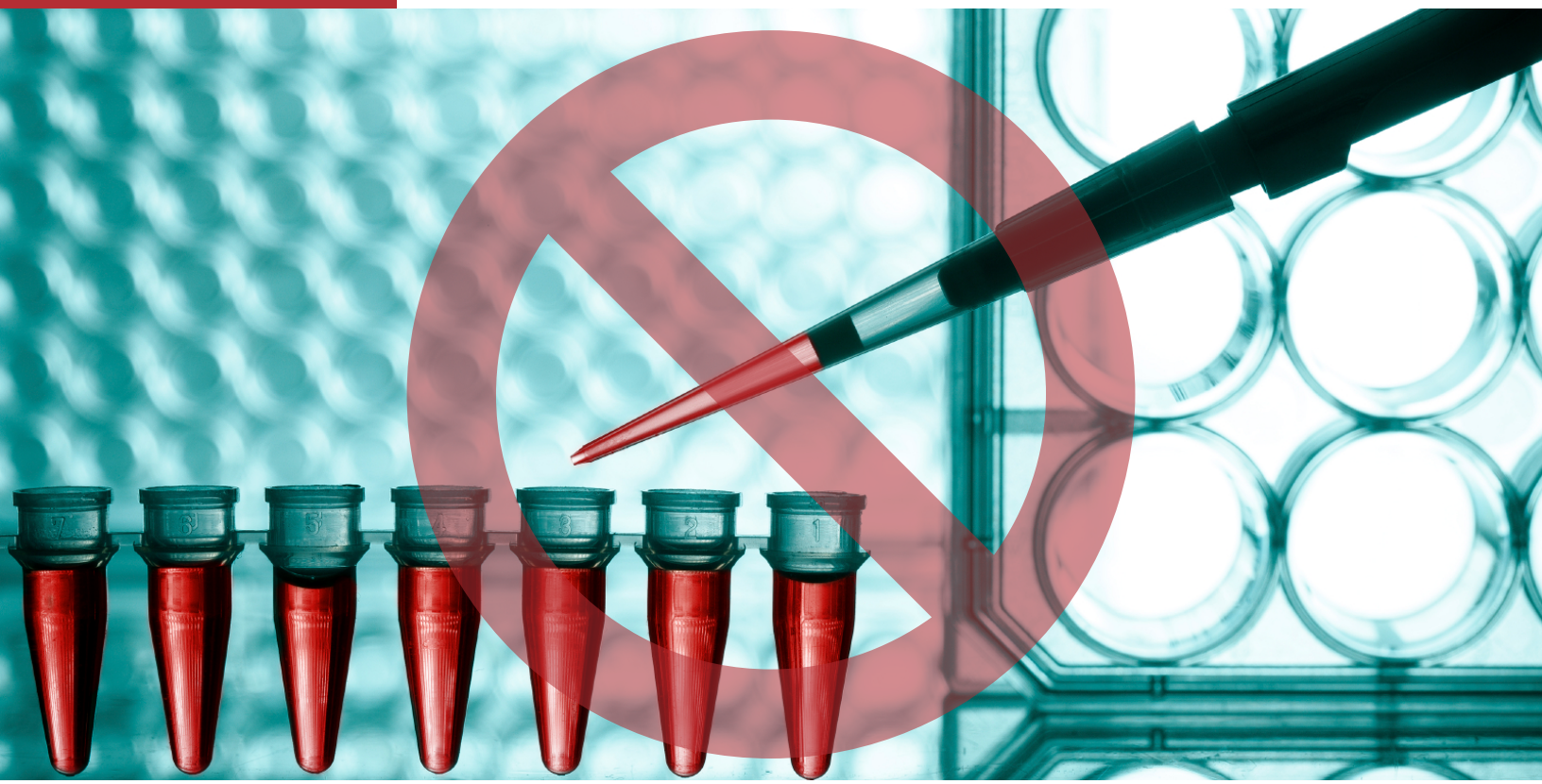
Laboratory Test Discontinuation Guidance Tool



MARCH 2024

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

Contents

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The authors thank Bertina Su for project management and support.

Association of Public Health Laboratories

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

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Background

All public health laboratories occasionally face a decision on whether to keep or delete a test from their test menu. Unlike private sector laboratories where the business considerations drive these decisions, public health laboratories face more complex dilemmas. Questions of test discontinuation are sometimes easily answered based on public health needs in the jurisdiction, but other considerations must also be accounted for and ultimate decisions may differ by jurisdictional and laboratory needs.

This guide walks users through a variety of considerations that may influence the decision to discontinue a test, including disease prevalence, test availability from other sources, staff capacity, grant commitments and legislative code requirements. Use the checklists and fill fields in each section to identify relevant information and work through the implications of discontinuing a test.

Test Under Review

Identify key information about the test under consideration for discontinuation, what prompted this review and the personnel responsible for the review:

Test Name: _____

Test Name in LIMS: _____

Lead Analyst: _____ **Lead Supervisor:** _____

Laboratory Director: _____

Initial Information / What Prompted the Review:

Reason for Test Discontinuation

Due to rapidly evolving technologies, a common question asked in a laboratory setting is when and why we should evaluate and revise or update available testing platforms. It is critical that laboratories periodically review their testing platforms and make decisions on whether to keep, update or discontinue tests performed on this testing platform.

An example is the advancement of laboratory molecular-based assays for infectious disease diagnosis. This is perhaps one of the most common reasons to discontinue a conventional (e.g., culture-based) test and replace it with a more advanced molecular assay. One good example is the emergence of molecular serotyping of infectious disease agents of public health importance like Salmonella, which in many laboratories replaced traditional serotyping methods. With the widespread implementation of molecular diagnostic testing and pathogen characterization, a shortage of trained laboratory scientists with knowledge and expertise in conventional methods exists. Another consequence of this emerging technology is that reagents, supplies, and proficiency test materials used for conventional methodologies are becoming increasingly difficult to procure as a direct result of supply and demand issues.

It is reasonable to consider discontinuing a particular test if a request for testing has not been made in a year or more. Still, careful consideration should be given to laboratory testing with a significant impact on public health and patient management before discontinuation. Another consideration for discontinuation is the laboratory's inability to offer reasonable turnaround times. If a delay in test results might negatively impact patient management, it may be advantageous to consider an alternative laboratory (commercial or reference) and discontinue the testing at the public health laboratory.

Scenarios that could potentially trigger a test discontinuation review can include a change in technology, low volume of tests, concerns with test performance, unavailability of trained personnel, or a lack of reagents, supplies or proficiency testing materials.

Identify Relevant Reasons to Discontinue the Test

- ☐ Change in technology
- ☐ Concerns with test performance
- ☐ Unavailability of trained personnel
- ☐ Low volume of tests
- ☐ Lack of reagents, supplies, PT material, etc.
- ☐ Other: _____

Please elaborate on your selection(s):

Clinical Considerations

What is the impact on patients of (dis)continuing this test?

While not every assay performed in a public health laboratory is utilized for individual patient care, it is still critical to consider a test's impact on individual patient testing and reporting.

When deciding whether to (dis)continue a test, consider the clinical implications of your decision. Does performing and reporting the test impact the patient's treatment or outcome/prognosis? This includes (but is not limited to) considering whether treatment options are available, and, if available, how much the turnaround times matter. Does clinical urgency/acuity justify keeping the test within the jurisdiction? Does the negative impact of delayed results/treatment outweigh the arguments favoring discontinuing the test? Once discontinued, if needed for an emergent situation/outbreak, is it feasible to bring the test back, or do you have an acceptable backup for such a situation?

Understanding the implications may involve feedback from subject matter experts—especially from your jurisdiction—such as providers, clinicians and geneticists, depending on the test or condition under consideration. Their input will allow you to make informed decisions regarding test discontinuation.

Identify Relevant Clinical Considerations for the Test

- ☐ Clinical implications of test results (is treatment available?)
- ☐ Feedback from clinicians/geneticists/experts
- ☐ Clinical urgency
- ☐ Other: _____

Please elaborate on your selection(s):

Epidemiological Considerations

What is the impact on public health of (dis)continuing this test?

As the bulk of work done by public health laboratories supports epidemiological investigations for public health response, it is essential to consider the broader population health implications when discontinuing a laboratory test for public health purposes. These epidemiological considerations ensure that the test is no longer necessary or can be replaced with more effective alternatives. The prevalence of the disease or condition that the laboratory test aims to detect directly impacts epidemiological surveillance for that jurisdiction. If the disease is rare or its prevalence has significantly decreased, discontinuation of the test may be warranted. However, monitoring disease prevalence by public health epidemiologists is important to detect potential resurgences or changes in disease patterns.

Additionally, the public health impact of discontinuing the laboratory test directly impacts public health epidemiologists. Consider the consequences of false-negative or false-positive results prevalence, potential delays in diagnosis or treatment, and the overall impact on disease surveillance and control efforts. Public health officials, including epidemiologists, should weigh these potential risks against the benefits of discontinuing the test.

Further, epidemiologists engage with relevant community partners, including healthcare providers, laboratory professionals, patient advocacy groups and policymakers. Gathering their input and perspectives may impact the decision to discontinue the laboratory test. This collaborative approach ensures that the decision considers the diverse viewpoints and experiences of those affected by the test.

Finally, public health epidemiology requires a robust surveillance and monitoring system to track the impact of discontinuing the laboratory test. This system should include ongoing data collection and analysis to detect any unexpected changes in disease patterns, diagnostic accuracy or public health outcomes after discontinuation. Such monitoring helps identify any necessary adjustments or reevaluation of the decision.

By considering epidemiological factors, public health officials can make informed decisions regarding discontinuing a laboratory test, ensuring that public health resources are allocated optimally while maintaining effective disease surveillance and control measures.

Identify Relevant Epidemiological Considerations for the Test

- ☐ Disease prevalence in your jurisdiction
- ☐ Presence of appropriate vector in your jurisdiction
- ☐ Disease prevalence in neighboring jurisdictions
- ☐ Circulation globally
- ☐ Likelihood of importation to your jurisdiction
- ☐ Epidemiological urgency
- ☐ Test availability for health equity
- ☐ Agency or epidemiology needs or reportable conditions
- ☐ Other: _____

Please elaborate on your selection(s):

Financial and Business Considerations

What is the financial impact to the laboratory of (dis)continuing this test?

There are multiple financial or business-related considerations to take into account when determining if a test can be discontinued with minimal impact on laboratory customers and partners.

Public health laboratories exist as part of jurisdictional laboratory systems and are frequently the only providers of certain tests in the geographic area. Therefore, the question of whether there are other providers of the test available in the jurisdiction is of primary importance. The availability and accessibility of testing services must be considered not only in the geographic sense (distance to the laboratory provider) but also in terms of the cost to the current laboratory clients. For example, a test may be widely available but not accessible due to the fees charged by commercial providers; in this case, a public health laboratory may choose to continue to offer a test (otherwise commercially available) for healthcare providers serving certain communities or populations at a reasonable cost or assure the availability of the

test through an agreement with another laboratory.

For most tests, a cost-benefit analysis will guide a decision of whether a test should be provided by a public health or commercial laboratory. The cost-benefit analysis is a systematic process of examining all costs of performing a test and weighing it against the public health benefits achieved through the test's availability and delivery.

Consider all the costs associated with conducting the laboratory test. These costs include, but are not limited to, personnel compensation, laboratory infrastructure, equipment, supplies, quality control, biosafety precautions, training, and maintaining accreditation and regulatory compliance. Some of these costs are fixed (e.g., the cost of an existing facility) and are not likely to be impacted by a single test discontinuation. Others (e.g., the cost of reagents or supplies) would change significantly if the test is no longer performed.

In a commercial setting, the fee charged for a test is expected to cover all associated costs with anticipation of a profit margin. Assessing all potential benefits of providing a test can be more difficult in a public health setting, where the primary benefit is likely not the revenue brought in by the test. At the societal level, the potential benefits may include reduced disease transmission, improved outbreak response, and improved public health interventions. These benefits can be more difficult to quantify as they involve the potential cost savings associated with early detection, and the value of lives saved or improved quality of life for affected individuals and communities.

One of the unique roles of public health laboratories is to provide the capability to test for rarely occurring but highly consequential pathogens, e.g., polio or smallpox virus. Many public health laboratories have governmental (federal or state) funding for such purposes and maintaining readiness to deploy a test when needed (e.g., in the event of an outbreak) is a condition of receiving these funds; therefore these tests cannot be discontinued for otherwise valid business reasons.

Similarly, partnerships with academic institutions and community organizations—whether formal or informal—that include a commitment to provide a test for research collaborations will impact the feasibility of discontinuing a test for business reasons only.

Identify Relevant Financial or Business Considerations for the Test

- ☐ Availability/accessibility of timely testing in other laboratories
- ☐ Cost-benefit analysis
- ☐ Existing funding sources
- ☐ Grant requirements
- ☐ Financial impact to submitters if test is discontinued
- ☐ Academic institution input (collaborations)
- ☐ Other: _____

Please elaborate on your selection(s):

Physical Need Considerations

What is the impact to the physical laboratory space of (dis)continuing this test?

When considering whether to discontinue a clinical or environmental test within a public health laboratory the physical considerations surrounding the test need to be taken into account.

Some public health laboratories' facilities are antiquated and located within buildings with an aging infrastructure. This can make it challenging to maintain adequate HVAC, plumbing and electrical systems, and to safety store items such as high-consequence pathogens, compressed gases, and chemical, biological or radioactive waste. Factors such as these can be arguments to support test discontinuation.

Another critical consideration is the physical security of the laboratory. As regulatory requirements or other factors change, the laboratory must consider physical security when deciding whether to continue or discontinue a test. For testing that falls under select agent regulations, the laboratory must have a prescribed number of secured entries between the outside of the laboratory and the registered space. Testing involving radioactive or controlled substance (drug) materials also requires stringent security and controlled access to spaces where these materials are manipulated and stored, including waste products generated. If security measures cannot meet regulatory requirements for various tests, then the discontinuation of the test should be considered.

Above all else, safety considerations should be prioritized. Safety considerations could include the safety of testing and support personnel, patient safety, safety of the community or environment. Performing a risk assessment could provide valuable information regarding safety considerations that should be considered for a given test method.

Identify Relevant Physical Considerations for the Test

☐ Safety

☐ Security (e.g., select agents, physical security)

☐ Facility issues (e.g., space, HVAC)

☐ Other: _____

Please elaborate on your selection(s):

Other Considerations

In addition to the aforementioned considerations, other factors to review when deciding to (dis)continue a test include:

- **Staffing capacity**; laboratories that are short-staffed or have limited staff with the relevant skills may be unable to perform certain testing.
- **Work schedules**; some labor-intensive tests can affect the daily work schedule and make it difficult to meet the other demands within the laboratory.
- **Federal recommendations**, such as a recommended change in the testing algorithm, may alter a laboratory's capability to perform a test.
- **State legislative requirements**, such as the state public health code or statute, may require the public health laboratory to conduct a test; if so, legislation would be needed to discontinue that test.
- **Ease of reestablishing the test**, in the event that it is needed again.

Identify Other Relevant Considerations for the Test

☐ Staffing capacity and work schedules

☐ Federal recommendations

☐ State legislative requirements

☐ Newsworthy/political considerations

☐ Ease of test reestablishment

☐ Other: _____

Please elaborate on your selection(s):

Identification and Notification of Partners

Before deciding that a test should be deleted/discontinued, the laboratory must consider and consult with impacted partners as they may have information the laboratory has not considered that will impact the decision. These partners are typically other state agencies, clinical laboratories, commercial laboratories, local health departments, hospitals, clinicians and anyone else identified by the laboratory as a recipient of the test results.

The laboratory must notify the impacted partners as soon as possible about the decision to discontinue a test. If the partner still wants the test to be available, the laboratory may offer alternative solutions, such as sending the test to another laboratory. An important aspect is to allow sufficient time to permit them to make other arrangements.

Identify Partners for Input

☐ Notification of change to impacted parties Effective Date: _____

List of partners potentially impacted:

Conclusion

While the discontinuation of a test may appear to be a simple decision, it can be very complex. The decision may have ramifications beyond the laboratory that must be addressed so as to not impact public health and/or patient management.

By using this toolkit to go through the thought process, laboratories can build structure into their decision-making tree. Through structure, standardization can be achieved. By keeping a record of the decision process, the rationale behind the decision can help future laboratory leadership gain a deeper understanding of the thought process and what was considered.