



NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Oxiris Barbot, MD
Commissioner

April 7, 2020

Dear Colleague,

We appreciate your work on the front lines during this pandemic and are here to support your critical mission. Recently updated policy from the Food and Drug Administration (FDA) has led to some confusion around serology tests and has created opportunity for false claims by distributors. It is your responsibility to ensure that all testing performed in your practice is in compliance with applicable regulations. The intention of this letter is to ensure that you are aware of what tests may and may not be performed.

Note that a list of tests that have been granted an Emergency Use Authorization (EUA) by the FDA can be found [here](#). Included in that list are two nucleic acid amplification-based tests that have been approved for point of care (POC) use (Abbott ID NOW and Cepheid XpertXpress). This means that these two POC tests can be used in clinical practice.

However, there are currently no serology tests that are approved for use in the POC setting. Serology cannot be used to diagnose infection with SARS-CoV-2, and there are no CDC guidelines for the interpretation of serology tests. Using a test inappropriately in the POC or moderate complexity laboratory setting may put your practice out of compliance and may result in regulatory action.

Please see the FDA's frequently asked questions (FAQ) site [here](#) for more information. The first two questions in the "General FAQs" section were recently updated and provide more clarity on the use of tests that have not been granted an EUA. In short, serology tests without an EUA have not been categorized by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and therefore are considered "high complexity" tests by default and may only be performed in a laboratory that meets the CLIA requirements to perform this class of tests.

Serology tests being made available under section IV.D. of the FDA [Policy for Diagnostic Tests for Coronavirus Disease-19](#) are listed in the FDA FAQ (see the "What Laboratories and Manufacturers are Offering Tests for COVID-19?" section). Note that these serology tests have **not** been reviewed by the FDA, have **not** been granted authorization or approval by the FDA, and **cannot** be performed in a CLIA-waived or moderate complexity laboratory setting. We are aware that some of these serology tests are being falsely marketed as "FDA authorized" or "FDA approved" and as CLIA-waived POC tests, which they are not. The performance of these serology tests have not been appropriately evaluated or reviewed, and using these serology tests may put your staff, patients, and their contacts in danger due to incorrect results leading to inappropriate action.

Providers and laboratories are responsible for ensuring that any testing performed is done so in compliance with all applicable state and federal regulations (i.e., NYS Physician Office Laboratory Evaluation Program (POLEP)/Clinical Laboratory Evaluation Program (CLEP) and CLIA). Please ensure that any testing offered in your facility meets all applicable regulatory requirements. Again, thank you for your work and commitment to the health of New Yorkers in this very challenging time.

Sincerely,
Jennifer L. Rakeman, PhD
Assistant Commissioner and Laboratory Director
NYC Public Health Laboratory