
40. State laboratories should have adequate resources available to provide overtime and on-call pay to employees.

#### ***Training and Continuing Education***

41. Food chemists and microbiologists should be required to participate in continuing education (CE) programs. For states that do not require professional licensure, laboratorians should be required to earn *at least* twelve hours of CE credits per year, with the number of hours documented in personnel files.
42. Analysts should be provided with hands-on and Web-based bench training opportunities specific to food safety testing and sample collection, as appropriate to each analyst's subject area. Appropriate federal and/or state agencies should provide the infrastructure for this training at state and/or federal facilities. The National Laboratory Training Network (NLTN) and state training coordinators should maintain a resource file for food safety training opportunities.
43. Each state laboratory should have a designated training coordinator.
44. Each SPHL should cross-train employees within and between food and clinical laboratories, with career advancement as one incentive for cross-training.

**Information Management*****Information Management Systems***

- 45. Every SPHL should have a laboratory information management system (LIMS) that complies with National Electronic Disease Surveillance System (NEDSS) communication standards.
- 46. Every LIMS should interface with state and local epidemiology and environmental health computer systems to facilitate rapid electronic data exchange.
- 47. Each LIMS should be capable of electronically transmitting data to the CDC computer system, Public Health Laboratory Information System.

***Data Accuracy/Security***

- 48. The accuracy of data entry of all test results should be verified at the time of entry.
- 49. Every SPHL should have a written policy to protect the confidentiality of patient data.
- 50. Data security measures should include locked files, password and ID protected access to sensitive laboratory areas, and other safeguards depending on the type of media (paper file, electronic file, etc.).

***Laboratory Web site***

- 51. Each SPHL should have a Web site that provides necessary information in a user-friendly manner.

**SUBMISSION OF SPECIMENS/SAMPLES**

- 52. Each SPHL should have written collection protocols for specimens and samples within the scope of testing performed.
- 53. Each SPHL should have written rejection criteria for specimens and samples within the scope of testing performed.
- 54. Each SPHL should have a standard requisition form for specimens and samples within its scope of testing. The requisition form should meet the needs of the program, be readily available to submitters, and include a list of collection requirements to maintain the identity and integrity of test specimens/samples.
- 55. Each SPHL should provide collection kits for specimens and samples of all types *or* provide detailed submission information (acceptable packaging, temperature control requirements, etc.) and laboratory contact information.
- 56. Each state laboratory should confirm the identity of all isolates, regardless of submitter or point of origin.
- 57. Each SPHL should have an accessioning system with a unique number assigned to each specimen/sample for tracking and identification.

**ANALYTICAL ISSUES****Recommended Test Capabilities**

- 58. All laboratory test methods should be available electronically.
- 59. Each state should fund at least one governmental laboratory capable of testing foodborne disease pathogens in a timely manner in clinical specimens, as well as food and water samples. *At a minimum*, each state should be able to perform confirmatory testing for the foodborne illness agents indicated in Table 11 of the full report.

60. All SPHLs should have the capability to perform food chemistry tests for non-infectious, foodborne disease agents of public health significance - including environmental contaminants, natural toxins, chemical agents, and radiation - or should have access to another laboratory with such capability. At a minimum, state laboratories should have access to testing for a number of chemical agents listed in the full report.
61. Every SPHL that uses rapid test kits to identify foodborne pathogens should also culture isolates for further characterization and sub-typing whenever possible.
62. Each SPHL should have the capability to prepare media in-house, if it cannot be acquired commercially during foodborne disease outbreaks.
63. Each SPHL should be capable of testing clinical specimens and food and water samples for agents of bioterrorism.
64. All SPHLs should have full ova and parasite identification capabilities.

### **Assay Validation**

65. Each SPHL should have written protocols defining how new assays should be validated.
66. Each SPHL should be able to execute unvalidated procedures 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.

### **PulseNet Activities**

*(See also recommendations 7, 8, 75, and 83.)*

67. Each SPHL should confirm the identification of isolates that are further sub-typed. Sequential confirmation should be performed for surveillance purposes and simultaneous confirmation performed during outbreaks.
68. SPHLs should perform routine, real-time pulsed-field gel electrophoresis (PFGE) sub-typing of the following isolates: *E. coli* O157:H7, *Listeria monocytogenes*, all *Salmonella* serotypes, and *Shigella sonnei*. In addition, all SPHLs should be capable of typing *Campylobacter*, *C. perfringens*, *Vibrio*, and *Yersinia* upon request.
69. Each SPHL should have the ability to perform second enzyme sub-typing during outbreaks.

### **Storage of Isolates**

70. Each SPHL should store isolates of reportable diseases for one year.
71. All etiologic agents and infectious materials should be stored with at least two levels of security (e.g., locked storage cabinets in a restricted access area). A tiered system for various levels of risk should be developed and implemented at each state lab, with appropriate security measures (including background checks of staff members) for each risk level.

### **DATA ANALYSIS AND REPORTING**

72. Each SPHL should enter test results into PHLIS daily, with data electronically uploaded.
73. Each SPHL should report outbreak testing results on a daily basis, via both phone and computer, to the specimen submitter, state epidemiologist, and other relevant stakeholders (e.g., CDC, local health department).
74. All e-mail containing test result data should be sent with verification of receipt requested.
75. PulseNet patterns and case information should be uploaded daily. Each SPHL should respond to PulseNet postings within 24 hours.

- 76.** Results of tests that are not physician-ordered, but are administered as part of an investigation for a suspected foodborne disease outbreak, should be reported in the same manner as any test performed at the request of a physician.
- 77.** SPHLs should report unvalidated or research-procedure results with appropriate disclaimers.
- 78.** The testing methods used in studies for which Institutional Review Board approval is required must receive IRB review as part of the approval. Test result should be reported in the manner specified in the IRB approval document.
- 79.** Isolates found in non-clinical samples (e.g., food) should be reported in a common database such as the Electronic Laboratory Exchange Network (eLEXNET). Resources should be provided by the SPHL to encourage submission of samples and isolates by identifying laboratories.
- 80.** Local, state, and federal agencies should work together to standardize laboratory culture and sub-typing methods and reporting standards so that test data can be integrated and shared.
- 81.** Laboratories testing out-of-state food samples should send test reports to the submitting state rather than the state in which the food sample originated (if the two are different).
- 82.** Each SPHL should analyze laboratory data - visually and electronically - for cluster trends before reporting it to epidemiology. A “threshold” for cluster identification should consist of a statistically significant deviation from background levels rather than a specified number of cases.
- 83.** SPHLs should assign a unique name to each pathogen strain (exact match) and include this name in reports of PFGE results. In addition, laboratories should work with epidemiology officials to document information on strain relatedness as needed (including dendrograms and lists of related strains).

## INTRODUCTION

### *Foodborne Illness Is Common in the United States*

The Centers for Disease Control and Prevention (CDC) estimates that 76 million illnesses, 300,000 hospitalizations, and 5,000 deaths in the United States are caused by foodborne illnesses each year.<sup>1</sup> Moreover, the agency predicts that the incidence of investigated foodborne outbreaks affecting at least ten individuals will more than double in coming years. CDC's report of foodborne illness in the U.S. in 2002 notes that while illnesses from *Campylobacter* and *Listeria* showed a sustained decline, those caused by *E. coli* O157:H7 and *Salmonella* did not, indicating that increased efforts are needed to reduce further the incidence of foodborne illnesses.<sup>2</sup> The threat is twofold: researchers are identifying new foodborne pathogens and toxins (including antimicrobial resistant bacteria), and the changing nature of food production and commerce facilitates the widespread distribution of tainted food products. Since the terrorist attacks of the fall of 2001, the possibility of a deliberate attack on the food supply has become more tangible as well.

The causes and long-term consequences of most foodborne illnesses are unknown, and research continues to raise concerns about emerging threats from microorganisms and chemical contaminants such as pesticides. Familiar foodborne pathogens are showing up in new foods, even as new foodborne pathogens and toxins - including antimicrobial-resistant bacteria - are identified.

In recent years, the nature of reported outbreaks has changed markedly. While outbreaks in localized small groups still occur, multi-cluster epidemics involving people in multiple states are encountered more often each year. Large-scale food production, the globalization of the food supply, and increased consumption of foods prepared outside the home all increase the risk for inadvertent, widespread distribution of contaminated food products. The CDC estimates that the incidence of investigated foodborne outbreaks affecting at least ten individuals was 3.6 per million population in 1998, but that this figure will more than double to 8 per million in coming years (excluding chemical or biological terrorist events).<sup>3</sup>

### *Public Health Laboratories Take the Lead in Responding to Foodborne Illness*

Foodborne illness detection may begin when hospital and other clinical and public health laboratories screen specimens from patients being treated for suspected foodborne illness. With few exceptions, state and local public health laboratories are the primary facilities responsible for confirming the presence of foodborne microbes and toxins in clinical specimens, and for characterizing these agents in support of epidemiologic investigations. The CDC notes that state public health laboratories (SPHLs) act as "next-to-last reference centers for definitive identification of pathogenic microorganisms," with capabilities that extend beyond the routine work of clinical diagnostic laboratories.<sup>4</sup>

Despite the important role public health laboratories play to safeguard the public health, there has been little work to date to define ideal laboratory capacity to detect and respond to a foodborne disease outbreak. Without such objective benchmarks, it is difficult to pinpoint and prioritize legitimate laboratory needs; crucial gaps in equipment or staffing may be overlooked by health officials or

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<sup>1</sup> Mead PS, Slutsker L, et al. Food-related illness and death in the United States. *Emerging Infectious Diseases* 1999;5(5). Available at [www.cdc.gov/ncidod/eid/vol5no5/mead.htm](http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm), accessed on April 29, 2003

<sup>2</sup> Preliminary FoodNet Data on the Incidence of Foodborne Illnesses – Selected Sites, United States, 2002. *MMWR* 52(15): 340-343, April 18, 2003

<sup>3</sup> CDC. Essential Epidemiology and Laboratory Components of a State Foodborne Disease Prevention and Control Program. Official Memo to State Epidemiologists. Atlanta, GA; February 23, 2000.

<sup>4</sup> Ibid.

policymakers until extraordinary or tragic events focus their attention. The U.S. General Accounting Office found that “reductions in public health laboratory staffing and training have affected the ability of state and local authorities to identify biological agents.”<sup>5</sup> A coherent response to food safety hazards and foodborne diseases must be predicated upon a set of minimal, common response capabilities across jurisdictions, with well-documented mechanisms to boost laboratory capacity and coordinate with higher-level laboratories, state epidemiologists, and other responders.

The Association of Public Health Laboratories (APHL) has identified food safety as a core function of public health laboratories, noting three core capacities necessary to monitor and investigate foodborne health threats:<sup>6</sup>

- The ability to test specimens from people, foods, and beverages implicated in foodborne illness outbreaks to identify causes and sources.
- The ability to analyze food samples to detect, identify, and quantify toxic contaminants such as pesticide residues, heavy metals and volatile organic compounds.
- The ability to provide, or ensure, radiation control studies to monitor radioactive contamination of water, milk, shellfish, and other foods.

In 1999, the association published the results of a survey that characterizes the pastiche of state laboratories and other agencies responsible for regulatory compliance testing of foods and food products, and testing of suspect foods in outbreak situations. These data illustrate the complex nature of the U.S. food safety system and underscore the need for measurable benchmarks to gauge the capacity of that system over time.<sup>7</sup> The APHL Strategic Plan states the objective to, “Promote the continued development of an integrated network of public and private laboratories to assure the quality and coordination of testing.”<sup>8</sup> The association supports this objective through numerous activities, including its involvement in developing connectivity through demonstration projects of the National Laboratory System (NLS) concept. The NLS will enhance communication and cooperation between public and private laboratories assuring the coordinated delivery of public health laboratory services to detect and respond to public health threats.<sup>9</sup>

Finally, APHL members and staff participated in the development of the CDC report “*Essential Epidemiology and Laboratory Components of a State Foodborne Disease Prevention and Control Program*,” a significant step in documenting adequate public health capacity related to food safety. It outlines the basic identification capabilities laboratories must possess for almost two-dozen foodborne pathogens. In addition, the report provides a short list of necessary, specialized laboratory services, such as parasite identification, and spells out core staffing guidelines for laboratory personnel.<sup>10</sup>

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<sup>5</sup> U.S. General Accounting Office. Bioterrorism: Federal Research and Preparedness Activities. Washington, DC: GAO-01-915; September 2001.

<sup>6</sup> Witt-Kushner J, Astles RJ, et. al. Core functions and capabilities of state public health laboratories; a report of the Association of Public Health Laboratories. *MMWR* 2002;51(RR14):1-8.

<sup>7</sup> APHL. Laboratory Responsibilities for Food Safety: Results of 1999 APHL Food Safety Survey. Washington, DC; September 1999.

<sup>8</sup> APHL Strategic Plan 2002-2005, June 2002, available at [http://www.aphl.org/About\\_APHL/newstrategicplan.pdf](http://www.aphl.org/About_APHL/newstrategicplan.pdf), accessed April 23, 2003

<sup>9</sup> More information on the NLS is available at <http://www.phppo.cdc.gov/mlp/nls.asp>, accessed April 25, 2003

<sup>10</sup> CDC. Essential Epidemiology and Laboratory Components of a State Foodborne Disease Prevention and Control Program. Official Memo to State Epidemiologists. Atlanta, GA; February 23, 2000.



### ***Food Safety and Emergency Preparedness***

The CDC has identified a number of foodborne pathogens as agents that could be used by terrorists to cause illness. The “Category B” agents listed in Table 12, when used to inflict intentional harm, have the potential to cause morbidity and mortality, and can be easily disseminated.<sup>11</sup> A responsive food safety system provides laboratory capability to test for these agents, the ability to recognize small or unusual clusters of illness promptly, and the capacity needed to handle heavy testing volumes during a large-scale event.

APHL is a founding member of the Laboratory Response Network for Bioterrorism (LRN),<sup>12</sup> a CDC-supported nationwide network of private and government laboratories providing sentinel and reference testing for agents of bioterrorism. Reference testing, performed at geographically dispersed public health and other government laboratories nationwide, is conducted using standardized protocols and common reagents. Methods and reagents for foodborne pathogens are being developed and delivered to reference laboratories in the LRN. The LRN is a national asset, with state public health laboratories as its backbone, assuring quality and timeliness in testing for bioterrorist agents, and assuring national surge capacity in an event.

The threat of terrorism requires that laboratorians have access to written protocols, training, and equipment to test for rare or exotic agents that could be used to contaminate food or drinking water. State laboratories must be well connected to other public health programs, to clinical laboratories (where many human specimens will likely be first examined), to federal laboratories and agencies, to law enforcement agencies, and to emergency responders (who may collect human or environmental samples at the scene of an emergency). Finally, the laboratories and laboratorians themselves must have adequate protection to prevent inadvertent exposure to harmful agents or the unauthorized removal of dangerous biological agents.

While the Food Safety Laboratory Capacity Assessment Project was begun before the terrorist attacks in the fall of 2001, those events have necessarily influenced the final recommendations contained herein. Public health laboratories’ experience testing thousands of potential anthrax samples underscores the need for a robust laboratory system that can rapidly assess threats and can draw upon reserve assets to increase throughput - and sustain that increase over a period of weeks or months.

### ***The APHL Food Safety Laboratory Capacity Assessment Project***

The APHL Food Safety Laboratory Capacity Assessment Project is the first attempt to quantify both current and optimal laboratory capacity in a comprehensive fashion. Project findings are based on data from 51 state and territorial public health laboratories, and the considered input of experts in state public health and agriculture laboratories, federal agencies, and other professional organizations - notably the Council of State and Territorial Epidemiologists (CSTE) and the National Association of County and City Health Officials (NACCHO). The project was developed in cooperation with the CDC National Center for Infectious Diseases and is part of a larger effort, the National Food Safety Initiative, a multi-agency effort begun in 1997 to reduce the incidence of foodborne illness in the United States.

<sup>11</sup> CDC. Biological and chemical terrorism: Strategic plan for preparedness and response. *MMWR*. 2000;49(RR04):1-14.

<sup>12</sup> More information on the LRN is available at <http://www.phppo.cdc.gov/nltn/pdf/LRN99.pdf>, accessed April 24, 2003

Although project findings primarily address state public health laboratory needs, they also apply to large local public health laboratories, particularly those in populous metropolitan areas or in geographically remote locations. Project findings will also be of interest to health officials, food and drug officials, legislators, and other decision makers at the state and national levels who are responsible for allocating public health funds, setting policy, and/or coordinating the response to foodborne disease outbreaks.

APHL and partners recognize that any successful food safety response must involve close cooperation among a number of local, state, and federal entities, and especially between state epidemiologists and state laboratorians. The CDC has funded complementary projects to assess the food safety response capabilities of state epidemiology programs and of local health agencies (carried out by NACCHO and CSTE, respectively).<sup>13, 14</sup> Taken together, the findings from these two projects and the laboratory project presented here should provide a starting point for the development of state food safety response plans that clearly delineate the resources and roles of essential public health programs and the necessary points-of-contact among them.

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<sup>13</sup> NACCHO. Food Safety Programs in the United States. Results From NACCHO's 2000 Food Safety Assessment Project. Washington, DC; January 2002

<sup>14</sup> CSTE. National Assessment of Epidemiologic Capacity in Food Safety: Findings and Recommendations. Atlanta, GA; September 2002.

## METHODOLOGY

### *APHL Food Safety Laboratory Capacity Assessment Questionnaire*

The APHL Food Safety Laboratory Capacity Assessment Questionnaire was developed by the APHL Food Safety Workgroup to document public health laboratories' current food safety testing abilities. The workgroup includes representatives of state and local public health laboratories, the CDC, CSTE, and NACCHO. The survey is organized around Clinical Laboratory Improvement Act (CLIA) focus areas since these are the only widely used laboratory standards that encompass all important aspects of laboratory operations, ranging from staffing to physical plant to administrative systems. The four CLIA focus areas are infrastructure, pre-analytical issues, analytical issues, and post-analytical issues.

The initial survey was piloted in six representative public health laboratories (Florida Bureau of Laboratories, Los Angeles County Public Health Laboratory, Maine Health and Environmental Testing Laboratory, Mississippi State Public Health Laboratory, Texas Bureau of Laboratories, and Wisconsin State Laboratory of Hygiene). After revisions, the final survey was approved by the APHL Food Safety Workgroup and the APHL Board of Directors. It was mailed in July 2001 to the directors of laboratories in the 50 states, four territories, and the District of Columbia. The survey instrument is available in Appendix C.

Survey results were received at APHL headquarters in August 2001 and entered into SPSS for Windows (Release 11.0) for analysis. Descriptive statistics were generated since no theoretical model was tested. Efforts were made to use the appropriate statistic to describe prevalent national trends and the range of responses, while moderating the effect of non-representative outliers.

Fifty-one (51) of 55 laboratories (93%) completed the questionnaire, and, unless otherwise noted, survey statistics are based upon data from all respondents. Non-responders were contacted by phone and email until two weeks past the survey response deadline. Non-responders included one state and three territorial public health laboratories.

### *APHL Food Safety Consensus Conference*

The two-day APHL Food Safety Consensus Conference was convened on January 31, 2002, in Austin, Texas. Attendees are listed in Appendix B, and include laboratory experts drawn from state public health and/or agricultural laboratories in 33 states and the District of Columbia, federal agencies; CDC, the Food and Drug Administration (FDA) and the Food Safety and Inspection Service of the U. S. Department of Agriculture (FSIS/USDA), and professional associations; APHL, CSTE, and NACCHO. Conference participants were provided with a report of the findings of the APHL Food Safety Laboratory Capacity Assessment Questionnaire. Using the survey responses as a guide, attendees were asked to develop a set of consensus recommendations for *optimal* laboratory capacity and capability.

### *Study Limitations*

Because of its length and comprehensive nature, completing the APHL Food Safety Laboratory Capacity Assessment Questionnaire often required input from multiple laboratory staff. As is the case whenever multiple respondents complete a survey, the possibility for differing interpretations of questions exists.

By itself, this report cannot be assumed to identify *all* factors necessary to ensure a safe food supply. The needs of laboratories that were not surveyed by APHL or that did not participate in the consensus conference also must be considered. Finally, because there is great diversity among the population of public health laboratories included in this report, readers are advised to exercise care in making comparative analyses.

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## HIGHLIGHTS AND NEXT STEPS

The Food Safety Project survey, conducted in August 2001, pre-dated the terrorist attacks of 2001. In their aftermath policymakers and laboratorians have shifted priorities and adopted the wisdom of lessons learned that fall. Two pieces of legislation have tightened the restrictions laboratories must apply for those working with potential bioterrorism agents. State public health laboratories have received increased federal funding to build basic infrastructure for bioterrorism preparedness. These funds may or may not have affected food safety programs, and may have been offset in some cases by deep cuts in state budgets. An awareness of the risk of intentional contamination of the food supply has expanded opportunities for training and collaboration, while at the same time tying laboratorians to the bench as heightened terror alerts have resulted in travel restrictions. The landscape of the food safety laboratory has changed in ways that would have been unusual in any other similar timeframe.

### *Food Safety Laboratory Workforce Shortage*

All states and other U.S. jurisdictions must have the personnel needed to conduct core food safety functions. Yet, almost three-quarters of APHL survey respondents indicated that they were “having trouble recruiting qualified personnel” in 2001, and the majority of these respondents noted the inability to offer salaries competitive with other public and private sector opportunities as a primary factor.

While optimum staffing will vary with the size of the population served and the expected volume and complexity of food safety testing and reporting, at a minimum every jurisdiction must have staff with doctoral-level expertise in microbiology and chemistry, supported by additional staff as necessary. A significant number of the nation’s SPHLs do not meet this standard. Half of survey respondents (26) reported having no full time doctoral-level microbiologist within the food safety testing program and almost a quarter (11) indicated the presence of just one doctoral-level microbiologist assigned to food safety testing. While only half the respondents (26) noted that the SPHL conducted food testing for chemicals, only eight of these reported having a doctoral-level chemist on staff to support these activities.

Skilled workforce shortages exist across the spectrum of public health laboratory activities. Unlike equipment, which can be purchased, growing and sustaining an adequate food safety laboratory workforce will require a long-term national strategy.

### *Complex Mix of Agencies Responding to Food Safety Challenges*

State public health laboratory activities include analysis of human (clinical) specimens, such as blood or stool specimens, for foodborne disease agents including bacteria, viruses, parasites and toxins. Laboratories may analyze clinical specimens or isolates referred by clinical laboratories within the healthcare system, or may obtain these specimens or isolates directly in the course of outbreak investigations. Encouraging referral of specimens and isolates from clinical laboratories, to support epidemiologic investigation, remains a public health challenge. Most SPHLs are involved in confirmation and characterization of foodborne disease agents, using a variety of techniques, including molecular sub-typing coordinated through national databases in the PulseNet program. Food and water samples are tested in the public health laboratory in some states and in a separate agriculture or environmental quality laboratory in others. The public health response to illness and outbreaks identified by the laboratory is coordinated with epidemiologists in the health department.

A state response to foodborne illnesses may require coordination of the activities of multiple laboratories, and will involve laboratorians, epidemiologists, food and drug officials and others, depending on the nature of the health threat and the specific make-up of food safety services in each state. In addition, federal agencies are involved as needed. The U.S. Department of Agriculture, Food Safety and Inspection

Service (USDA/FSIS) inspects meat, poultry and liquid egg products in interstate commerce, and will coordinate trace-back and recall of products implicated in an outbreak. The Food and Drug Administration (FDA) is responsible for all other types of food in commerce, and offers similar support to states. The Centers for Disease Control and Prevention (CDC) may be asked by states to assist in outbreak investigation; their assistance is especially helpful when illnesses occur in multiple states. Before a source is implicated in a multi-state outbreak, all three federal agencies may be involved in an outbreak investigation, along with one or more agencies in each affected state.

### ***Gaps in Emergency Preparedness***

A third or more of responding laboratories indicated that they lack adequate space, staff, and/or equipment to handle a foodborne disease emergency. Thirty-one (31) percent reported that they have inadequate communication tools (e.g. cellular phones, pagers) to use during a foodborne disease emergency. Many laboratories reported that if needed in an emergency, they would request help from the CDC or other state or federal agencies, borrow communications equipment, re-deploy staff to foodborne disease testing, and/or require staff to work overtime.

About 40% of laboratories noted that they do not have a written plan for responding to a foodborne disease emergency either because such a plan is deemed “not necessary” or because the epidemiology program maintains such a plan. Survey responses pre-dated the terrorist attacks of 2001, and it is expected that most states now do have such plans in place.

### ***The “Chemistry Gap”***

Only about half the SPHLs report conducting food chemistry testing. Whether food chemistry is routinely conducted by another state laboratory or represents an absolute gap in capability in some states could not be determined from this project. If food chemistry capability is an absolute gap in some states, it would mirror a similar gap in SPHL capability to conduct chemical testing on clinical specimens and other types of environmental samples. In a recent APHL study of SPHL chemical terrorism capability, states reported varied activities in this area, but few states reported any breadth of capability for chemical testing.<sup>15</sup>

Just as building basic public health infrastructure for infectious disease control is the cornerstone of bioterrorism readiness, basic capabilities in analytical chemistry, delivered to states, will improve national readiness for chemical terrorism events. Such assets can be tapped for routine use to support state biomonitoring activities, the means to correlate environmental exposures with health outcomes. With chronic diseases leading the list of causes of death in Americans, states must be able to ask the right questions, and support these investigations analytically, when they are faced with cancer clusters, asthma epidemics, and other chronic disease challenges.<sup>16</sup>

### ***Recommendations for Government Officials***

While the vast majority of the more than eighty recommendations developed at the APHL Food Safety Consensus Conference are directed at laboratorians themselves, a handful involve actions that can only be taken by state and federal policymakers (Table 1). Though few in number, these include some of the most important recommendations to emerge from the project because they spell out the conditions necessary to enable state laboratories to achieve optimum analytical capabilities for food safety.

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<sup>15</sup> “An Assessment of State Public Health Laboratory Capability and Capacity to Respond to Chemical Terrorism.” APHL report, in press.

<sup>16</sup> For more information on biomonitoring programs, see <http://www.cdc.gov/nceh/dls/biomonitoring.htm>, accessed April 29, 2003.

For example, laboratories cannot meet their objectives without adequate legal authority - for the SPHL or its administrative agency - to conduct investigations of foodborne disease outbreaks. Only lawmakers can grant this authority. Similarly, outbreak investigations can be delayed or handicapped when laboratorians and other health officials are not alerted to the presence of high-priority disease agents in local or state populations. Again, only lawmakers can mandate that positive test results and isolates for high-priority pathogens be quickly forwarded from parties in the healthcare system to public health officials.

Policymakers are called upon to provide the funding to support recommendations contained herein. Recognizing that public health laboratories are an integral part of the nation's homeland security system, federal public health agencies are tasked with supporting and sustaining an adequate state and local public health laboratory infrastructure.

Other recommendations call for increased rigor and professionalism in the fields of laboratory science and public health. Government officials and professional organizations should work together to standardize laboratory testing and reporting methods so data can be integrated and shared at the state and national levels. Policymakers should mandate professional licensure and/or minimum continuing education requirements for food chemists and microbiologists. And CDC officials should communicate the results of PulseNet proficiency tests in a timely manner.

### *Next Steps*

APHL intends to conduct a follow-up survey of SPHLs to determine how laboratories stack up against the project recommendations, and to gauge changes resulting from heightened terrorism preparedness activities. Workforce trends, a perennial challenge, will receive special emphasis.

A follow-up survey will also allow exploration of unexpected findings from the first survey. For example, only about half the SPHLs report conducting food chemistry testing. On re-survey SPHLs lacking food chemistry capability will be asked to explain whether this activity resides in a different state agency, to determine whether this type of testing is available in all states. Food chemistry capability will be better described by asking questions about testing for specific types of agents, such as industrial and agricultural chemicals, drug residues, mycotoxins and histamines, and by further exploring the types of foods (meat, produce, milk, water etc.) routinely subjected to chemical testing. Questions about radiochemistry capability will be proposed similarly.

APHL plans to conduct a series of tabletop exercises to explore the response to foodborne illness challenges in a sample of SPHLs representing the spectrum of food safety testing activities. Scenarios will be developed to reflect expected challenges, to determine the responsiveness of the laboratories to situations likely to occur; a multi-state outbreak is an example. Systems will also be tested using unlikely scenarios or those with little historical precedent, to determine the flexibility of the laboratories in response to novel situations; a suspected terrorist event involving food, and a foodborne outbreak linked to an unusual food vehicle are examples. The exercises will shed light on the effectiveness of activities leading to laboratory investigation, analytical capability, results reporting, and the interaction of a variety of experts and jurisdictions in achieving an effective public health outcome.

**Table 1. Selected Recommendations for Government Officials**

- |            |  |
|------------|--|
| <b>#1</b>  | <b>Each state public health laboratory (SPHL) should have clear legal authority to conduct outbreak investigations, even if this authority does not rest directly with the laboratory.</b>   |
| <b>#2</b>  | <b>State law should mandate that hospital 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 laboratory.</b>  |
| <b>#8</b>  | <b>CDC officials should communicate PulseNet certification and proficiency test results in written format to all submitters within 60 calendar days.</b>   |
| <b>#17</b> | <b>The SPHL budget should be based on defined optimal capacity and capability. The budget should include a fund to support enhanced laboratory activities during a public health emergency and a fund to support continuing education activities.</b>  |
| <b>#18</b> | <b>Federal public health agencies should contribute funding to build and maintain state and local public health laboratory infrastructure. SPHLs should proactively participate in requests for federal funding.</b>   |
| <b>#41</b> | <b>Food chemists and microbiologists should be required to participate in continuing education (CE) programs. For states that do not currently require professional licensure, laboratorians should be required to earn <i>at least</i> twelve hours of CE credits per year, with the number of hours documented in personnel files.</b> |
| <b>#80</b> | <b>Local, state, and federal agencies should work together to standardize laboratory culture and sub-typing methods and reporting standards so that test data can be integrated and shared.</b>  |



## DETAILED RECOMMENDATIONS AND SURVEY FINDINGS

### LABORATORY INFRASTRUCTURE

#### Administration/Organization

##### *Legal Issues*

- 1. Each state public health laboratory (SPHL) should have clear legal authority to conduct outbreak investigations, even if this authority does not rest directly with the laboratory.** In cases where the state laboratory does not have direct legal authority, the agency with administrative oversight of the laboratory should possess such authority. Currently, the majority of SPHLs (47 laboratories representing 92% of survey respondents) have “adequate legal authority” based on state laws (61%) and/or regulations (69%) to conduct testing for foodborne disease investigations. While fewer state laboratories have direct legal authority to collect laboratory or clinical reports on notifiable foodborne diseases (33%) or suspected foodborne diseases (26%), this authority generally rests with the state epidemiology office. In no case did respondents indicate that the public health system lacked legal authority.
- 2. State law should mandate that hospital 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 laboratory.** In 2001, mandatory isolate referral for reportable foodborne pathogens occurred in 20 SPHLs (of 50 reporting), with most of these laboratories receiving voluntary submissions of isolates from laboratories within the state. Laboratories in states where such submissions are not mandated may consider developing a means to encourage voluntary submission of samples, such as providing collection kits and pre-paid addressed mailers. Thirty SPHLs (of 50 reporting) indicated that they lack the authority to obtain specimens and/or isolates for foodborne disease testing during an outbreak. Only 41% (of 46 respondents) affirmed that out-of-state laboratories generally forward positive results of tests for reportable foodborne diseases to the SPHL.
- 3. SPHLs testing specimens for legal or regulatory purposes must have chain-of-custody procedures in place.** About two-thirds of survey respondents (33 of 49 reporting) noted that they do not have chain-of-custody procedures in place.<sup>17</sup>
- 4. Each SPHL should have a policy clearly defining entities to which public health laboratories have the authority to ship isolates (e.g., universities, CDC, other federal agencies, other public health laboratories). The policy must conform to state and federal regulations.** Just under a third of APHL survey respondents (31%) reported that such a policy was in place in 2001.
- 5. States should verify compliance with all relevant state and federal laws and regulations regarding licensure agreements with commercial companies for the use of proprietary technologies, supplies or reagents.** Only a few respondents (8 of 45 reporting) noted that they possess licensure agreements with commercial vendors.

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<sup>17</sup> This statistic pre-dates the terror attacks of 2001. As all SPHLs were involved in anthrax testing to support the Federal Bureau of Investigation’s Amerithrax investigation (see <http://www.fbi.gov/anthrax/amerithraxlinks.htm>, accessed April 29, 2003) it is expected that on re-survey most or all SPHLs will be compliant with this recommendation.

### **Laboratory Certifications**

6. **Every SPHL should be accredited for its scope of testing by a recognized accrediting authority using internationally recognized criteria.** All SPHLs are required to meet the certification requirements of the Clinical Laboratory Improvement Act (CLIA). Passed by Congress in 1967, CLIA provides for federal regulation of all U.S. laboratories that receive Medicare reimbursements or are involved in interstate commerce. Additionally, conference participants endorsed the resolution on laboratory accreditation issued by the Association of Food and Drug Officials in 1999.<sup>18</sup> This statement supports laboratories' acceptance of ISO 17025 "as a minimum standard to define laboratory operations and quality practices," provided that:
- This standard is accepted by all accrediting bodies.
  - Only a single auditing body is necessary to ensure that the standards are being maintained by a laboratory.
  - Acceptance of ISO 17025 is contingent upon the necessary proficiency testing and laboratory operations being in place and auditable to the type of testing - medical, food safety, or environmental - that distinguishes the analysis performed by the laboratory.

As shown in Table 2, all survey respondents reported CLIA certification, but only one indicated current compliance with ISO 17025 standards. Other certifications may reflect the variety of food and beverage testing conducted by SPHLs.

**Table 2. State Public Health Laboratory Certifications - 2001**

<b>Certification</b>	<b>Number of SPHLs reporting (n=51)</b>
CLIA	51
EPA	39
Interstate Milk Shippers	22
State	17
College of American Pathologists	14
Interstate Shellfish Sanitation Conference	7
NELAC	7
ISO 17025	1
Other (FDA, AIHA, NRC, others)	20

7. **All SPHLs should complete PulseNet certifications for *E. coli* O157:H7, *Listeria monocytogenes*, *Salmonella* Typhimurium, and *Shigella sonnei*.** PulseNet is the CDC network of public health laboratories that perform a DNA "fingerprinting" method called pulsed-field gel electrophoresis (PFGE) on foodborne bacteria. The network permits rapid comparison of fingerprint patterns through an electronic database, providing critical data for the early recognition and timely investigation of outbreaks, thus reducing the burden of foodborne disease. PulseNet participants include all 50 state public health laboratories.<sup>19</sup>

Of 51 survey respondents, most had submitted data for PulseNet certifications for *E. coli* O157:H7 (44) and *Salmonella* Typhimurium (39). Less than half had done so for *Listeria monocytogenes* (20) and *Shigella sonnei* (19).

<sup>18</sup> Association of Food and Drug Officials. Resolution 99-10, "Endorsing Vision for ISO 17025 Standards of Accreditation." Issued during the AFDO annual meeting, San Antonio, Texas, June 1999.

<sup>19</sup> More information about PulseNet is available at the CDC PulseNet home page, <http://www.cdc.gov/pulsenet/>

- 8. CDC officials should communicate PulseNet certification and proficiency test results in written format to all submitters within 60 calendar days.** As of the time of survey completion, slightly more than half of the SPHLs that submitted data for certification had received results for *E. coli* O157:H7 and *Salmonella* Typhimurium. Slightly less than half of those submitting data for *Shigella sonnei* had received results, and about a third of those for *Listeria monocytogenes* had received results. Cooperative activities between CDC and APHL to improve timely reporting are ongoing, and it is likely that these measures will show marked improvement upon re-survey.

### ***Coordination with Partners***

An overview of state food safety laboratory activities is provided in Table 3. State public health laboratory activities in food safety microbiology are depicted in Table 4.

- 9. The organization of laboratories is not as significant as their ability to communicate, coordinate funding, and share resources. Working relationships among state public health programs should be formally defined in a written communication plan before a crisis arises.**
- 10. Ideally, the SPHL, state office of epidemiology, and state food protection program should be located in the same building, but regardless of location, communication and interaction must take place.** Just 24% of survey respondents indicated that the SPHL and state office of epidemiology are located within the same building, while 88% are located within the same agency administratively.

Most respondents rate the relationship between the SPHL and state epidemiology program as a positive one, earning an average score of 8.6 on a ten-point scale, where 10 equates to *excellent*. Asked to rate state epidemiologists' "capacity to act on laboratory data," respondents assigned an average score of 7.8. However, only two-thirds of respondents felt that laboratory capability is being "adequately utilized" by the state epidemiology program. According to laboratorians, factors that limit epidemiologists' full utilization of laboratory resources include limited staff, poor interdepartmental communication, lack of defined policies, lack of electronic data systems, lack of statistical support, and lack of perceived importance. Of these, the factor most commonly cited was limited staff (noted by roughly 40% of respondents).

Fully 80% of respondents reported that the SPHL is routinely notified by the state epidemiologist when outbreaks are suspected, while 18% are "occasionally" notified. Only one respondent reported that the laboratory is generally not notified.

- 11. Each public health laboratory should initiate an agreement with the state epidemiology office whereby the epidemiology program routinely provides feedback to the laboratory on the status of outbreak investigations and on disease clusters identified by the laboratory. If the epidemiology program fails to provide this feedback, the laboratory should proactively follow up with epidemiology.** On a scale from 1 to 10 (with 10 being *excellent*) survey respondents assigned an average score of 7.5 to "feedback from epidemiology regarding ongoing or completed investigations." Forty-four percent of respondents (of 50 reporting) noted that they "always" receive feedback from the epidemiology program regarding investigations initiated as a result of specific laboratory results. Fifty-one percent noted that they "sometimes" receive this feedback, and only two respondents indicated that they "never" receive feedback.

Three quarters of respondents indicated that they routinely follow up with the epidemiology program if no feedback is received on disease clusters identified by the laboratory.

**Table 3. State Laboratory Food Safety Functions - 2001**

Food Safety Function	State Laboratories Conducting the Function (# respondents=51. Row totals may exceed 51 if multiple state laboratories conduct the food safety function)			
	Public Health	Agriculture	Environmental	Other*
<b>Food Microbiology:</b>				
• Outbreak investigation	49	9	4	1
• Surveillance	27	19	3	3
<b>Clinical microbiology:</b> (human specimens)				
• Outbreak investigation	51	0	0	1
• Surveillance	46	0	0	1
• Epidemiologic investigation	51	4	4	6
<b>Food Chemistry:*</b>				
• Outbreak investigation	24	13	4	4
• Surveillance	17	16	4	7
<b>Environmental Health Specialist Program (sanitarians)</b>	32	10	13	3

\* Other includes federal, private sector and law enforcement laboratories

\* 26 respondents stated that the SPHL conducted food chemistry testing, either outbreak investigation or surveillance. All SPHLs conducted food microbiology.

**Table 4. SPHL Food Safety Microbiology Testing Activities - 2001**

Specimens or samples tested	Number of states reporting that testing is conducted (n=51)			Range of reported annual test volume	
	Yes	No	Non-response	Low	High
<b>Human (clinical) specimens</b>					
• for any agent	50	1	0	-	-
• for bacteria	49	2	0	30	16,000
• for viruses	28	18	5	10	500
• for parasites	40	9	2	4	6,410
<b>Food samples</b>					
• for any agent	48	3	0	-	-
• for bacteria	48	3	0	5	7000
• for viruses	7	39	5	10	200
• for parasites	10	38	3	1	70
<b>Water samples</b>					
• for bacteria	33	17	1	1	65,000
• for viruses	3	40	8	1	30
• for parasites	12	35	4	1	100

- 12. State public health officials should ensure that decisions involving laboratory and epidemiologic data be made by teams that include staff from the SPHL and other appropriate state programs and/or agencies. All identified disease clusters should be investigated by the state epidemiology program, and all team members should be notified.** Twenty-five laboratories reported identifying clusters based on formal criteria. Four of these involve state epidemiologists in setting thresholds for reporting a cluster to epidemiology. Almost all respondents indicated that epidemiologists investigate reported clusters for most organisms 100% of the time.
- 13. Each SPHL should have formal access to a laboratory testing *all* known foodborne pathogens in clinical specimens and food, and water samples.** Because some tests require complex protocols or the use of difficult-to-maintain reagents, not all state laboratories may be capable of performing testing for *all* known foodborne pathogens (e.g., isolating Norwalk-like virus from water or food samples or performing mouse inoculation assays for botulinum toxin). Therefore, each SPHL should maintain an arrangement with another laboratory - either a working agreement with another SPHL or a contract with a commercial laboratory - for testing that cannot be performed in the state lab.

### *Emergency Planning*

- 14. Each SPHL should have a written plan - developed in cooperation with the state office of epidemiology, the state food protection program, state department of agriculture, and other relevant agencies - outlining the roles and responsibilities of each entity in the event of a foodborne disease outbreak.**
- 15. Emergency plans should include provisions to secure adequate laboratory space for surge capacity through agreements with local or regional facilities.**

In emergency situations state laboratories must have the ability to communicate and share resources with a multitude of other programs and agencies, including state epidemiology programs, state food protection programs, state boards of health, the CDC, FDA, FSIS/USDA and state departments of agriculture, and state and federal law enforcement agencies. Communication and resource-sharing policies should be clearly delineated in formal agreements that include provisions for use of facilities, equipment, and connectivity for surge capacity needs. In addition, an emergency plan should define the roles of each of the agencies involved, current and after-hours contact information for emergency response staff, and a process for reporting test results.

APHL survey data suggest that there is a need to enhance SPHLs' capacity to handle surge events. One-third or more of responding laboratories indicated that they lack adequate space (39%), staff (33%), and/or equipment (35%) to handle a foodborne disease emergency. Thirty-one (31) percent reported that they have inadequate communication tools (wireless phones, pagers, etc.) to use during a foodborne disease emergency. In the event a foodborne crisis occurs, many respondents noted that they would request help from the CDC or other state or federal agencies, borrow communications equipment, reassign staff to foodborne disease testing, and/or require staff to work overtime. About 40% of laboratories reported that they do not have a written plan that can be implemented during a foodborne disease emergency either because such a plan is deemed "not necessary" or because the epidemiology program maintains such a plan. Survey responses predated the terrorist attacks of 2001, and it is expected that most states now do have such plans in place.

- 16. Each SPHL should have a plan for rapid delivery of samples/specimens to the laboratory during an emergency.** Hand delivery is generally considered the most efficient method to ensure rapid transport of material requiring time-dependent testing (e.g. water samples within 6 hours, clinical specimens and shellfish samples within 24 hours). Use of public health and private couriers that operate entirely in-state is advantageous because these entities may be exempt from interstate shipping regulations that can be costly and burdensome to laboratories. Statewide public health courier systems also encourage reporting and isolate submission by avoiding submitter shipping costs, and are able to re-prioritize deliveries in an emergency. But, like all state services, public health courier systems are vulnerable to budget cuts.

In practice, virtually all state laboratories use a variety of delivery methods, such as commercial shipping services (92%), the U.S. Postal Service (84%), public health couriers (43%), and other methods (98%), including hand delivery by epidemiologists, specimen submitters, collecting agencies, hospital couriers, highway patrol officers and others (Table 5). With the notable exception of the U.S. Postal Service, the average transport time is generally 48 hours or less. Unless specimens are hand-carried or transported by public health courier, respondents indicated that specimen submitters are usually required to pay transportation costs.

**Table 5. Methods for Transport of Samples/Specimens to SPHLs (n=51)**

Transport Methods	# Respondents	% Respondents
Commercial shipping service (e.g., UPS)	47	92
U.S. Postal Service	43	84
Public health courier	22	43
Other	50	98

### *Budget*

- 17. The SPHL budget should be based on defined optimal capacity and capability. The budget should include a fund to support enhanced laboratory activities during a public health emergency and a fund to support continuing education activities.** Ideally, each SPHL will strive to meet the recommended capacities and capabilities defined in this document, and will therefore use it as the basis for budget development. It is difficult to develop a formula for a base budget, since funding sources for food safety programs vary by state. SPHLs may find it useful to review the food safety budgets and capabilities of other laboratories within their region to justify appropriations necessary to achieve optimum recommended capacities and capabilities. (See Table 10.)
- 18. Federal public health agencies should contribute funding to build and maintain state and local public health laboratory infrastructure. SPHLs should proactively participate in requests for federal funding.** States reported a variety of funding sources their food safety laboratories, though 16 respondents stated they received no federal support for these activities. Among federal funding sources reported, one state reported receiving support from both USDA and FDA. Thirty-four respondents reported receiving federal funds from CDC, through Epidemiology and Laboratory Capacity/Emerging Infections Programs cooperative agreements.<sup>20</sup> Eight of these also reported additional funding through CDC bioterrorism capacity grants.

<sup>20</sup> See <http://www.cdc.gov/ncidod/osr/ELC.htm> and <http://www.cdc.gov/ncidod/osr/EIP.htm>.

Ideally, funding should be available through CDC, FDA, FSIS/USDA, and other federal public health agencies to support the infrastructure needed to assure a minimum level of food safety test capability across the country. SPHLs should also have the ability to request emergency funds to support heightened activities in response to a large foodborne disease outbreak. Further analysis is needed to assess budget constraints and possible funding mechanisms to address gaps in laboratory food safety programs. As funding opportunities arise, laboratories should take advantage of them by documenting laboratory needs and meeting with other public health staff as necessary to assure that laboratories are included in any request for funds.

## Facilities

- 19. Each SPHL should have physical space sufficient to accommodate bench testing, equipment storage, office and administrative support functions, and surge capacity. Every SPHL should have lockable evidence space.**<sup>21</sup> SPHLs must have adequate facilities for research, testing, and analysis. Between half and two-thirds of APHL survey respondents reported that they currently have adequate space for: bench testing (61%), equipment (65%), administrative activities (57%) and general storage (53%). Space needs reported included; “15,000 square feet for bench testing;” “four offices;” “75% increase in storage space;” “two rooms for virology work;” and a “clean room.”
  - 20. Each SPHL should have a secure area - with appropriate environmental controls - for receipt and storage of samples and specimens.** Staff with access to this area should follow delineated sample/specimen protocols and have appropriate security reviews, including criminal background checks. This secure area should include:
    - A log-in area/station for receipt of samples.
    - Locked freezers/storage.
    - Electronic access with tracking of entry and exit.
    - Back-up power supply.
- See footnote #21 below regarding the Select Agent regulation. This recommendation now has the force of law when certain foodborne agents (as listed in Table 12) are handled.
- 21. Each SPHL should have access to an animal facility in which to perform bioassays for detection of foodborne illness in humans.** In 2001, just 41% of SPHLs had access to an animal facility. Thirty-nine percent of respondents indicated that they perform animal assays for detection/identification of foodborne agents. Of these, 60% indicated that they perform assays for identification of botulinum toxin, the most common agent identified via animal assays. Laboratories that are not able to perform animal assays rely mainly on the CDC for this service, although a few laboratories also send samples to other state laboratories or to the FDA.
  - 22. Each SPHL should have access to a satellite downlink system and other appropriate distance-learning equipment within the building housing the laboratory.**
  - 23. Each SPHL should have a back-up power supply.**

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<sup>21</sup> This statistic pre-dates the effective date of the Select Agent regulation, 42 CFR 73. As of February 2003, laboratories handling potential agents of bioterrorism must restrict access to the agents. More information about the Select Agent program is available at <http://www.cdc.gov/od/sap/>, accessed April 24, 2003

## Equipment

### *Testing/Safety Equipment*

Tables 6, 7 and 8, listing minimum recommended laboratory equipment and described below, are not meant to imply that other tools are not also necessary for specific laboratory activities. It is also assumed that laboratories will replace older devices with new instrumentation as it becomes commercially available.

- 24. Each SPHL should have equipment available to perform all necessary culture and identification testing, rapid diagnostics, and characterization of isolates for investigation of foodborne disease pathogens. (See pathogens/ toxins listed in Table 11). In addition to the equipment needed for traditional food microbiology testing, *at a minimum* each SPHL should have the molecular diagnostic equipment listed in Table 6.** As shown in Table 6, no piece of recommended equipment was available on-site in *all* SPHLs in 2001. Notably, essential polymerase chain reaction (PCR) equipment and spectrophotometers were lacking in nearly 40% of SPHLs, and three-quarters lacked fluorimeters.

**Table 6. Minimum Recommended Molecular Diagnostic Equipment for SPHLs**

Minimum Equipment Recommended	% SPHLs where available – 2001 (n=51)
Pulsed-field gel electrophoresis equipment	90
Microplate washer	82
Reagent grade water purification system	92
Thermal cyclor	82
Real-time polymerase chain reaction cyclor	63
Spectrophotometer	61
Fluorimeter	24
Microplate reader	78
Computerized gel documentation	75

- 25. Each SPHL should have at least one biological safety cabinet, readily available for food safety testing.** As of 2001, four SPHLs (of 50 reporting) had no biological safety cabinets available for foodborne disease testing. The optimum number of biosafety cabinets overall must be determined by individual laboratories, based on the type of testing performed in the laboratory and anticipated level of surge capacity needed. SPHLs should coordinate with all laboratories in the state to accommodate surge capacity if the optimum number of biosafety cabinets cannot be acquired.
- 26. Each SPHL should have at least one Biological Safety Level-3 (BSL-3) isolation room readily available for food safety testing, with one reserved as back-up for emergency use.** As of 2001, 20% of SPHLs (10 of 51 reporting) indicated that they had no BSL-3 facilities. Thirteen laboratories had only one BSL-3 isolation room.
- 27. Each SPHL should have at least one radiation detector to screen samples upon arrival at the laboratory.**



- 28. Each SPHL should have the equipment to perform organic and inorganic analyses to detect, separate, and quantify chemical contaminants in food. At a minimum, SPHLs should have each piece of equipment listed in Table 7.** As shown in Table 7, some of the 26 SPHLs that report that they conduct food chemistry lack access to essential equipment.

**Table 7. Minimum Recommended Food Chemistry Equipment for SPHLs**

Equipment	# of SPHLs where available - 2001 (n=26)
High pressure liquid chromatograph	25
Gas chromatography mass spectrometer	26
Atomic absorption analyzer	24
Fourier transform infrared spectroscopy	8
Liquid chromatography mass spectrometer	8
Inductively coupled plasma analyzer	18
Graphite furnace atomic absorption analyzer	18
Immunoassay	18

- 29. Each SPHL should have access to specialized equipment, such as a DNA Sequencer.** If not available within the laboratory, states should coordinate the use of this equipment locally or regionally, as necessary. In 2001, 31% of SPHLs had a DNA sequencer available for use.

### *Communications Equipment*

- 30. All SPHLs should have a complete set of telediagnostic equipment available on-site.** This equipment - digital cameras, camera adapters, trinocular microscope, computer and peripherals with modem hook-up, etc. - electronically transmits microscopic images to reference laboratories for rapid identification of parasites and other disease agents and, in some cases, eliminates the need for further analysis. As shown in Table 8, a significant number of SPHLs did not have basic telediagnostic equipment in 2001.

**Table 8. Minimum Recommended Telediagnostic Equipment for SPHLs**

Equipment	Number SPHLs where available - 2001 (n=51)
Digital camera	30
Camera adapters	27
Trinocular microscope	24
Computer and peripherals	35

- 31. To ensure communication with critical partners in emergency situations, each SPHL should possess, at a minimum, pagers or mobile phones for essential staff and a two-way radio for the laboratory.** Just over two-thirds (69%) of survey respondents indicated that their laboratories have adequate communications tools such as mobile phones and pagers, to use during a foodborne disease outbreak. Ideally, pagers and/or mobile phones should have dedicated phone number(s). These communications tools should be used only during drills and emergencies and staff should

know where equipment is at all times. If necessary, many respondents indicated that they would contact the state epidemiology office or borrow equipment to enhance communication capabilities.

- 32. Every SPHL should have an adequate number of computers with sufficient capability - including Web-based reporting - to carry out the work of the laboratory.** Ideally, each supervisor/manager should have his/her own computer, and sufficient additional computers should be available in laboratory areas to *efficiently* enter patient information, test results, and quality control data and to create all necessary statistical reports in routine and emergency situations. It is especially important that SPHLs be able to electronically exchange data with other laboratories and agencies as part of routine disease surveillance and during foodborne disease outbreaks. Essential personnel should have immediate access to a portable computer with modem during an emergency. Twenty (20) APHL survey respondents (39%) reported that they lack sufficient computer hardware for foodborne disease testing. A similar number (21 respondents) noted that they do not have adequate software for their food safety testing programs.

## Personnel

### *Staffing*

- 33. Every state, regardless of population, should have laboratory staff trained in a) quality assurance, b) molecular microbiology, c) food microbiology, and d) analytical chemistry. In addition, every SPHL must have clerical and support staff in sufficient numbers to serve the needs of the state population.** See Table 9 for a display of staff proficient in various analytic activities. While all respondents reported that at least two persons are trained to conduct clinical enteric bacteriology, 28 respondents did not have anyone trained to perform food chemistry testing.

**Table 9. Number of Persons Trained/Proficient to Perform Testing - 2001**

Analytic Activity	Number of Labs at Staffing Level (N=51)				Median # of Staff Reported (N=51)
	Reporting 0 persons	Reporting 1 person	Reporting 2 persons	Reporting > 2 persons	
Conventional Food Microbiology	1	5	13	32	3
Clinical Enteric Bacteriology	0	0	6	45	4
Clinical Enteric virology	12	10	12	17	2
Serology	13	4	2	32	3
Parasitology	4	8	15	24	2
Food Chemistry	28	8	5	10	0
Molecular Biology – PCR	9	12	9	20	2
Molecular Biology - PFGE	3	15	17	16	2

- 34. SPHLs should have staff with doctoral-level expertise in both microbiology and chemistry.** Optimum staffing must consider the size of the population served and the anticipated volume and complexity of food safety testing, analysis, and reporting. However, every jurisdiction must have the human resources needed to conduct core food safety functions. The CDC suggests that core staffing needs can generally be met with one full-time-equivalent (FTE) doctoral-level microbiologist for every 10 million population and one FTE bachelors-level microbiologist per 0.5 million population.<sup>22</sup> Half of APHL survey respondents (26) reported that they have no full time doctoral-level microbiologist within the food safety test program and almost a quarter (11) indicated the presence of just one doctoral-level microbiologist assigned to food safety testing. While only half the respondents (26) noted that the SPHL conducted food testing for chemicals, only eight of these reported having a doctoral-level chemist on staff to support these activities.
- 35. Each SPHL should have a preplanned on-call schedule, with support available 24 hours a day, 7 days a week.** An on-call schedule should be posted in the laboratory with contact information for each staff member. Each laboratory must determine the number and type of on-call personnel required, but on-call staff would probably include testing personnel and specimen processors at a minimum. Since the terror attacks of 2001, public health laboratories have learned that testing volume can increase dramatically in emergency situations extending over a period of weeks or months, necessitating sustained increases in laboratory capacity. In addition to the use of on-call staff, strategies may include ‘borrowing’ staff from clinical laboratories, or developing a pool of qualified volunteers that can be called upon during extraordinary surge events. Almost all survey respondents (94%) indicated that the state laboratory is available for emergency response 24 hours a day/7 days a week. Four of the 51 respondents noted that their laboratories have routine hours on Saturdays.
- 36. Every SPHL should have dedicated computer support personnel.**

### *Compensation*

- 37. Staff salaries should be based upon training and experience, with experienced new staff compensated at a rate above the standard entry-level salary for their position. In addition, SPHLs should provide a clear career development path for laboratorians to advance professionally through the organization.**
- 38. SPHLs should offer competitive compensation packages (including benefits and local cost-of-living adjustments) to hire and retain qualified personnel.**

Almost three-quarters of APHL survey respondents indicated that they were “having trouble recruiting qualified personnel” in 2001, and the majority of these respondents noted that the inability to offer salaries competitive with other public and private sector opportunities was a major contributing factor.

Since funding sources and cost-of-living standards vary considerably across the country, it is not appropriate to define “ideal” salary ranges to apply to all states. Laboratory directors may find it useful to compare staff salaries to the ranges reported in Table 10, though incomplete reporting may decrease the utility of this information. Recognizing that salaries and benefits must be competitive to hire and retain qualified personnel, data in Table 10 suggest that at least some states may be unable to offer compensation at levels adequate to hire more highly trained staff.

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<sup>22</sup> CDC. Essential Epidemiology and Laboratory Components of a State Foodborne Disease Prevention and Control Program. Official Memo to State Epidemiologists. Atlanta, GA; February 23, 2000.

**Table 10. SPHL Reported Staff Salary Ranges by Program and Training - 2001**

	Annual Salary Range
<b>Microbiology Program</b>	
Doctoral-level (n=23)	\$25,600 – 130,000
Masters-level (n=29)	\$25,600 – 80,000
Bachelors-level (n=47)	\$18,000 – 70,000
<b>Chemistry Program</b>	
Doctoral-level (n=8)	\$27,900 – 93,000
Masters-level (n=13)	\$23,000 – 80,000
Bachelors-level (n=24)	\$18,000 – 75,000

39. The salary ranges for professional laboratory staff within a state (e.g., microbiologists, chemists, forensic analysts) should be comparable, although individual pay may vary based on education and experience.
40. State laboratories should have adequate resources available to provide overtime and on-call pay to employees.

#### *Training and Continuing Education*

41. Food chemists and microbiologists should be required to participate in continuing education (CE) programs. For states that do not require professional licensure, laboratorians should be required to earn *at least* twelve hours of CE credits per year, with the number of hours documented in personnel files. Just over three-quarters (77%) of SPHLs have no job-related continuing education requirement for laboratory staff. Among those that do, the median requirement is 12 CE hours per year. Even though most states do not have a job-related CE requirement for laboratory staff, fully 90% of all SPHLs document continuing education and other professional training “in an official manner” (usually in the personnel file or on the performance evaluation).

Survey respondents mentioned training in molecular methods as the most common area for which available training opportunities should be expanded.

42. Analysts should be provided with hands-on and Web-based bench training opportunities specific to food safety testing and sample collection, as appropriate to each analyst’s subject area. Appropriate federal and/or state agencies should provide the infrastructure for this training at state and/or federal facilities. The National Laboratory Training Network (NLTN) and state training coordinators should maintain a resource file for food safety training opportunities. Laboratories can use training as a mechanism for professional growth and an incentive to begin or continue careers with the SPHL. Training must be adequate to allow analysts to stay current in their field and to meet all federal requirements. The vast majority of survey respondents noted that their state laboratory either provides training for foodborne disease testing and/or supports training through the use of external sources such as the NLTN.

- 43. Each state laboratory should have a designated training coordinator.** In the 2002 APHL Core Functions survey, 38 of 48 SPHL respondents stated that they had a designated laboratory training coordinator.<sup>23</sup>
- 44. Each SPHL should cross-train employees within and between its food and clinical laboratory sections, with career advancement as one incentive for cross-training.** Cross-training—training employees in areas beyond their primary work responsibilities—is at least a partial solution for laboratories that are unable to hire new staff due to budget constraints. Individuals with adequate cross-training can provide coverage for staff in other positions in both routine and surge capacities. All but one of APHL survey respondents noted that cross-training is provided in their laboratories.

## Information Management

### *Information Management Systems*

- 45. Every SPHL should have a laboratory information management system (LIMS) that complies with National Electronic Disease Surveillance System (NEDSS) communication standards.** NEDSS is a CDC initiative to create integrated surveillance systems capable of transferring public health, laboratory, and clinical data efficiently and securely over the Internet.<sup>24</sup> In 2001, just over two-thirds of SPHLs (69%) had a LIMS. Of these, at least a third were developed or customized “in-house.” At least 14% of SPHLs use the CDC’s LIMS software, LITS Plus™, and another 14% use Epic software (Epic Systems Corporation).
- 46. Every LIMS should interface with state and local epidemiology and environmental health computer systems to facilitate rapid electronic data exchange.** As of 2001, just nine SPHLs (18% of 50 reporting) affirmed that the laboratory computer system directly interfaced with the state epidemiology computer system. Only four SPHLs (of 49 reporting) reported that the laboratory system interfaced with the state environmental health computer system.
- 47. Each LIMS should be capable of electronically transmitting data to the CDC computer system, Public Health Laboratory Information System (PHLIS).** As of 2001, about half of SPHLs had this capability.

### *Data Accuracy/Security*

- 48. The accuracy of data entry of all test results should be verified at the time of entry.**
- 49. Every SPHL should have a written policy to protect the confidentiality of patient data.** Eight-eight percent of APHL survey respondents indicated that such a policy is in place.<sup>25</sup>
- 50. Data security measures should include locked files, password and ID protected access to sensitive laboratory areas, and other safeguards depending on the type of media (paper file, electronic file, etc.).** Although respondents report a variety of security measures, including secure building and ID and password protections, a third noted that data are stored in unlocked files.

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<sup>23</sup> APHL Core Functions Survey (FY2002), Summary of Results, September 2002

<sup>24</sup> More information is available at [www.cdc.gov/nedss](http://www.cdc.gov/nedss). See also the APHL publication *Advancing the National Electronic Disease Surveillance System: An Essential Role for Public Health Laboratories* (January 2002).

<sup>25</sup> Public health and other laboratories are responsible for updated patient confidentiality protections under provisions of Health Insurance Portability and Accountability Act, PL 104-191 (1996). Regulatory privacy provisions became effective April 2003.

*Laboratory Web site***51. Each SPHL should have a Web site that provides necessary information in a user-friendly manner.** At a minimum, SPHL Web sites should contain:

- The laboratory's physical address and mailing address
- Main phone and fax numbers
- E-mail contact for Web site content
- Hours of laboratory operation
- Emergency contact information
- Contact information for essential staff
- Current list of services and fee schedule
- The process for submitting clinical specimens and food/water samples to the laboratory
- An alphabetical directory of laboratory departments, if applicable

At least 82% of SPHLs report having a Web site. However, on a scale from 1 to 10 (where 10 is *excellent*), survey respondents rate the "adequacy" of the laboratory Web site as 5.3 on average.

**SUBMISSION OF SPECIMENS/SAMPLES****52. Each SPHL should have written collection protocols for specimens and samples within the scope of testing performed.** Almost all respondents (96%) reported the use of written collection protocols for clinical specimens, and 73% reported the use of written collection protocols for food samples.**53. Each SPHL should have written rejection criteria for specimens and samples within the scope of testing performed.** Ideally, the same rejection criteria should be used for routine diagnostic testing and outbreak testing. Specimens that meet the criteria for rejection may be analyzed at the discretion of the laboratory, with the test record and report documenting specimen problems. Fully 90% of APHL survey respondents report that their agencies possess rejection criteria for "clinical outbreak specimens"; 69% (of 50 reporting) possess criteria for rejection of "food outbreak samples." Just over a quarter of respondents (14 of 48 reporting) noted that their laboratories employ different rejection criteria for routine diagnostic and outbreak specimens.**54. Each SPHL should have a standard requisition form for specimens and samples within its scope of testing. The requisition form should meet the needs of the program, be readily available to submitters, and include a list of collection requirements to maintain the identity and integrity of test specimens /samples.** Fully 98% of SPHLs use a standard requisition form for clinical specimens and about 80% use a standard form for food samples. Innovative features of these forms, although employed by only a few laboratories, include bar coding, a description of chain-of-custody procedures for each food type, and on-demand printing to allow forms to be customized.**55. Each SPHL should provide collection kits for specimens and samples of all types or provide detailed submission information (acceptable packaging, temperature control requirements, etc.) and laboratory contact information.** Most SPHLs provide collection kits to public and/or private entities for submission of human specimens (96% of 50 reporting), human isolates (82% of 49 reporting), environmental isolates (64% of 45 reporting), food samples (75% of 48 reporting), and water samples (94% of 49 reporting). In some states, the cost of providing collection kits is a significant portion of the laboratory budget, totaling as much as \$1 million.

- 56. Each state laboratory should confirm the identity of all isolates, regardless of submitter or point of origin.**
- 57. Each SPHL should have an accessioning system with a unique number assigned to each specimen/sample for tracking and identification.** Forty-one percent of responding laboratories report the use of bar codes to identify specimens received by the laboratory.

## ANALYTICAL ISSUES

### Recommended Test Capabilities

- 58. All laboratory test methods should be available electronically.**
- 59. Each state should fund at least one governmental laboratory capable of testing foodborne disease pathogens in a timely manner in clinical specimens, as well as food and water samples. *At a minimum*, each state should be able to perform confirmatory testing for the foodborne illness agents indicated in Table 11.** The SPHL is responsible for clinical food safety testing in virtually all states and for testing related to foodborne disease outbreaks in most states. In states where the SPHL does not perform this work, it should assure that timely, quality testing is performed elsewhere.
- 60. All SPHLs should have the capability to perform food chemistry tests for non-infectious, foodborne disease agents of public health significance - including environmental contaminants, natural toxins, chemical agents, and radiation - or should have access to another laboratory with such capability. At a minimum, state laboratories should have access to testing for the following:**
  - Allergens - Enzyme-linked immunosorbant assay (ELISA) or immunoassay
  - Biotoxins (Mycotoxins) - ELISA and high pressure liquid chromatography (HPLC)
  - Cyanide - Traditional chemistries or ion chromatography
  - Filth - Microscopy
  - Heavy metals - Atomic absorption or inductively coupled plasma analysis
  - Histamines - Screening ELISA, thin layer chromatography, liquid chromatography
  - Marine toxins - Mouse bioassay and HPLC
  - Pesticides/Residues - Gas/liquid chromatography mass spectrometry
  - Radionuclides
  - Sulfites/Sulfates/Nitrates - Traditional chemistries or ion chromatography
  - Volatile and Semi-volatile organics - Gas/liquid chromatography mass spectrometry
  - Others on a regional basis.
- 61. Every SPHL that uses rapid test kits to identify foodborne pathogens should also culture isolates for further characterization and sub-typing whenever possible.** The majority of SPHLs use rapid detection methods either routinely (55%) or during outbreaks (16%), and most of these conduct further sub-typing of at least some organisms. This recommendation echoes existing APHL policy on non-culture assays, which states that “all positive results from (rapid non-culture assay methods) be confirmed by additional analyses performed on an isolate of the pathogenic organism.”<sup>26</sup>

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<sup>26</sup> APHL Position Statement, “Use of Non-Culture Assays to Detect Communicable Infectious Agents,” June 2001, available at [http://www.aphl.org/Public\\_Policy/Non\\_Culture\\_Assays.pdf](http://www.aphl.org/Public_Policy/Non_Culture_Assays.pdf), accessed April 29, 2003

- 62. Each SPHL should have the capability to prepare media in-house, if it cannot be acquired commercially during foodborne disease outbreaks.** Virtually all SPHLs (96%) have this capability.

**Table 11. Recommended Requirements/Test Capabilities for Foodborne Disease Pathogens**

Pathogen	? Recommended Laboratory Requirements/Test Capabilities ?									
	Antigen Detection	Culture	Isolate Submission Mandatory	Microscopy (m) or Fluorescence Microscopy (fm)	Modified Acid Fast	Molecular Subtyping	PCR Detection	Sequencing/Amplification Methods <sup>1</sup>	Serotyping	Toxin Testing
<i>Bacillus cereus</i>		X						X		X <sup>2</sup>
<i>Clostridium botulinum</i> <sup>3</sup>		X	X					X		
<i>Campylobacter</i> sp.		X	X <sup>4</sup>							
<i>Clostridium perfringens</i>		X				X		X		X
<i>Cryptosporidium</i> sp.	X			m	X			X		
<i>Cyclospora</i> sp.				fm				X		
<i>Giardia</i> sp.	X <sup>5</sup>			m				X		
Hepatitis A	X							X		
<i>Listeria monocytogenes</i>		X	X			X <sup>6</sup>		X	X <sup>6</sup>	
Norwalk-like virus <sup>7</sup>							X			
<i>Salmonella</i> sp.		X	X			X		X	X	
Shiga-toxin producing <i>E. coli</i>		X	X <sup>8</sup>			X		X	X <sup>9</sup>	X <sup>2</sup>
<i>Shigella</i> sp.		X	X			X <sup>6</sup>		X	X	
<i>Staphylococcus aureus</i>		X				X		X		X
<i>Vibrio</i> sp.		X	X <sup>10</sup>			X		X	X	X <sup>6</sup>
<i>Yersinia enterocolitica</i>		X						X		

<sup>1</sup> Should be performed when protocols are validated and available.

<sup>2</sup> Toxin testing should be performed by EIA for *Bacillus cereus* and by both EIA and PCR for *E. coli*.

<sup>3</sup> *C. botulinum* also requires mouse bioassay (either in-house or contracted out) and back-up testing by EIA.

<sup>4</sup> Isolate submission should be mandatory *only* if there is a good method to differentiate the organisms.

<sup>5</sup> Can be detected using any of various methods: microscopy, DFA, EIA.

<sup>6</sup> Service should be contracted out if SPHL is unable to perform in-house.

<sup>7</sup> Sequencing should also be performed, possibly centralized.

<sup>8</sup> Isolate submission should be mandatory, if available or broth or stool if isolate unavailable.

<sup>9</sup> Serotyping should be performed for O157, O111, O26, and other significant serotypes.

<sup>10</sup> Isolate submission should be mandatory for *V. cholera* O1 and other pathogenic Vibrios, including *V. parahaemolyticus* and *V. vulnificus*.



- 63. Each SPHL should be capable of testing clinical specimens and food and water samples for agents of bioterrorism.** To maintain a state of readiness, staff training and access to test procedures, reagents and supplies must be assured in advance.

The highest priority, *Category A*, biological agents include pathogens that are infrequently seen as naturally-occurring pathogens in the United States. They pose a risk to national security because they can be easily disseminated or transmitted, cause high mortality, may cause public panic, and require special action for public health preparedness. Second highest priority, *Category B* agents are moderately easy to disseminate, cause moderate morbidity and low mortality, and require specific enhancements of diagnostic capacity and enhanced disease surveillance to detect and monitor. Third highest priority, *Category C* agents include emerging pathogens that could be engineered for mass dissemination in the future. All current, CDC-recognized bioterrorism agents are listed in Table 12. Of special significance for food safety programs are the food and waterborne *Category B* agents.

**Table 12. CDC-Recognized Agents of Bioterrorism**

<u>Category A</u>	<u>Category B</u>	<u>Category C</u>
<ul style="list-style-type: none"> <li>• Variola major (smallpox)</li> <li>• <i>Bacillus anthracis</i> (anthrax)</li> <li>• <i>Yersinia pestis</i> (plague)</li> <li>• <i>Clostridium botulinum</i> toxin</li> <li>• <i>Francisella tularensis</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>Coxiella burnetii</i> (Q fever)</li> <li>• <i>Brucella</i> species</li> <li>• <i>Burkholderia mallei</i></li> <li>• Alphaviruses               <ul style="list-style-type: none"> <li>– Venezuelan encephalomyelitis</li> <li>– E./W. equine encephalomyelitis</li> </ul> </li> <li>• Ricin toxin</li> <li>• Epsilon toxin of <i>C. perfringens</i></li> <li>• <i>Staphylococcus</i> enterotoxin B</li> </ul>	<ul style="list-style-type: none"> <li>• Nipah virus</li> <li>• Hantaviruses</li> <li>• Tickborne hemorrhagic fever viruses</li> <li>• Tickborne encephalitis</li> <li>• Yellow fever</li> <li>• Multidrug-resistant tuberculosis</li> </ul>
<b>Viruses</b> <ul style="list-style-type: none"> <li>• Filoviruses               <ul style="list-style-type: none"> <li>– Ebola hemorrhagic fever</li> <li>– Marburg hemorrhagic fever</li> </ul> </li> <li>• Arenaviruses               <ul style="list-style-type: none"> <li>– Lassa</li> <li>– Junin and related viruses</li> </ul> </li> </ul>	<b>Food/Waterborne B Agents</b> <ul style="list-style-type: none"> <li>• <i>Salmonella</i> species</li> <li>• <i>Shigella dysenteriae</i></li> <li>• <i>Escherichia coli</i> O157:H7</li> <li>• <i>Vibrio cholerae</i></li> <li>• <i>Cryptosporidium parvum</i></li> </ul>	

Source: CDC. Biological and chemical terrorism: Strategic plan for preparedness and response. *MMWR*. 2000;49(RR04):1-14.

- 64. All SPHLs should have full ova and parasite identification capabilities.** Such capabilities include light and fluorescence microscopy and special stains, as well as antigen detection kits when appropriate.

## Assay Validation

- 65. Each SPHL should have written protocols defining how new assays should be validated.** Just over three-quarters (77%) of respondents reported the use of these protocols.
- 66. Each SPHL should be able to execute unvalidated procedures 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.**

## PulseNet Activities

(See also recommendations 7, 8, 75, and 83.)

- 67. Each SPHL should confirm the identification of isolates that are further sub-typed. Sequential confirmation should be performed for surveillance purposes and simultaneous confirmation performed during outbreaks.** All but two responding laboratories reported that they routinely confirm the identification of isolates that are further sub-typed.
- 68. SPHLs should perform routine, real-time pulsed-field gel electrophoresis sub-typing of the following isolates: *E. coli* O157:H7, *Listeria monocytogenes*, all *Salmonella* serotypes, and *Shigella sonnei*. In addition, all SPHLs should be capable of typing *Campylobacter*, *C. perfringens*, *Vibrio*, and *Yersinia* upon request.**
- 69. Each SPHL should have the ability to perform second enzyme sub-typing during outbreaks.**

## Storage of Isolates

- 70. Each SPHL should store isolates of reportable diseases for one year.** Laboratories should also have access to long-term storage either on-site or in regional cryogenic facilities. About half of respondents reported that isolates are stored for one year or longer (even indefinitely), but many also noted that length of storage varies by isolate type. Just under half of survey respondents (23 of 50 reporting) noted they lack adequate laboratory storage facilities.
- 71. All etiologic agents and infectious materials should be stored with at least two levels of security (e.g., locked storage cabinets in a restricted access area). A tiered system for various levels of risk should be developed and implemented at each state lab, with appropriate security measures for each risk level.**<sup>27</sup>

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<sup>27</sup> This recommendation is largely superseded by the Select Agent regulation, 42 CFR 73, which became effective in February 2003. More information about the Select Agent program is available at <http://www.cdc.gov/od/sap/>, accessed April 24, 2003

**DATA ANALYSIS AND REPORTING**

- 72. Each SPHL should enter test results into PHLIS daily, with data electronically uploaded.** Just one fourth of APHL survey respondents (of 46 responding to this question) enter results into PHLIS daily, while the rest perform weekly (59%), biweekly (9%), or monthly (9%) data entry. The most prevalent problem contributing to data entry delays is staff limitations, cited by 70% of respondents.
- 73. Each SPHL should report outbreak testing results on a daily basis, via both phone and computer, to the specimen submitter, state epidemiologist, and other relevant stakeholders (e.g., CDC, local health department, etc.).** It is less important whether results are reported individually or in summary format, so long as all necessary information is conveyed and other documents, such as paper reports for patient charts, are generated as necessary.
- 74. All e-mail containing test result data should be sent with verification of receipt requested.** About 37% of respondents reported that the laboratory had a mechanism in place in 2001 to confirm that test results were received.
- 75. PulseNet patterns and case information should be uploaded daily. Each SPHL should respond to PulseNet postings within 24 hours.** PulseNet provides a means for timely sharing of food safety data across jurisdictions, critical for outbreak detection. The responsiveness of the PulseNet system depends upon timely user activity at all levels. Most laboratories (38 of 45 responding) respond to PulseNet postings within 48 hours. Those that don't cite limited staff and "match of posted pattern" as the primary hindrances to a more timely response.
- 76. Results of tests that are not physician-ordered, but are administered as part of an investigation for a suspected foodborne disease outbreak, should be reported in the same manner as any test performed at the request of a physician.**
- 77. SPHLs should report unvalidated or research-procedure results with appropriate disclaimers.** Disclaimers may include "testing for research and development" or "internally validated but not FDA-approved."
- 78. Testing methods used in studies for which Institutional Review Board approval is required must receive IRB review as part of the approval. Test result should be reported in the manner specified in the IRB approval document.** (Tests performed for surveillance programs often do not require IRB approval.)
- 79. Isolates found in non-clinical samples (e.g., food) should be reported in a common database such as the Electronic Laboratory Exchange Network (eLEXNET). Resources should be provided by the SPHL to encourage submission of samples and isolates by identifying laboratories.** The Electronic Laboratory Exchange Network is an integrated Web-based information network that facilitates real-time sharing of food safety laboratory data among federal, state, and local agencies. All federal, state, and local food safety laboratories are eligible to participate in the network at no cost.<sup>28</sup>

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<sup>28</sup> More information is available at [www.elexnet.com](http://www.elexnet.com), accessed April 24, 2003

- 80. Local, state, and federal agencies should work together to standardize laboratory culture and sub-typing methods and reporting standards so that test data can be integrated and shared.** Examples are the National Electronic Disease Surveillance System and eLEXNET. The Association of Food and Drug Officials in 2000 approved a resolution stating that all food safety laboratories use Health Level 7 (HL7) as the standard for messaging in the exchange of health information, Systemized Nomenclature of Medicine and Veterinary Medicine (SNOMED) as the standard vocabulary for the transmission of health information, and Logical Observation Identifier, Names and Codes (LOINC) as the standard terminology of fully specified observation names for the exchange of health information.<sup>29</sup>
- 81. Laboratories testing out-of-state food samples should send test reports to the submitting state rather than the state in which the food sample originated (if the two are different).** This is in contrast to recommendation #2 for clinical specimens, in which the state of residence of the affected case patient should receive the report.
- 82. Each SPHL should analyze laboratory data - visually and electronically - for cluster trends before reporting it to epidemiology. A “threshold” for cluster identification should consist of a statistically significant deviation from background levels rather than a specified number of cases.** About half of state laboratories now routinely assess data for cluster trends before it is reported to other agencies, but only 10 laboratories (of 47 reporting) have pre-established thresholds for cluster identification, and only one of these noted that the threshold was established in collaboration with the state epidemiology program.
- 83. SPHLs should assign a unique name to each pathogen strain (exact match) and include this name in reporting PFGE results to epidemiologists and other state public health laboratories. In addition, laboratories should work with epidemiology officials to document information on strain relatedness as needed (including dendrograms and lists of related strains).**

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<sup>29</sup> Association of Food and Drug Officials, Resolution Number 6 (2000): Concerning: Data Standards for the exchange of laboratory information. Available at <http://www.afdo.org/resolutions.asp?resyear=2000>, accessed April 24, 2003

**APPENDIX A: ACRONYMS USED IN THIS REPORT**

AFDO	Association of Food and Drug Officials
AIHA	American Industrial Hygiene Association
APHL	Association of Public Health Laboratories
CAP	College of American Pathologists
CDC	Centers for Disease Control and Prevention
CE	Continuing education
CLIA	Clinical Laboratory Improvement Act
CSTE	Council of State and Territorial Epidemiologists
DFA	Direct Fluorescent Antibody test
EIA	Enzyme Immunoassay
eLEXNET	Electronic Laboratory Exchange Network
ELISA	Enzyme-linked immunosorbant assay
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service (USDA)
FTE	Full time equivalent
HL7	Health Level 7 (coding system)
HPLC	High pressure liquid chromatography
ID	Identification
IRB	Institutional review board
ISO	International Standards Organization
LIMS	Laboratory information management system
LOINC	Logical Observation Identifier, Names and Codes
NACCHO	National Association of County and City Health Officials
NEDSS	National Electronic Disease Surveillance System
NELAC	National Environmental Laboratory Accreditation Conference
NLTN	National Laboratory Training Network
NRC	Nuclear Regulatory Commission
PCR	Polymerase chain reaction
PFGE	Pulsed-field gel electrophoresis
PHLIS	Public Health Laboratory Information System
SNOMED	Systemized Nomenclature of Medicine and Veterinary Medicine
SPHL	State public health laboratory
TLC	Thin layer chromatography
USDA	United States Department of Agriculture
USPS	United States Postal Service

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## APPENDIX C: APHL Laboratory Capacity Assessment Survey Questionnaire August 2001

(Document has been re-formatted to conserve space.)

### INFRASTRUCTURE

#### ORGANIZATION

1. Which agencies are involved in the following functions? Please "X" where appropriate.

	Public Health	Agriculture	Environmental	Other (Describe)
Microbiologic Analysis of Food -Outbreak Investigations				
Microbiologic Analysis of Food -Surveillance				
Microbiologic Analysis of Clinical Specimens -Outbreak Investigations				
Microbiologic Analysis of Clinical Specimens -Surveillance				
Epidemiologic Investigations				
Environmental Health Specialist Program (Sanitarians)				
Chemical Analysis of Food - Outbreak Investigations				
Chemical Analysis of Food -Surveillance				

2. What is your laboratory's physical location, routine hours of operation and emergency availability? (use the table below to record your response. For hours of operation, please write in the box provided.)

	Laboratory	Epidemiology	Environmental Health (Sanitarians)
Physical Location	N/A	<input type="checkbox"/> same building with lab <input type="checkbox"/> not in building with lab approx. distance to lab ___miles	<input type="checkbox"/> same building with lab <input type="checkbox"/> not in building with lab approx. distance to lab ___miles
Routine Hours			
Available 24/7 in emergency?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

3. Does your laboratory have adequate legal authority to conduct testing for foodborne disease investigations?  
☐ Yes, No, Not Sure
4. Is this authority specifically defined in your statutes (law)?  
☐ Yes, No, Not Sure
5. Is this authority specifically defined in your department regulations?  
☐ Yes, No, Not Sure
6. Does your laboratory have legal authority to collect laboratory or clinical reports on notifiable foodborne diseases? If no, which agency in your state/county/city possesses this authority?  
☐ Yes, No, Not Sure (If no, agency? \_\_\_\_\_)
7. Does your laboratory have legal authority to collect laboratory or clinical reports of suspected (not confirmed) foodborne diseases? If no, which agency in your state/county/city possesses this authority?  
☐ Yes, No, Not Sure (If no, agency? \_\_\_\_\_)
8. Does your laboratory have legal authority to perform environmental facilities inspections? If not, which agency in your state/county/city possesses this authority?  
☐ Yes, No, Not Sure (If no, agency? \_\_\_\_\_)

9. Does your laboratory have legal authority to take action to condemn food? If not, which agency in your state/county/city possesses this authority?
- Yes, No, Not Sure (If no, agency? \_\_\_\_\_)
10. Are laboratories within your state/county/city required to send isolates associated with reportable foodborne diseases to the Public Health Laboratory?
- Yes, No
11. If submission is not mandated, do laboratories voluntarily submit isolates associated with reportable foodborne diseases to the PHL?
- Yes, No
12. Does your laboratory have the authority to obtain appropriate specimens and isolates for foodborne disease testing during an outbreak? If not, who possesses this authority in your state/county/city?
- Yes
- No \_\_\_\_\_
- Not Sure

**STAFFING**

13. Respond to the following questions on staffing for the food safety program.
- Total Surge Capacity is the number of staff trained and capable of working in an area.
  - Approximate Total Years of Experience would be defined as all lab experience, *not only food testing experience.*

	Number of Staff	FTE Admin.	FTE Bench Testing	FTE Currently Vacant	Total Surge Capacity	Approx. Total Yrs. Of Exp.	Salary Range
<b>Microbiology Program</b>							
Doctoral Level							
Masters Level							
Bachelors Level							
Student/Fellows							
Other							
<b>Chemistry Program</b>							
Doctoral Level							
Masters Level							
Bachelors Level							
Student/Fellows							
Other							
<b>INFORMATION MANAGEMENT</b>							
Data Manager							
Clerical							
Support Staff							

14. Are you having trouble recruiting qualified personnel? If yes, what are the contributing factors?
- Yes, No, (If yes, contributing factors):

**TRAINING**

15. Please indicate the number of persons adequately trained to perform the listed areas of laboratory testing:

Areas of Training	Number of Persons Trained and/or Proficient to Perform Testing
Conventional Food Microbiology	
Clinical Enteric Bacteriology	
Clinical Enteric Virology	
Serology	
Parasitology	
Food Chemistry	
Molecular Biobgy	
-PCR (Standard/Real-time)	
-PFGE subtyping	
-Other Subtyping	

16. Is cross training provided in your laboratory?
- Yes, No, If no cross training is provided, please specify the reason why in the space below.
17. Is there a job-related continuing education requirement for Laboratory Staff?
- Yes Number hours/year \_\_\_\_\_
- No

18. Are records of continuing education and/or completed training maintained for all laboratory personnel and are they documented in an official manner?  
 o Yes, No, If yes, where and how is this documented? (e.g., personnel file, performance evaluation, professional licensing agency etc.) \_\_\_\_\_
19. Does your laboratory provide training to staff for foodborne diseases testing?  
 o Yes, No, Not Sure

If not, does your laboratory support the training of personnel through the use of external training sources?

- o Yes, No, Not Sure
20. If training were made available to your laboratory staff, what would be the preferred format? Indicate order of preference.
- Conference \_\_\_\_\_
  - Satellite conference \_\_\_\_\_
  - Web based \_\_\_\_\_
  - Hands-on \_\_\_\_\_
  - Other (specify) \_\_\_\_\_
21. What subject matters relating to foodborne disease(s) and/or foodborne disease testing are not adequately covered by current training courses available to laboratorians?

### EQUIPMENT

22. Which of the following molecular diagnostic equipment does your laboratory have available for use? Please "X" all that apply
- |  |  |
|--|--|
| <input type="checkbox"/> Thermal Cycler  | <input type="checkbox"/> Reagent Grade Water Purification System (i.e., Milli-Q)           |
| <input type="checkbox"/> PFGE equipment (i.e., CHEF Mapper, DRII, etc...)        | <input type="checkbox"/> Spectrophotometer/Genequant                                       |
| <input type="checkbox"/> DNA Sequencer   | <input type="checkbox"/> UV Crosslinker (i.e., Stratalinker)                               |
| <input type="checkbox"/> Real-Time PCR Cycler (i.e., Light Cycler, Smart Cycler) | <input type="checkbox"/> Vacuum Transfer Apparatus   |
| <input type="checkbox"/> Riboprinter   | <input type="checkbox"/> Autoradiograph/Film Processor                                     |
| <input type="checkbox"/> Microarray System (i.e., Luminex)                       | <input type="checkbox"/> Fluorimeter   |
| <input type="checkbox"/> Computerized Gel Documentation                          | <input type="checkbox"/> Commercial PCR Assay System (i.e., Qualicon/BAX Detection System) |
| <input type="checkbox"/> Robotics  | <input type="checkbox"/> PCR Hoods   |
| <input type="checkbox"/> Gel Dryer   | <input type="checkbox"/> Agarose or Polyacrylamide Gel                                     |
| <input type="checkbox"/> Microplate Reader                                       | <input type="checkbox"/> Hybridization Oven  |
| <input type="checkbox"/> Microplate Washer                                       | <input type="checkbox"/> Other (specify) _____   |
| <input type="checkbox"/> Biological Safety Cabinet                               |  |
23. Which of the following Parasitology CDC-linked Telediagnosis equipment does your laboratory have available for use? Please "X" all that apply.
- ☐ Digital Camera
- ☐ Camera adapters
- ☐ Trinocular microscope
- ☐ Computer and peripherals with modem hook-up
24. Which of the following Food Chemistry equipment does your laboratory have available for use? Please "X" all that apply.
- ☐ HPLC
- ☐ TLC
- ☐ Immunoassay
- ☐ LC-MS
- ☐ GC-MS
- ☐ Capillary Electrophoresis
- ☐ Ion Chromatography
- ☐ ICP
- ☐ AA
- ☐ GFAA Spectroscopy
- ☐ FTIR
- ☐ Other (specify) \_\_\_\_\_

## FACILITY

25. Does your laboratory have access to an animal facility?  
☐ Yes, No
26. Do you have adequate space for the following? If insufficient, note approximately how much more space is needed. (For additional, respond by referring to terms such as square footage, number of room, etc...)
- |                 |           |          |                  |
|-----------------|-----------|----------|------------------|
| Bench space     | Yes _____ | No _____ | Additional _____ |
| Office space    | Yes _____ | No _____ | Additional _____ |
| Equipment space | Yes _____ | No _____ | Additional _____ |
| Storage space   | Yes _____ | No _____ | Additional _____ |
27. Does your laboratory have a BSL3 facility? If yes, please note how many isolation rooms this facility possesses.  
☐ Yes #of BSL-3-isolation rooms \_\_\_\_\_  
☐ No
28. How many total biological safety cabinets does your laboratory have available for foodborne disease testing? \_\_\_\_\_

**BUDGET**

29. How much funding does your laboratory receive (total budget) for food safety or foodborne disease testing? (Indicate approximate amount below.)  
 \$ \_\_\_\_\_
30. What are your laboratory's sources for funding for the food safety program? Please "X" all that apply.  
 \_\_\_\_\_ Federal \_\_\_\_\_ CDC-BT  
 \_\_\_\_\_ CDC-ELC/EIP  
 \_\_\_\_\_ FDA  
 \_\_\_\_\_ USDA  
 \_\_\_\_\_ Fee for Service  
 \_\_\_\_\_ State  
 \_\_\_\_\_ Other (specify) \_\_\_\_\_
31. What is the population that your laboratory serves? Please "X" where applicable.  
 \_\_\_\_\_ State Jurisdiction  
 \_\_\_\_\_ County Jurisdiction  
 \_\_\_\_\_ City Jurisdiction  
 \_\_\_\_\_ Other (specify) \_\_\_\_\_
- What is the approximate size of that population? \_\_\_\_\_

**INFORMATION MANAGEMENT**

32. Does your laboratory have a website?  
☐ Yes, No, Not Sure
33. On a scale of 1 to 10, with 10 being excellent, rate the overall adequacy of your website. Please circle the number below.  
 1 2 3 4 5 6 7 8 9 10
34. On a scale of 1 to 10, with 10 being excellent, rate the quality of food safety or foodborne disease testing information provided on your website. Please circle the number below.  
 1 2 3 4 5 6 7 8 9 10
35. Does your laboratory have a Laboratory Information Management System(LIMS)?  
☐ Yes If yes, what kind? \_\_\_\_\_  
☐ No  
☐ Not Sure
36. If your laboratory has a LIMS system, is it used for?  
 Clinical Specimens \_\_\_\_\_Yes \_\_\_\_\_ No  
 Food Microbiology Specimens \_\_\_\_\_Yes \_\_\_\_\_ No  
 Food Chemistry Specimens \_\_\_\_\_Yes \_\_\_\_\_ No
37. Are the data entered into your LIMS system maintained in a secure manner?  
☐ Yes, No, Not Sure
38. Is your laboratory working toward reporting data in a NEDSS-compliant format?  
☐ Yes, No, Not Sure
39. Do you have adequate computer hardware for your food safety or foodborne disease testing program?  
☐ Yes, No, Not Sure  
 If you do not have adequate hardware, what do you feel you are lacking? (PCs, laptops, servers, palm pilots, digital cameras, etc..)

40. Do you have adequate software to support your food safety or foodborne disease testing program?
- ☐ Yes, No, Not Sure
- If you do not have adequate software, what do you feel you are lacking? (spreadsheets, internet access, statistics package, database, graphics, e-mail, GIS, etc.,)
41. Does your laboratory data management computer system directly interface with the epidemiology computer system?
- ☐ Yes, No, Not Sure
42. Does your laboratory data management computer system directly interface with the Environmental Health computer system?
- ☐ Yes, No, Not Sure
43. Does your Environmental Health computer system directly interface with the Epidemiology computer system?
- ☐ Yes, No, Not Sure
44. Does your laboratory data management computer system directly interface with the CDC computer system (PHLIS)?
- ☐ Yes, No, Not Sure

### EMERGENCY RESPONSE

45. Do you have adequate laboratory space for surge capacity needs that might arise in the event of a foodborne disease outbreak? If no, what is needed?
- ☐ Yes, No, Not Sure, Needs:
46. Does your laboratory have a written plan that can be implemented during a foodborne disease outbreak? If no, please explain reason below.
- ☐ Yes
  - ☐ No \_\_\_\_\_
47. Does your laboratory have adequate staff to respond to foodborne disease outbreaks? If no, please write what action you would take if there were a large foodborne outbreak occurring in your state.
- ☐ Yes
  - ☐ No \_\_\_\_\_
48. Does your laboratory expand its hours during a foodborne disease outbreak?
- ☐ Yes, No
49. Does your laboratory have adequate communication tools (cell phone, pagers, etc.) to use during foodborne disease outbreaks? If no, please write what action you would take to communicate as necessary during a foodborne outbreak.
- ☐ Yes
  - ☐ No \_\_\_\_\_
50. Does your laboratory have adequate equipment (computers, freezers, power back up, etc.) available for foodborne disease emergency response? If no, please write what action you would take below to respond to the outbreak?
- ☐ Yes
  - ☐ No \_\_\_\_\_
51. Does your laboratory utilize rapid detection kits/reagents for the identification of foodborne pathogens (i.e., Shiga toxin or Rotavirus) from clinical, food or environmental specimens? If so, please list the kits or reagents used for this purpose.
- ☐ Yes, routinely
  - ☐ Yes, only during outbreaks
  - ☐ No
- If yes, what kits do you use: \_\_\_\_\_
52. If your laboratory utilizes rapid detection kits/reagents for the identification of foodborne pathogens, does the laboratory attempt to isolate an organism from the positive specimen?
- ☐ Yes, for all organisms
  - ☐ Yes, for only some organisms
  - ☐ No
53. Does your laboratory have the capacity to prepare media in house, if it cannot be acquired commercially during foodborne disease outbreaks? If no, please write what action you would take if you did not have sufficient media to deal with an outbreak.
- ☐ Yes
  - ☐ No \_\_\_\_\_
54. Does your lab have other infrastructure needs that we did not cover? If so, please describe.
- ☐ Yes, No, Not Sure

### PRE-ANALYTICAL

Question 55-58: annual volume can be approximate

55. Does your laboratory test human specimens ( i.e. Stool, blood) for foodborne disease pathogens?

- ☐ Yes                                      annual volume \_\_\_\_\_  
☐ No
56. Does your laboratory test clinical specimens for foodborne disease pathogens or perform confirmatory testing of isolates?
- Bacterial:                      \_\_\_\_\_ Yes \_\_\_\_\_ No                      annual volume \_\_\_\_\_  
 Viral:                                \_\_\_\_\_ Yes \_\_\_\_\_ No                      annual volume \_\_\_\_\_  
 Parasitic:                      \_\_\_\_\_ Yes \_\_\_\_\_ No                      annual volume \_\_\_\_\_
57. Does your laboratory test food specimens for foodborne disease pathogens?
- Bacterial:                      \_\_\_\_\_ Yes \_\_\_\_\_ No                      annual volume \_\_\_\_\_  
 Viral:                                \_\_\_\_\_ Yes \_\_\_\_\_ No                      annual volume \_\_\_\_\_  
 Parasitic:                      \_\_\_\_\_ Yes \_\_\_\_\_ No                      annual volume \_\_\_\_\_
58. Does your laboratory test water specimens for foodborne disease pathogens?
- Bacterial:                      \_\_\_\_\_ Yes \_\_\_\_\_ No                      annual volume \_\_\_\_\_  
 Viral:                                \_\_\_\_\_ Yes \_\_\_\_\_ No                      annual volume \_\_\_\_\_  
 Parasitic:                      \_\_\_\_\_ Yes \_\_\_\_\_ No                      annual volume \_\_\_\_\_
59. Does your laboratory test food specimens for non-infectious agents (i.e. histamines)?
- ☐ Yes                                      annual volume \_\_\_\_\_  
☐ No
60. Does your laboratory offer a catalog of services to customers?
- ☐ Yes, No
61. If your laboratory possesses a catalog of services, is it computerized and available on your website?
- ☐ Yes, No
62. Does your laboratory have written specimen collection protocols for clinical specimens?
- ☐ Yes, No
63. Does your laboratory have written specimen collection protocols for food samples?
- ☐ Yes, No
64. Are human and food specimen collection protocols made available to submitters?
- ☐ Routinely  
☐ Upon request  
☐ During outbreak conditions  
☐ Never
65. Has your laboratory established rejection criteria for submission of clinical outbreak specimens?
- ☐ Yes, No
66. Has your laboratory established rejection criteria for submission of food outbreak specimens?
- ☐ Yes, No
67. Are rejection criteria different for routine diagnostic specimens versus outbreak specimens?
- ☐ Yes, No
68. Does your laboratory have a standard requisition form for clinical specimens?
- ☐ Yes, No
69. Does your laboratory have a standard requisition form for food specimens?
- ☐ Yes, No
70. How are requisition forms distributed to customers/submitters within your state?
71. Does your requisition form utilize any technological advances that might be shared with other states?
- ☐ Yes                      If Yes, explain \_\_\_\_\_  
☐ No
72. Does your laboratory use bar coding to identify food safety or foodborne disease specimens?
- ☐ Yes, No
73. Does your laboratory use bar coding to identify any specimens received by your laboratory? If yes, please specify.
- ☐ Yes                      \_\_\_\_\_  
☐ No
74. Who submits specimens to your laboratory for food safety or foodborne disease related testing? (Give estimates of the percentage of specimens received from each submitter)

Submitter	Approx. % of total food samples	Approx. % of total foodborne disease clinical specimens	Approx. % of total water samples	Approx. # of facilities within your state submit specimens
County/City HD				
State HD				
Epidemiology				
Sanitarians				
Hospital/Clinical/Physicians				
Private Commercial Labs				
Other Agencies				
Other State Labs				
Consumers/Citizens				
	100%	100%	100%	

75. What certifications does your laboratory have? Please "X" all that apply.

- a. CLIA \_\_\_\_\_
- b. EPA \_\_\_\_\_
- c. CAP \_\_\_\_\_
- d. State \_\_\_\_\_
- e. NELAC \_\_\_\_\_
- f. ISO 17025 \_\_\_\_\_
- g. USDA \_\_\_\_\_
- h. Interstate Milk Shippers \_\_\_\_\_
- i. Interstate Shellfish Sanitation \_\_\_\_\_
- j. Other (specify) \_\_\_\_\_

76. Does your laboratory provide collection kits to public and/ or private agencies for the collection and submission of human, food and water specimens/isolates to the laboratory? Please "X" all that apply.

	Private Provider	Public Provider	Not Provided
Human Specimens			
Human Isolates			
Environmental Isolates			
Food Specimens			
Water Specimens			
Environmental Specimens			

77. How much does your laboratory spend each year for collection kits? (give estimate)  
\$\_\_\_\_\_ per year

78. How are specimens transported to your laboratory and what is the average transport time?  
Note: Average transport time is defined as the time from collection of sample to receipt of sample in the laboratory. Please "X" all that apply

		Average Transport Time		
Transport Methods	X	Less than 24hrs	24-48hrs	Greater than 48hrs
Commercial Courier (ex. Fedex, UPS)				
USPS (mail)				
PH Courier				
Hand Delivered				
Private Courier				
Other (specify)				

79. Who pays specimen transportation costs? (use table below for response, check all that apply)

	PH Laboratory	Submitter	Epidemiology
Commercial Courier			
USPS			
PH Courier			
Hand Delivered			
Private Courier			
Other			

80. Does your laboratory have a chain of custody procedure in place for the testing of regulatory and/ or foodborne outbreak specimens? If yes, please attach a copy of the protocol.  
o Yes, No
81. Does epidemiology routinely notify the laboratory if an outbreak is suspected?  
o Yes  
o No  
o Occasionally
82. On a scale from 1 to 10, with 10 being excellent, how would you rate or characterize your relationship with the following. (Please circle a number below.)
- |   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| a. Epidemiology   | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| b. EH Specialist  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| c. Agriculture Dept.                                    | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| d. Local Health Dept.                                   | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| e. Other Laboratories within your state (i.e. clinical) | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
83. Is your laboratory administratively under the same agency as:
- |                                  |          |         |
|----------------------------------|----------|---------|
| Epidemiology                     | ____ Yes | ____ No |
| Agriculture                      | ____ Yes | ____ No |
| Environmental Health/Sanitarians | ____ Yes | ____ No |



84. Does your laboratory perform animal assays for the detection/identification of foodborne disease toxins (*i.e.* *Botulinum* toxin)? If so, please list which pathogens.  
☐ Yes List:  
☐ No
85. If your laboratory does not perform animal assays, where do you send isolates requiring this testing?

## Section 3: ANALYTICAL

86. For the following eleven tables, please indicate whether the disease is reportable in your state, whether isolate submission is mandatory, and what testing you currently perform on the selected agent. (✓ = yes)

	<i>C.botulinum</i> toxin
Reportable	
Isolate Submission Mandatory	
Culture (Direct Detection)	
Molecular Detection	
- Amplified	
- Non-Amplified	
Mouse Bioassay	
Other Detection	
-EIA	
-Other (specify)	
Serotyping	
Molecular Subtyping	
- PFGE	N/A
- RFLP	N/A
- Ribotyping	N/A
- PCR	N/A
-Sequencing	N/A

	Salmonella
Reportable	
Isolate Submission Mandatory	
Culture (Direct Detection)	
Molecular Detection	
- Amplified	
- Non-Amplified	
Other Detection	
-EIA	
-Other (specify)	
Serotyping	
Molecular Subtyping	
- PFGE	
- RFLP	
- Ribotyping	
- PCR	
-Sequencing	
AST	
- Disk Diffusion	
- Microscan	
- Vitek	
- E Test	

	<i>Listeria monocytogenes</i>
Reportable	
Isolate Submission Mandatory	
Culture (Direct Detection)	
Molecular Detection	
- Amplified	
- Non-Amplified	
Other Detection	
-EIA	
-Other (specify)	
Serotyping	
Molecular Subtyping	
- PFGE	
- RFLP	
- Ribotyping	
- PCR	
-Sequencing	
AST	
- Disk Diffusion	
- Microscan	
- Vitek	
- E Test	

	<i>E. coli</i> 0157:H7
Reportable	
Isolate Submission Mandatory	
Culture (Direct Detection)	
Molecular Detection	
- Amplified	
- Non-Amplified	
Other Detection	
-EIA	
-Other (specify)	
Serotyping	
Molecular Subtyping	
- PFGE	
- RFLP	
- Ribotyping	
- PCR	
-Sequencing	
AST	
- Disk Diffusion	
- Microscan	
- Vitek	
- E Test	

	<b>Shigella</b>
Reportable	
Isolate Submission Mandatory	
Culture (Direct Detection)	
Molecular Detection	
- Amplified	
- Non-Amplified	
Other Detection	
-EIA	
-Other (specify)	
Serotyping	
Molecular Subtyping	
-PFGE	
-RFLP	
-Ribotyping	
-PCR	
-Sequencing	
AST	
- Disk Diffusion	
-Microscan	
- Vitek	
-E Test	

	<b>Vibrio</b>
Reportable	
Isolate Submission Mandatory	
Culture (Direct Detection)	
Molecular Detection	
- Amplified	
- Non-Amplified	
Other Detection	
-EIA	
-Other (specify)	
Serotyping	
Molecular Subtyping	
- PFGE	
- RFLP	
- Ribotyping	
- PCR	
-Sequencing	
AST	
- Disk Diffusion	
- Microscan	
- Vitek	
- E Test	

	<i>Norwalk-like virus</i>
Reportable	
Specimen Submission Mandatory	
Molecular Detection	
- Amplified	
- Non-Amplified	
Other Detection	
-EIA	
-Other (specify)	
Serotyping	
Molecular Subtyping	
- PFGE	N/A
- RFLP	N/A
- Ribotyping	N/A
- PCR	
-Sequencing	

	<b>Campylobacter</b>
Reportable	
Isolate Submission Mandatory	
Culture (Direct Detection)	
Molecular Detection	
- Amplified	
- Non-Amplified	
Other Detection	
-EIA	
-Other (specify)	
Serotyping	
Molecular Subtyping	
- PFGE	
- RFLP	
- Ribotyping	
- PCR	
-Sequencing	
AST	
- Disk Diffusion	
- Microscan	
- Vitek	
- E Test	

	<i>Hepatitis A</i>
Reportable	
Specimen Submission Mandatory	
Molecular Detection	
- Amplified	
- Non-Amplified	
Other Detection	
-EIA	
-Other (specify)	
Serotyping	
Molecular Subtyping	
- PFGE	N/A
- RFLP	N/A
- Ribotyping	N/A
- PCR	
-Sequencing	

	<i>Giardia</i>
Reportable	
Specimen Submission Mandatory	
Direct Detection	
-Stool Microscopic	
-DFA	
-Other (specify)	
Molecular Detection	
- Amplified	
- Non-Amplified	
Other Detection	
-EIA	
-Other (specify)	
Molecular Subtyping	
- PFGE	N/A
- RFLP	
- Ribotyping	
- PCR	
-Sequencing	

	<i>Cryptosporidium</i>
Reportable	
Specimen Submission Mandatory	
Direct Detection	
-Stool Microscopic	
-DFA	
-Modified Acid-Fast	
-Other (specify)	
Molecular Detection	
- Amplified	
- Non-Amplified	
Other Detection	
-EIA	
-Other (specify)	
Molecular Subtyping	
- PFGE	N/A
- RFLP	
- Ribotyping	
- PCR	
-Sequencing	

### PulseNet Activities

87. Does your laboratory confirm the identification of isolates prior to performing further subtyping studies, simultaneously confirm and subtype or sequentially confirm then subtype?
- ☐ Yes      ☐ Simultaneous      ☐ Sequential
- ☐ No
88. Has your laboratory submitted data for PulseNet certifications for the following agents:
- a. *E. coli* O157:H7      ☐ Yes      ☐ No
- b. *Listeria monocytogenes*      ☐ Yes      ☐ No
- c. *Shigella sonnei*      ☐ Yes      ☐ No
- d. *Salmonella typhimurium*      ☐ Yes      ☐ No
89. Has your laboratory received results for PulseNet certification submission for the following?
- a. *E. coli* O157:H7      ☐ Yes      ☐ No      ☐ N/A
- b. *Listeria monocytogenes*      ☐ Yes      ☐ No      ☐ N/A
- c. *Shigella sonnei*      ☐ Yes      ☐ No      ☐ N/A
- d. *Salmonella typhimurium*      ☐ Yes      ☐ No      ☐ N/A
90. Under what circumstances do you perform PFGE subtyping of isolates of *E. coli* O157:H7? (please circle letter below.)
- a. Upon request
- b. During an outbreak
- c. All isolates submitted of the agent are subtyped
- d. Other (specify) \_\_\_\_\_
91. Under what circumstances do you perform PGFE subtyping of isolates of *Listeria monocytogenes*? (please circle letter below.)
- a. Upon request
- b. During an outbreak
- c. All isolates submitted of the agent are subtyped
- d. Other (specify) \_\_\_\_\_
92. Under what circumstances do you perform PFGE subtyping of isolates of *Shigella sonnei*? (please circle letter below.)
- a. Upon request
- b. During an outbreak
- c. All isolates submitted of the agent are subtyped
- d. Other (specify) \_\_\_\_\_
93. Under what circumstances do you perform PFGE subtyping of isolates of *Salmonella* serotype Typhimurium? (please circle letter below.)
- a. Upon request
- b. During an outbreak
- c. All isolates submitted of the agent are subtyped
- d. Other (specify) \_\_\_\_\_
94. Under what circumstances do you perform PFGE subtyping of isolates of non-Typhimurium *Salmonella* serotypes? (please circle letter below)
- a. Upon request
- b. During an outbreak
- c. All isolates submitted of the agent are subtyped

- d. Other (specify) \_\_\_\_\_
95. How does your laboratory process *E. coli* 0157:H7 isolates for PFGE subtyping? (please circle the letter below.)
- Isolates are batched and run when there is a sufficient number.
  - Isolates are batched unless there is an outbreak, at which time they are run continuously.
  - Isolates are batched and run after a PulseNet listserve posting.
  - Isolates are run as they arrive, (in "real time")
  - Other (specify) \_\_\_\_\_
96. How does your laboratory process *Listeria monocytogenes* isolates for PFGE subtyping? (please circle letter below.)
- Isolates are batched and run when there is a sufficient number.
  - Isolates are batched unless there is an outbreak, at which time they are run continuously.
  - Isolates are batched and run after PulseNet listserve posting.
  - Isolates are run as they arrive (in "real time")
  - Other (specify) \_\_\_\_\_
97. How does your laboratory process *Shigella sonnei* isolates for PFGE subtyping? (please circle letter below.)
- Isolates are batched and run when there is a sufficient number.
  - Isolates are batched unless there is an outbreak, at which time they are run continuously.
  - Isolates are batched and run after PulseNet listserve posting.
  - Isolates are run as they arrive (in "real time")
  - Other \_\_\_\_\_
98. How does your laboratory process *Salmonella* serotype Typhimurium isolates for PFGE subtyping? (please circle letter below.)
- Isolates are batched and run when there is a sufficient number.
  - Isolates are batched unless there is an outbreak, at which time they are run continuously.
  - Isolates are batched and run after PulseNet listserver posting.
  - Isolates are run as they arrive (in "real time")
  - Other (specify) \_\_\_\_\_
99. How does your laboratory process non-Typhimurium *Salmonella* serotype isolates for PFGE subtyping? (please circle letter below.)
- Isolates are batched and run when there is a sufficient number.
  - Isolates are batched unless there is an outbreak, at which time they are run continuously.
  - Isolates are batched and run after PulseNet listserver posting.
  - Isolates are run as they give arrive (in "real time")
  - Other (specify) \_\_\_\_\_
100. Do you subtype other organisms by PFGE ?
- Foodborne, specify \_\_\_\_\_
- Non-foodborne, specify \_\_\_\_\_

#### Validation of Laboratory Protocols

101. Does your laboratory have a written protocol for defining how a new assay should be validated?
- ☐ Yes, No
102. Does your laboratory have signed Standard Operating Procedures (SOP's) for all validated assays used for foodborne disease testing?
- ☐ Yes, No
103. Does your laboratory run unvalidated procedures and report results in emergency circumstances?
- ☐ Yes, No
104. Does your laboratory report results of unvalidated or research based procedures with disclaimers?
- ☐ Yes, No
- What disclaimer is used by your laboratory? \_\_\_\_\_
105. If you need to use an unvalidated test procedure, does your laboratory have a mechanism in place to confirm the test results?
- ☐ Yes, No

#### Section 4: POST-ANALYTICAL

106. Considering the reporting methods listed below, what percentage of each is used by your laboratory for the communication of laboratory results during a foodborne disease outbreak?

REPORTING METHODS	PERCENTAGE
Electronic	
Phone	
Mail	
Fax	
Courier	

107. When reporting by the above methods, do you give individual results or a summary of results?

Reporting Methods	Individual	Summary
Electronic		
Phone		
Mail		
Fax		
Courier		

108. When reporting results relating to a foodborne disease outbreak, whom are results reported to? Please "X" all that apply.

REPORT SENT TO	ROUTINELY	Reportable diseases only	Outbreak Suspected
Submitter			
Epidemiologist			
CDC via PHLIS			
CDC via other means			
Other, (specify)			

109. How frequently are results entered into PHLIS?  
 \_\_\_\_ daily \_\_\_\_ weekly \_\_\_\_ biweekly \_\_\_\_ monthly

110. What is the official job title of the individual who enters data? \_\_\_\_\_

111. Are data electronically uploaded to PHLIS or is duplicate data entry required?

- ☐ Yes
- ☐ No
- ☐ Duplicate data entry required

112. If Data entry to PHLIS is delayed, what contributes to the delay?

- \_\_\_\_ Staff limitations
- \_\_\_\_ Computer problems
- \_\_\_\_ Other (specify) \_\_\_\_\_

113. When reporting summary or individual test results relating to a foodborne disease outbreak investigation, how often are they reported to health department Epidemiologist? Please "X" which applies.

	Individual	Summary
<b>Daily</b>		
<b>Weekly</b>		
<b>Biweekly</b>		
<b>Monthly</b>		

114. When reporting summary or individual test results relating to a foodborne disease outbreak investigation, how often are they reported to PulseNet? Please "X" which applies.

	Individual	Summary
<b>Daily</b>		
<b>Weekly</b>		
<b>Biweekly</b>		
<b>Monthly</b>		

115. Does the Laboratory perform quality assurance assessment (verify) of the data transmitted to epidemiology, CDC, and Submitters?

- ☐ Yes, No      If yes, how often \_\_\_\_\_

116. Does the laboratory check data submitted to epidemiology from outside sources prior to it being reported to CDC or counted as a case of food poisoning?

- ☐ Yes, No, N/A

117. Does your laboratory have a written policy for protecting the confidentiality of patient data?

- ☐ Yes, No

118. How are data stored to protect confidentiality? Please "X" all that applies.

- \_\_\_\_ Locked Files
- \_\_\_\_ Without Identifiers
- \_\_\_\_ Password Required
- \_\_\_\_ Other (specify) \_\_\_\_\_

119. How long are patient data stored?

120. How long are isolates stored?

121. Does your state have a policy which clearly defines to whom you have authority to ship isolates?  
☐ Yes, No
122. Do you receive feedback from epidemiology regarding investigations initiated as a result of specific laboratory results?  
☐ Always, Sometimes, Never
123. When reporting test results to epidemiology, is there a mechanism in place for confirming whether results were received? (email to notify of receipt, confirmation of receipt from fax, etc..)  
☐ Yes, No
124. Do you follow up with epidemiology if no feedback is received regarding a cluster identified by the laboratory?  
☐ Yes, No
125. On a scale from 1 to 10, with 10 being excellent, how would you rate feedback from epidemiology regarding ongoing or completed investigations? (circle number below.)  
 1 2 3 4 5 6 7 8 9 10
126. Does your laboratory analyze laboratory data for cluster trends before reporting it to epidemiology?  
☐ Yes, No
127. Who do you notify if a cluster is identified? Please "X" where appropriate.  
☐ Local Epidemiology  
☐ State Epidemiology  
☐ Other (specify) \_\_\_\_\_

128. How are results reported when a cluster is identified? Please "X" all that apply.

Mail	
Electronic	
Phone	
Fax	

129. Do you have thresholds for cluster identification?  
☐ Yes If yes, what are they? \_\_\_\_\_  
☐ No
130. Were laboratory thresholds for cluster identification established in collaboration with Epidemiology?  
☐ Yes, No
131. What percentage of clusters get investigated by epidemiology? (Use the table below to give percentage, use estimates)

Organism	% of Clusters Investigated
<i>E. coli</i> 0157:H7	
<b>Salmonella</b>	
<b>Listeria</b>	
<i>Norwalk</i> -like virus	
<b>Hepatitis A</b>	
<b>Campylobacter</b>	
<b>C. botulinum</b>	
<i>S. aureus</i>	
<i>Shigella</i>	
<i>Vibrio</i>	
Other(specify)	

132. On a scale 1 to 10, with 10 being excellent, how do you rate epidemiology's capacity to act on laboratory data? (Circle the number below)  
 1 2 3 4 5 6 7 8 9 10
133. Is the laboratory's existing capability being adequately utilized by the epidemiology program?  
☐ Yes, No
134. If the laboratory capability is not being adequately utilized by the epidemiology program, what factors limit this capability?
- |   |   |
|---|---|
| <input type="radio"/> Expertise                 | <input type="radio"/> Delayed notification        |
| <input type="radio"/> Statistical support       | <input type="radio"/> Lack of apparent importance |
| <input type="radio"/> Limited staff             | <input type="radio"/> Politics                    |
| <input type="radio"/> Ability to pay overtime   | <input type="radio"/> Jurisdictional issues       |
| <input type="radio"/> Travel policy constraints | <input type="radio"/> Other (specify) _____       |

135. What is the level of detail of PFGE results reported to Epidemiology?
- ☐ Pattern numbers reported
  - ☐ Pattern matches noted
  - ☐ Other, explain \_\_\_\_\_
136. Do you reply to PulseNet listserv posting in a timely manner (i.e., within 24-48 hours)? If not, why?
- ☐ Yes, No \_\_\_\_\_
137. Does your Laboratory perform testing for disease investigation that was not ordered by the physician? If yes, then "x" the appropriate response to the right.
- ☐ Yes \_\_\_ when evaluating new methods \_\_\_ during a suspected outbreak
  - ☐ No
138. How do you report positive results when that particular test was not ordered?
139. How do you deal with Institutional Review Board issues relating to laboratory based surveillance testing?
140. Does your laboratory possess licensure agreements with commercial companies and / or vendors for the use of proprietary technologies, supplies or reagents (i.e. Roche)? If so, please list which ones.
141. When clinical diagnostic testing is performed by an out of state laboratory (i.e. Quest, LabCorp.) are positive results of reportable foodborne diseases sent to the Public Health Laboratory by the out of state laboratory?
- ☐ Yes, No
142. When clinical diagnostic testing is performed by an out of state laboratory (ex. Quest, LabCorp.) are foodborne disease isolates submitted to your laboratory as required in your state regulations?
- ☐ Yes, No, N/A
143. When conducting clinical diagnostic testing, are positive results of reportable foodborne diseases sent to the local/state epidemiology by the out of state laboratory?
- ☐ Yes, No, Unsure

Summary:

Are there any questions that you feel we have overlooked in trying to assess your laboratory's capacity in the area of foodborne disease/food safety testing?

(space for answer)

Laboratory Contact Person \_\_\_\_\_  
Phone number \_\_\_\_\_