Department of Public Health
CITY OF PHILADELPHIA

Philadelphia Department of Public Health
Division of Disease Control

THOMAS A. FARLEY, MD, MPH
Health Commissioner

CAROLINE JOHNSON, MD
Deputy Health Commissioner

STEVEN ALLES, MD, MS
Director, Division of Disease Control

Health Advisory

COVID-19 Updates: Guidance for the Use of Serologic Assays and Rapid Diagnostic Tests

April 17, 2020

SUMMARY POINTS

- COVID-19 testing is available at public health and commercial laboratories.
- New tests include rapid and point of care options.
- Molecular assays that have received emergency use authorization from the FDA should be used preferentially.
- Serologic assays should not be used for diagnosis of acute COVID-19 infection.

Widespread transmission of COVID-19 continues to occur in Philadelphia. To date, 8,563 laboratory-confirmed COVID-19 cases have been reported with cases occurring in all zip codes across the City. The ability to identify cases in a timely manner is a crucial component of management and response efforts. As such, significant focus has been placed on increasing access to testing services and identifying opportunities for rapid, point of care tests.

To support timely availability of COVID-19 testing platforms, the Food and Drug Administration (FDA) has established policies to allow laboratories to rapidly develop and validate diagnostic test and fast-track applications for Emergency Use Authorization. This pathway has allowed for the introduction of several molecular assays in commercial, public health and academic laboratories, including newer rapid assays. The FDA has also implemented a policy to allow companies to develop and market tests without submitting an emergency use authorization, as long as the FDA is notified AND as long as materials include a disclaimer. Under this pathway, there are several rapid, point of care immunoassays that are designed to detect IgM and IgG. The proliferation of available tests, especially rapid tests, that can provide results within a few hours of presentation or at the point of care has the potential to significantly improve our ability to identify and manage cases. However, because of rapid emergency use authorization and in some cases lack of FDA review, care should be taken in selecting a testing platform and interpreting results.

Molecular Assays: Molecular assays that detect nucleic acid from the SARS-CoV-2 virus are considered a gold standard for the detection of SARS-CoV-2 in persons suspected of having COVID-19. There are several molecular assays that have received an EUA, including two point of care tests that can be used outside of a laboratory setting and provide results within 30 minutes. These point of care tests are available for use in clinical practice, but supplies are currently limited. The FDA website includes a comprehensive list of all molecular tests that have received an EUA.

Serologies: There are several companies who have also developed rapid immunoassays, that are currently being marketed directly to providers. As above, these companies have begun development of tests under the FDA's policy for Diagnostic Tests for Coronavirus in the setting of an emergency situation. Companies need to inform the FDA of their product but can market it without pursuing an EUA as long as the following statements are included with product information:

- This test has not been reviewed by the FDA.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- 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.

The FDA has received notification for several such products. A comprehensive list of companies can be found here. These products do **NOT** have emergency use authorization and due to the limitations above should not be used. There are three immunoassays that have recently received an EUA. Despite their authorization, PDPH would also recommend against using these rapid immunoassays for diagnosis of acutely infected persons until more information is available about test validity. Serology cannot be used to diagnose acute COVID-19 infection and it is not yet known whether detection of IgG indicates immunity to SARS-CoV-2. The CDC has not issued any guidance regarding the interpretation of serologic assays.

PDPH will work with public health laboratories and local healthcare facilities to help facilitate access to recommended rapid testing platforms as they become available and reporting of results. Health providers, infection prevention practitioners, and other partner agencies should report point of care or in-house rapid tests to PDPH electronically or by phone at 215-685-6741 (after hours: 215-686-4514).

PDPH will work with public health laboratories and local healthcare facilities to help facilitate access to recommended rapid testing platforms as they become available. For additional information and updates about COVID-19 and diagnostic testing, please see:

- **Surveillance:** https://www.phila.gov/programs/coronavirus-disease-2019-covid-19/testing-and-data/
- **Guidance:** https://hip.phila.gov/EmergentHealthTopics/2019-nCoV