Proficiency Testing is Essential to Evaluate the Accuracy and Reliability of COVID-19 Clinical Laboratory Tests

As the nation faces the COVID-19 pandemic, accurate and reliable clinical laboratory tests are critical to the nation's response and will play an important role as the country slowly reopens. Typically, clinical laboratory test kits undergo review by the Food and Drug Administration (FDA) and the tests performed by clinical laboratories are regulated by the Clinical Laboratory Improvement Amendments (CLIA). Together, this oversight monitors the accuracy and reliability of clinical laboratory tests.

During the COVID-19 public health emergency, FDA has relaxed its oversight of clinical laboratory tests through emergency use authorization regulations. As a result, the number of available COVID-19 tests has expanded significantly in the race to increase testing capacity. While access to testing is critical, the National Independent Laboratory Association (NILA) is increasingly concerned about the accuracy, reproducibility, and reliability of some of these tests, and we've learned that some companies are advertising false claims or marketing inaccurate tests. As more rapid and point-of-care tests are marketed, it is critical to evaluate the accuracy and reliability of these tests in this pandemic. Inaccurate or unreliable testing represents a public health threat, particularly in a time of emergency.

To ensure accurate and reliable COVID-19 testing, routine proficiency testing (PT) should be conducted by all laboratories running COVID-19 clinical laboratory tests, including waived tests. Accurate and reliable COVID-19 tests underpin the nation's ability to address and control this pandemic. Unfortunately, some clinical laboratory test manufacturers have taken advantage of the pandemic to market fraudulent tests that threaten lives and resources. In the push to increase testing capacity, it is important to note that *more* testing capacity does not always equate to *quality* testing capacity. As FDA and CLIA continue to regulate COVID-19 tests and the laboratories that perform them, the need for sufficient testing capacity must be balanced with the need for accurate and reliable test results.

Frequently Asked Questions About Clinical Laboratory Testing Quality Control

What is Proficiency Testing (PT)?

Proficiency testing is an external quality control measure to evaluate the performance of tests, including molecular and serology tests, in a laboratory where they are used to provide clinical laboratory test results to physicians and patients. Required under CLIA, laboratories must enroll in an HHS-approved proficiency testing program. On a scheduled basis, a set of unknown samples are forwarded to laboratories to test through their regular testing process. Results are reported back to the proficiency testing program and graded to monitor the laboratory's performance and the accuracy of the test when performed "in the field," instead of in an environment defined and controlled by the test kit manufacturer.

Why is proficiency testing important in COVID-19 testing?

Proficiency testing is an important tool for individual laboratories to evaluate and verify the accuracy and reliability of COVID-19 molecular and serology tests performed in their laboratory.

What are the consequences of inaccurate clinical laboratory tests in the COVID-19 pandemic?

Inaccurate clinical laboratory tests have significant and potentially deadly consequences. A false negative on a molecular COVID-19 test will allow infected individuals to unknowingly continue to spread the virus, potentially resulting in more hospitalizations and deaths. And a false positive molecular test result could unnecessarily require individuals to remain in quarantine, prevent them from interacting with their loved ones or returning to the workforce, and cause undue mental stress and anxiety. Serology tests are also subject to false positive and false negative results. Where a false negative molecular COVID-19 test may lead an individual to unknowingly infect more people, a false positive serology test may cause people to take unwarranted risks in exposing themselves to infection, believing incorrectly that the false positive test result means they are immune to infection by the COVID-19 virus.

What are waived tests?

Waived tests are either an FDA-approved "home use" test kit or device or a test that is simple to perform, has a very low risk of an incorrect test result, and poses no harm to the patient if performed incorrectly. Waived tests are not subject to regular CLIA oversight, are <u>not required</u> to undergo proficiency testing and, therefore, are not subject to adequate external quality control. As of April 18, 2020, FDA has waived four COVID-19 tests for use in patient care settings.

Why should COVID-19 waived tests undergo proficiency testing?

Monitoring the performance of COVID-19 tests in a clinical setting is impossible without proficiency testing. Given the significant consequences of inaccurate COVID-19 diagnoses in a pandemic setting, it is critical and necessary to collect data on waived COVID-19 tests to evaluate their accuracy and reliability. This is especially critical since FDA has stated that all point of care test that are authorized under an EUA will be waived. It is only through proficiency testing that inaccurate and flawed clinical laboratory tests can be pulled from the market to reduce the harm to patients and public health response efforts.

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