VERSION 2.0 WORK IN PROGRESS:
Public Health Laboratories
Expert Panel Summary
September 2018

The Public Health Accreditation Board is a 501(c)3 nonprofit organization dedicated to improving and protecting the health of the public by advancing and ultimately transforming the quality and performance of state, local, tribal, and territorial public health departments.

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- PHAB is continually working to ensure that the accreditation requirements are current and reflect state-of-the-art public health practice, as public health evolves. PHAB is in the information-gathering phase of the development of a Version 2.0 of the accreditation Standards and Measures. In 2019, PHAB will develop a proposed set of Version 2.0 standards and measures for public vetting in 2020.

- One of the key areas that PHAB identified for review and potential refreshing of the standards and measures is the public health laboratory. In partnership with the Association of Public Health Laboratories, PHAB held an Expert Panel meeting on September 6, 2018. The purposes of the expert panel were to review the current health department accreditation standards and measures related to public health laboratory capacity; to discuss any pertinent changes in public health laboratory practice and/or support for health departments work; and, to recommend potential revisions in the accreditation standards and measures as PHAB prepares Version 2.0.

- In general, health departments going through the accreditation process have performed well on the public health laboratory related measures. Specifics about the measures are included in a document entitled "What We Have Learned from Accredited Health Departments about Public Health Laboratory Capacity".

- One of PHAB's early think tanks prior to the launch of the accreditation program was a Public Health Laboratory Think Tank. That report from 2010 was reviewed as part of this recent expert panel meeting and is posted on the website with the other public health laboratory documents.

- In terms of the current standards and measures, some clarification regarding the following was discussed:
    - When discussing plans for surge capacity, greater clarity and some updated language is needed. Also, the requirement for a list of equipment is confusing. PHAB will explore concepts related to continuity of operations and will also consider the need for laboratories to sustain expanded capacity over a

longer period of time.
  - There have been some changes in the way that states manage notifiable disease follow-up. PHAB should connect with CSTE and others before Version 2.0 is finalized.
  - PHAB needs to clarify when a local health department handles only one type of specimen, the protocol will be less comprehensive than for those who handle multiple types of specimen.
  - Some additional clarification is needed regarding the types of services requiring certifications/accreditations by the public health laboratory and documenting those certificates accordingly.
  - Select agent certification is no longer required.

- There are several places in the current standards and measures related to the public health laboratory where recommendations were made to combine some areas to avoid redundancy.

- Since many of the public health laboratory related standards and measures also include emergency preparedness and epidemiology content, it is essential that PHAB connect with any of those updated requirements before changes are proposed.

- Measures should demonstrate an ongoing collaborative relationship of the laboratory with programs across the department, especially epidemiology and environmental health.

- Measures need to assure routine and 24/7 emergency access to laboratory services.

- Measures should address timeliness of laboratory services and reporting (e.g., newborn screening).

- In terms of emerging public health laboratory issues, the following were discussed:
  - The state health department laboratory's role in maintaining a statewide lab network to support public health functions.
  - The role of the laboratory as a source of information, analysis, and interpretation for decision making, as well as its production role.
  - Cross and inter-jurisdictional, as well as cross-border collaboration is a stronger need than ever before.
  - Bio-monitoring for environmental and other community health hazards
  - Radiological testing
  - Genomic sequencing
  - Point of care capacity

- Several suggestions related to workforce capacity and workforce development were discussed, including attention to the licensure and certifications needed for lab personnel.
  Inclusion of the laboratory staff in training others about safe, clean and timely specimen collection, packaging and shipping was also identified as a recommendation.

- In terms of ensuring that the health departments have good examples to consider as they prepare their documentation, PHAB will work with APHL to develop tip sheets and case examples for technical assistance use. This will highlight areas where laboratory examples could be included for measures that do not specifically reference labs—for example, related to strategic planning, policy work, etc.—to better engage laboratories throughout the accreditation and reaccreditation process.

- PHAB will consider APHL's Eleven Core Functions of Public Health Laboratories as it proposes revisions to the Standards and Measures.

- In terms of PHAB site visitors, there were two recommendations:
    - PHAB and APHL will work to recruit some additional public health laboratorians to serve as site visitors.
    - For those site visit teams where none of the site visitors have direct public health laboratory expertise, PHAB and APHL could develop some additional tips so that the measures that are public health laboratory focused can be assessed accurately.

Expert Panel Participants

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VERSION 2.0 WORK IN PROGRESS:
Evidence Related to Public Health Laboratories
September 2018

This document represents findings from a scan of the literature related to laboratory services and surveillance in public health. It is not meant to be an exhaustive search. If there are other resources on this topic of which you think PHAB should be aware, please contact Jessica Kronstadt at jkronstadt@phaboard.org.

According to Richards et al., "Public health surveillance is the foundation of effective public health practice"[1] and should support timely, efficient, flexible, scalable, and interoperable data acquisition, analysis, and dissemination. As an example of the impact of public health labs and surveillance, one study noted that "PulseNet activities prevent at least 260,000 cases of foodborne disease each year in the United States, saving the U.S. economy one-half billion dollars"[2]

As the field is evolving, there are several important considerations that emerge from the literature:

- Technological changes. Advances in in laboratory methods allow for much faster processing but also produce significantly larger data sets, requiring new IT and data infrastructure – including systems for data transmission, quality assurance, data standards, and data security[2,3,4,5]
    - For example, next-generation sequencing (NGS) and whole-genome sequencing (WGS) are high throughput lab methods that are replacing traditional techniques and allow for faster detection of outbreaks[1,2] but "will require fundamental changes in laboratory practice at multiple levels" to incorporate into practice.[2]
- Different types of data. Future of public health surveillance will depend more on secondary use of existing data – including clinical and social determinants of health data.[1]
- Sharing data. As testing can take place in a greater variety of locations, it requires systems that can compile results from decentralized testing in private and public health encounters.[1,2] This highlights the importance of standards-based interoperability[3,4] and greater collaboration.[2]
- Workforce. Advances in technology and changes in laboratory processes necessitate a workforce educated and trained in these new methods, which may be addressed through continuing education and specialized fellowships.[3,4]

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- Shared testing services. Public health laboratories may be able to partner with other laboratories to share testing services to reduce duplication and save on costs, but developing those partnerships requires addressing funding considerations and sharing agreements.[4,6]
- Shared training services. As part of the CDC's Advanced Molecular Detection (AMD) program, state and local health departments are being encouraged to form local or regional training networks with one lab taking the lead to partner with universities for capacity-building, long-term collaboration, and innovation.[2]
- Quality Improvement initiatives are a crucial part of the fabric of public health laboratories and have been helpful in improving operations, outcomes, and relationships in the community.[3,5,7]
- Inhorn identifies several other priority areas for state and local public health laboratories:
    - Effective communication with legislative and administrative bodies;
    - Emergency plans in place that ensure continuity of services; and
    - Effective communication with the public and with partners to build relationships and trust in the community.[3]

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[1] Richards CL, Iademarco MF, Atkinson D, et al. Advances in public health surveillance and information dissemination at the Centers for Disease Control and Prevention. *Public Health Rep.* 2017;132(4):403-410.
[2] Gwinn M, MacCannel DR, Khabbaz RF. Integrating advanced molecular technologies into public health. *J Clin Microbiol.* 2017;55(3):703-714.
[3] Inhorn SI, Astles JR, Gradus S, et al. The State Public Health Laboratory System. *Public Health Rep.* 2010;125(Suppl 2):4-17.
[4] Ridderhof JC, Moulton AD, Ned RM, et al. The laboratory efficiencies initiative: partnership for building a sustainable national public health laboratory system. *Public Health Rep.* 2013;128(Suppl 2):20-33.
[5] Ridderhof JC, Wilcke BW Jr. Public health laboratory systems: at the crossroads. *Public Health Rep.* 2013;128(Suppl 2):1-6.
[6] Hsieh K, Kimsey P, Buehring G. Using interorganizational partnerships to strengthen public health laboratory systems. *Public Health Rep.* 2013;128(Suppl 2):63-69.
[7] Su B, Vagnone PS. State public health laboratory system quality improvement activities. *Public Health Rep.* 2013;128(Suppl 2):34-39.

VERSION 2.0 WORK IN PROGRESS:
Laboratory Capacity – What Have We Learned from Accredited Health Departments?
August 2018

This document summarizes what PHAB has learned about how accredited health are addressing laboratory-related activities. In particular, it focuses on the reasons that health departments struggled with the seven measures in Domain 2 and one measure in Domain 11 that relate to public health labs. It also includes findings from Section II of accredited health departments' Annual Reports.

Below is a summary of the distribution of assessments for the selected Domain 2 and Domain 11 measures, as well as the percentage of health departments that were required to address each measure in an action plan. In general, performance on these measures is very strong. Most of these Measures fall within the top third of all Measures in terms of performance (i.e., higher proportion assessed as Fully or Largely Demonstrated and smaller proportion included in an Action Plan compared to most Measures). Performance on Measures 2.2.1 and 2.3.3 fall within in the middle third among all Measures (i.e., neither among the highest or the lowest performing Measures). It is important to note that these Measures were selected because they explicitly reference laboratories in their requirements. However, they are broader than laboratory capacity. Therefore, health departments may have been assessed as Not or Slightly Demonstrated on these Measures for reasons unrelated to their laboratory work. These data are for 34 state health departments (SHDs) and 234 local health departments (LHDs) whose Site Visit Reports have been finalized and reviewed by the Accreditation Committee.

Measure	Fully Demonstrated		Largely Demonstrated		Slightly Demonstrated		Not Demonstrated		Action Plans	
	SHD	LHD	SHD	LHD	SHD	LHD	SHD	LHD	SHD	LHD
2.1.4	79.4%	69.2%	20.6%	25.2%	0.0%	5.6%	0.0%	0.0%	0.0%	2.6%
2.1.5	70.6%	75.2%	23.5%	20.9%	5.9%	3.8%	0.0%	0.0%	0.0%	2.6%
2.2.1	73.5%	73.5%	26.5%	17.1%	0.0%	7.7%	0.0%	1.7%	0.0%	6.4%
2.3.1	64.7%	72.6%	35.3%	23.9%	0.0%	3.4%	0.0%	0.0%	0.0%	2.6%
2.3.2	88.2%	80.3%	11.8%	16.7%	0.0%	3.0%	0.0%	0.0%	0.0%	2.6%
2.3.3	52.9%	56.0%	26.5%	35.9%	20.6%	6.4%	0.0%	1.7%	2.9%	5.1%
2.3.4	73.5%	76.5%	23.5%	20.5%	0.0%	2.6%	2.9%	0.4%	2.9%	2.1%
11.1.7	55.9%	58.1%	44.1%	38.9%	0.0%	2.6%	0.0%	0.4%	0.0%	1.3%

To better understand health departments' performance on these Measures, PHAB conducted an analysis of the conformity comments of health departments that were assessed as Not or Slightly Demonstrated for the first 256 Site Visit Reports. The results of those analyses are shown below. For each Measure, the most common reasons for the assessment are listed, including the number of health departments for which that reason was indicated. One health department could have multiple reasons listed.

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Performance on Measure 2.1.4
Measure 2.1.4 requires that the health department demonstrate collaborative work through established governmental and community partnerships on investigation of reportable disease, disease outbreaks, and environmental public health issues. The most common challenges among health departments assessed as Not or Slightly Demonstrated were:

- Requirement 2 – Documentation did not clearly describe partners' roles in investigations (6 health departments)
- Documentation does not meet PHAB date requirements (5 health departments)
- Requirement 1 – Documentation submitted was not a contract or MOU (4 health departments)
- Requirement 1 – Documentation submitted did not pertain to disease or environmental health investigation (4 health departments)

Note: Requirement 3, which addresses "laboratory testing for notifiable/reportable diseases" was not among the most common challenges.

Performance on Measure 2.1.5
Measure 2.1.5 requires that health departments monitor timely reporting of notifiable/reportable diseases, lab test results, and investigation results. Among health departments assessed as Not or Slightly Demonstrated, the most common challenge was:

- Requirement 1 – Insufficient evidence of tracking various elements of investigation (8 health departments)

Performance on Measure 2.2.1
Measure 2.2.1 requires that health departments have protocols in place for the containment/mitigation of public health problems and environmental hazards. Among health departments assessed as Not Demonstrated or Slightly Demonstrated, the following were the most common challenges:

- Lacked evidence of the use of prophylaxis and emergency biologics (12 health departments)
- Lacked evidence of disease-specific containment and mitigation (10 health departments)
- Lacked evidence of clinical management (10 health departments)
- Lacked evidence of contact management (9 health departments)
- Lacked process for exercising legal authority for disease control (8 health departments)

Note: While it was not among the most common challenges, there were 5 health departments that did not document communication with the public health laboratory.

Performance on Measure 2.3.1
Measure 2.3.1 requires that health departments have 24/7 emergency access to epidemiological and environmental public health resources capable of providing rapid detection, investigation, and containment/mitigation of public health problems and environmental public health hazards. The challenges for health departments assessed as Not or Slightly Demonstrated varied, but the most common were:

- Requirement 1 – unclear provision for 24/7 access (3 health departments)
- Requirement 2 – insufficient call list for contacting epidemiological and environmental public health resources (3 health departments)
- Requirement 3 – no list/description of contracts/MOUs that define access to resources (3 health departments)
- Requirement 3 – MOUs provided, but access to resources not defined (3 health departments)

Note: None of these Not or Slightly Demonstrated conformity comments explicitly cited lack of laboratory access.

Performance on Measure 2.3.2

Measure 2.3.2 requires 24/7 access to laboratory resources capable of providing rapid detection, investigation, and containment of health problems and environmental public health hazards. The challenges for health departments assessed as Not or Slightly Demonstrated varied, but the most common were:

- Requirement 3 – Narrow scope of specimens submitted (4 health departments)
- Requirement 2 – Lack of contracts/MOUs with public and private laboratories to provide support services (3 health departments)

Performance on Measure 2.3.3

Measure 2.3.3 requires access to laboratory and other support personnel and infrastructure capable of providing surge capacity. The most common challenges for health departments assessed as Not or Slightly Demonstrated were:

- Requirement 2 – Lack of specific staffing (16 health departments)
- Requirement 1 – Personnel to provide surge capacity not pre-identified (14 health departments)
- Requirement 2 – Lack description of how staff can access staffing list for surge capacity (14 health departments)
- Requirement 1 – Lack surge capacity protocol (8 health departments)
- Requirement 5 – Lack listing and description of MOUs in place for additional staff and services for surge capacity (8 health departments)
- Requirement 1 – Documentation does not address surge capacity (7 health departments)
- Requirement 3 – Equipment list is incomplete or missing key components (7 health departments)
- Requirement 3 – Equipment list does not indicate how equipment will be deployed for surge capacity (6 health departments)
- Requirement 4 – Lack exercise schedule for training or exercises to prepare personnel who will serve in a surge capacity (6 health departments)
- Requirement 2 – Documentation does not address surge capacity (6 health departments)
- Requirement 5 – Lack MOUs/agreements that relate specifically to laboratory services (6 health departments)

Performance on Measure 2.3.4

Measure 2.3.4 requires that health departments collaborate among Tribal, state, and local health departments to build capacity and share resources to address Tribal, state, and local efforts to provide for rapid detection, investigation, and containment/mitigation of public health problems and environmental public health hazards. The challenges for health departments assessed as Not or Slightly Demonstrated varied, but the most common was:

- Requirement 1 – No evidence of collaboration with other health departments – local, Tribal, or state (5 health departments)

Performance on Measure 11.1.7

Measure 11.1.7 requires that facilities (including laboratories) are clean, safe, accessible, and secure. Requirement 1 specifically requires that health departments provide licenses for their laboratories. Of

the health department assessed as Not Demonstrated or Slightly Demonstrated, one did not provide the necessary laboratory licenses.

Annual Reports

As part of Section II of the Annual Reports, health departments are asked to describe a quality improvement project and to indicate to which Domain(s) the project relates. Twenty-seven health departments indicated their projects related to Domain 2, including 6 that specifically mention lab activities. Those projects focus on:

- Specimen processing time during surge
- "Too long in transit" blood lead specimens
- Tracking private well samples
- Distribution of private water testing kits being
- Morbidity reports for chlamydia
- Turnaround time of lab results for HIV

In addition, in the section on emerging public health issues, two health departments described laboratory services, including one description of work related to whole-genome sequencing infrastructure and another lab designated as an Antimicrobial Resistance Regional Laboratory.