



APHL Guidance

Considerations for Public Health, Commercial and Hospital-Based Testing for Novel Influenza A H1N1 Virus

This guidance document was developed by the APHL Influenza Workgroup in coordination with the APHL Infectious Diseases committee and is intended to assist PHLs in addressing the potential role of tests for novel influenza A H1N1 swine-like developed by private sector and commercial laboratories testing.

Public Health laboratories' primary responsibility during influenza epidemics and pandemics is surveillance and reference testing in support of early detection, public health response and control measures, and measuring the progress and "character" of a pandemic wave(s) as it progresses at the community and state level. In the early stages of an outbreak, this will involve a surge in diagnostic testing in the PHLs to detect cases and monitor the spread of the virus. As the outbreak evolves past the Introduction interval, the public health need to detect every case diminishes while the demand for testing in support of patient care may increase well beyond the capacity of the PHLs in the jurisdiction. As circumstances and resources will differ among the states, there may be different approaches for the use of laboratory diagnostics.

In the wake of the recent and on-going novel influenza A H1N1 outbreak, PCR tests are being developed by commercial and hospital laboratories to address the diagnostic demand. Public health departments and PHLs should consider the utility and impact of the availability of these tests, and partner with the private sector labs as appropriate to obtain the necessary public health data.

Testing in private sector laboratories

1. Diagnostic testing services provided by the private sector should be viewed as a valuable surge capacity resource.
2. Both commercial and larger hospital/university-based laboratories have the capability to rapidly develop molecular diagnostic assays for emerging diseases once genetic sequence information is publicly available. As with any diagnostic test, CLIA-compliant verification and validation must be performed, on-going QA must be maintained, and on-going monitoring must occur to ensure the test remains sensitive in the event of changes in the virus.
3. It will be necessary for PHLs to consider large national commercial labs and state-based private/ university-based labs as separate entities. The former are of **national** interest, while the latter are of interest to individual **states**.
4. The CDC (HHS) has the authority to help develop and access commercial lab capacity with or without PHL support. However, the CDC has no responsibility to provide test kits/reagents to any laboratory other than public health.

- a. These kits and reagents were developed by CDC with federal funds as a rapid, standardized, and adaptable (e.g. addition of new strains) test method for surveillance testing performed in public health laboratories. CDC does not have the capacity to expand distribution to the private sector, especially where the tests would be used primarily for diagnostic, fee-for-service testing. Additionally, mechanisms are not available to reimburse private sector labs for fee-exempt testing.
 - b. Laboratories may choose to develop their own tests based on the novel influenza A H1N1 genome sequence and the CDC developed assay protocol that are publicly available on the CDC and WHO websites. Biosearch Technologies, the company that manufactures the primers and probes for CDC, has made them available for to private sector laboratories for purchase.
 - c. The APHL Board of Directors has recommended that CDC not provide primers/probes or other reagents to private sector laboratories for diagnostic testing at this time.
5. Currently, the private sector performs testing of public health significance on a routine basis. All testing, including lab developed tests must comply with federal and state regulatory requirements. Reporting and specimen referral for supplemental testing must comply with state and local statutes.
 6. Much of the testing demand fills a diagnostic need not a public health need, particularly during the Acceleration and Peak interval periods. Demand for testing novel influenza A H1N1 can be expected to rise again in the fall when influenza season begins. Even without data from additional diagnostic laboratory testing, there should be more than adequate PHL test data to drive critical public health decisions and responses.

Recommendations:

1. PHLs need to communicate with clinical labs and clinicians about the role of existing (traditional) influenza diagnostic and surveillance testing. Subsequent guidance from PHL's to clinical laboratories should address the utility and limitations of existing rapid point-of-care (POC) tests, new rapid tests with the ability to subtype, laboratory developed tests (LDT's) for influenza A/B PCR, the capabilities and limitations of the Luminex respiratory assay, virus culture, etc. This guidance should be based on CDC guidance and state policies.
2. Since the release of the genome sequences for novel influenza A H1N1, large commercial and private/university-based laboratories are developing diagnostic test(s) for novel influenza A H1N1. Neither CDC nor PHLs can or should be expected to be responsible for verifying and validating these tests. It should be the responsibility of the private sector to validate tests to meet regulatory requirements including CLIA, and where relevant, New York State's regulatory (CLEP) requirements. If state PHLs require additional documentation of test performance, potential collaborations could include:
 - a. State PHLs may choose to support verification studies in clinical laboratories in their jurisdiction to gain better understanding of the performance of these assays.
 - b. A single PHL voluntarily working with a commercial lab to evaluate the performance of these tests, (perhaps for fee-for service) on behalf of all PHLs.

- c. Large commercial laboratories could submit their test to New York State’s regulatory (CLEP) requirements, and the validation results could be accepted by all state PHLs.
 - d. State PHLs may request results of the CLIA compliant verification studies from commercial and clinical laboratories providing novel H1N1 testing in their jurisdictions.
- 3. Confirmatory testing for every positive test result in the private sector is not recommended or even feasible. Private sector tests must meet CLIA requirements and no diagnostic test is 100% reliable. Therefore, there is no need for private sector labs to report results as “presumptive” with follow-up confirmation. Health care providers should act on these results as they would other clinical diagnostic tests, interpreting results based on clinical presentation. Epidemiologists may choose to count these cases as either confirmed or probable depending on the degree of specificity needed in case counts. Epidemiologic case definitions should never impact diagnosis and treatment decisions.
- 4. Public health laboratories and epidemiologists need to determine how much data is needed to support public health decision making AND how much testing is feasible for PHLs to accommodate.*
- 5. Diagnostic testing that does not meet public health surveillance priority needs should be routed to private sector labs in order to help protect PHL testing capacity.
- 6. CDC (in collaboration with IDSA, CSTE, APHL) needs to provide guidance to clinicians in setting criteria for **responsible testing**, to ensure that testing resources (personnel and reagents) are used judiciously (there is not enough master mix anywhere in the world to support uncontrolled testing demand) within PH and private sector laboratories. For example, testing among people with mild illness, especially during acceleration/peak, is not warranted in most instances. In addition, education of the general public is critical to help lessen testing demand.
- 7. State and local PHLs, **in collaboration with their HD/epidemiologists and Health Officers**, should work with lab and clinician networks to:
 - a. Encourage testing be done at their own PHL as appropriate during Recognition and Initiation intervals.
 - b. Assess/estimate how many clients within their jurisdictions will use private sector testing, and the likely impact on accurate surveillance.
 - c. Interact with commercial labs and hospital labs to define confirmatory testing requirements, if any. Requiring confirmatory testing for all cases would be self-defeating for PHL testing capacity, with backlogs potentially creating strained relations with the medical community. However, requiring confirmatory testing on a limited number of early positives may be desirable.
 - d. Interact with commercial labs to establish reporting requirements appropriate for the jurisdictional epidemiologic tracking resources.

*CDC- APHL modeling data can be used here.