PENNSYLVANIA DEPARTMENT OF HEALTH
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ALERT: Interim Guidelines for Serologic Testing and COVID-19 Diagnostics

DATE:	4/10/2020
TO:	Health Alert Network
FROM:	Rachel Levine, MD, Secretary of Health
SUBJECT:	**ALERT: Interim Guidelines for Serologic Testing and COVID-19 Diagnostics**
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This transmission is a "Health Alert": conveys the highest level of importance; warrants immediate action or attention.

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, NURSING AND LABORATORY STAFF IN YOUR HOSPITAL**; EMS COUNCILS:** PLEASE DISTRIBUTE AS APPROPRIATE; **FQHCs:** PLEASE DISTRIBUTE AS APPROPRIATE **LOCAL HEALTH JURISDICTIONS**: PLEASE DISTRIBUTE AS APPROPRIATE; **PROFESSIONAL ORGANIZATIONS:** PLEASE DISTRIBUTE TO YOUR MEMBERSHIP; **LONG-TERM CARE FACILITIES:** PLEASE SHARE WITH ALL MEDICAL, INFECTION CONTROL, AND NURSING STAFF IN YOUR FACILITY

- Two nucleic acid amplification-based tests have been granted an Emergency Use Authorization by the Food and Drug Administration for point of care (POC) use.
- There are no serological tests that are approved for use in POC setting.
- Serology cannot be used to diagnose infection with SARS-CoV-2.
- There are no CDC guidelines for interpretation of COVID-19 serology tests.
- Results from serology testing should not be used as the sole basis to diagnose or exclude COVID-19 infection or to inform infection control.

Recently updated policy from the Food and Drug Administration (FDA) has led to some confusion around serology tests. It is the healthcare provider's (HCP) responsibility to ensure that all testing performed in the HCP's practice is in compliance with applicable regulations.

Note that a list of tests that have been granted an Emergency Use Authorization (EUA) by the FDA for detection and/or diagnosis of SARS-CoV-2 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 have received FDA EUA 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.

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.

Negative serologic test results do not rule out SARS-CoV-2 infection, particularly in people who were exposed to the virus. Follow-up testing with a molecular diagnostic test should be considered to rule out infection in these individuals.

These serologic tests have been known to cross-react with other strains of coronavirus. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

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. DOH is 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 has not been appropriately evaluated or reviewed, and using these serology tests may put HCPs, patients, and 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. Please ensure that any testing offered in a facility meets all applicable regulatory requirements.

Categories of Health Alert messages:
Health Alert: conveys the highest level of importance; warrants immediate action or attention.
Health Advisory: provides important information for a specific incident or situation; may not require immediate action.
Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of April 10, 2020 but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.