

DATE:	5/4/2020
TO:	Health Alert Network
FROM:	Rachel Levine, MD, Secretary of Health
SUBJECT:	ALERT: SARS-CoV-2 Laboratory Testing Comparison
DISTRIBUTION:	Statewide
LOCATION:	n/a
STREET ADDRESS:	n/a
COUNTY:	n/a
MUNICIPALITY:	n/a
ZIP CODE:	n/a

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

- In order to perform testing for SARS-CoV-2, a laboratory must have CLIA certification.
- Currently, only molecular testing and serology tests have been authorized by the FDA.
- Certain testing assays can only be performed under specific CLIA Certificate types.
- Additional clarification is provided in the attached document.

Laboratories need a CLIA certificate to perform SARS-CoV-2 testing. Under CLIA, laboratories are prohibited from testing human specimens for the purpose of diagnosis, prevention, treatment, or health assessment without a valid CLIA certificate. Clinical laboratories and facilities such as academic laboratories, research laboratories, pharmacies, physician offices, urgent care clinics, and veterinary laboratories need CLIA certification to perform SARS-CoV-2 testing on human specimens.

This guidance is part of the Pennsylvania Department of Health’s (DOH) effort to clarify the types of SARS-CoV-2 testing, whether the tests are being offered under an EUA issued by FDA or as described in FDA’s COVID-19 Test Guidance, and the CLIA certifications and requirements under which testing can be performed.

As of today, there are two different types of SARS-CoV-2 testing. One type is molecular, which detects nucleic acid from SARS-CoV-2. The other type is serology, or antibody testing, which measures SARS-CoV-2 antibodies present in the blood. There is a third type of SARS-CoV-2 test which detects antigens present in the blood. As of today, no antigen tests for SARS-CoV-2 have been authorized by FDA. Such tests will be added to the FDA website when authorized.

Currently, COVID-19 tests are being offered that have been FDA authorized under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (these are listed on the FDA website here.) or under the policies outlined in the [FDA's Policy for Diagnostic Tests for Coronavirus Disease-2019](#) (“COVID-19 Test Guidance”). This document discusses policies applicable to testing for COVID-19, including

Laboratory Developed Tests (LDTs). “FDA notification” means that the laboratory or manufacturer has provided FDA with notification that it has validated its test as described in the policies outlined in FDA’s COVID-19 Test Guidance and is now listed on the FDA website [here](#).

The attached document delineates which assays offered can be performed by laboratories under each of the CLIA Certificate types. CLIA has four different certificate types, which are Certificate of Waiver, Certificate of Provider-Performed Microscopy Procedures, Certificate of Compliance and Certificate of Accreditation. The required certificate type depends on whether the test was issued an EUA, and if so, the authorized settings included in the [Emergency Use Authorization \(EUA\)](#).

Point-of-care molecular tests can be performed under all CLIA certificate types. Serology tests must be performed in a laboratory that meets moderate or high complexity testing requirements and can only be performed under the CLIA Certificate of Compliance and the CLIA Certificate of Accreditation. No serology tests have been authorized under the FDA EUA to date.

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 May 4, 2020 but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.