September 17, 2020

Health Notice for District of Columbia Health Care Providers
SARS-CoV-2 Antigen Testing – Outpatient Settings

SUMMARY

As of September 15th, 2020, there have been 14,743 laboratory-confirmed cases of COVID-19, and 617 deaths in DC residents. The District of Columbia is now in Phase 2 of re-opening and continues to experience moderate community spread. This Health Notice provides guidance and reporting guidelines for SARS-CoV-2 antigen testing.

BACKGROUND

To date the FDA has issued over 200 Emergency Use Authorizations (EUA) for diagnostic tests for use during the COVID-19 pandemic. Two main categories of tests for use for diagnosing a current COVID-19 infection: nucleic acid tests (also known as RT-PCR tests, molecular tests) and antigen tests (also known as rapid tests). Since May 8,2020 the FDA has issued 4 individual EUAs for antigen tests for SARS-CoV-2 (the causative viral pathogen of COVID-19). Antigen tests are immunoassays that detect the presence of a specific viral antigen and have been in common use to diagnose other respiratory pathogens (e.g., influenza, respiratory syncytial virus). They are typically conducted on nasopharyngeal or nasal swab specimens and are relatively inexpensive.

The RT-PCR test remains the gold standard for diagnosis of SARS-CoV-2 infection, however the turnaround time for test results can be relatively long, especially when demand is high. Antigen testing is a rapid point of care test and results are available in approximately 15 minutes. RT-PCR and antigen tests both have high specificity. However, antigen assays are less sensitive compared to RT-PCR. As a result, antigen testing is prone to more false negative results. False positives are expected to be unlikely, especially in the setting of a symptomatic patient with a high pretest probability for infection, such as ongoing community transmission.

Information on currently authorized SARS-CoV-2 antigen diagnostic tests can be found on the FDA website: www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas. More information on the performance of antigen tests can be found on the CDC website: www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html.

Uses of SARS-CoV-2 Antigen Testing

The antigen test for SARS-CoV-2 is most accurate early in the course of infection when viral load is usually highest. The EUA authorizes use of the antigen test in symptomatic patients within the first 5-7 days of illness. Antigen tests may also be informative in diagnostic testing situations in which the person has a known exposure to a confirmed case of COVID-19. The CDC does not currently recommend use of antigen testing to make decisions about discontinuing isolation.

Result Interpretation

- If a positive result is received using the rapid-antigen test, confirmatory testing is not necessary.
    - All positives from antigen testing shall be treated as true positives despite any subsequent negative test results obtained through any other testing method.
    - Patients should be provided guidance on isolating at home (see guidance documents on coronavirus.dc.gov/phasetwo).
    - Patients should be informed to expect to receive a call from the DC Health Contact Trace Force
- If a negative result is received using the rapid-antigen test, it must be confirmed with an FDA authorized RT-PCR test.
    - The confirmatory specimen should be collected immediately (as soon as possible after the negative antigen test is resulted, and no later than 48 hours).
    - Confirmatory testing utilizing a molecular test should be performed by a commercial laboratory.
    - Patients should be informed to quarantine until RT-PCR test results return.

Laboratory Requirements

This testing is deemed a waived test for Clinical Laboratory Improvement Amendments (CLIA), which means facilities are required to follow manufacturer's instructions when using the instrument. Laboratories wishing to utilize these devices must obtain a certificate of waiver (COW) to conduct testing.

Under the public health emergency, a laboratory may begin testing CLIA waived devices such as the antigen tests, while their application for a COW is being considered as long as a CLIA number is assigned. For more information on how to obtain a COW in the District, please email DCHealth.CLIA@dc.gov.

Reporting Requirements

In accordance with DCMR Chapter 22B 201.1(ff) and 201.1 (gg), and as part of DC's COVID-19 response, **all positive and negative results** for SARS-CoV-2 viral (nucleic acid or antigen) and antibody testing must be reported immediately to DC Health by the performing laboratory. For point-of-care (POC) testing, this means the healthcare facility.

- Healthcare providers must submit a case report form for all positive and negative SARS-CoV-2 antigen testing performed by the facility at the time the test is resulted.
    - Submit a "COVID-19 Reporting Form" on the DC Health COVID-19 Reporting website: dchealth.dc.gov/page/covid-19-reporting-requirements.
    - Any clinic that has been conducting antigen testing and not reporting results to DC Health should email coronavirus@dc.gov for further guidance.

The guidelines above will continue to be updated as the outbreak evolves. Please visit coronavirus.dc.gov and the DC Health - Health Notices website (dchealth.dc.gov/page/health-notices) regularly for the most current information.

Please contact DC Health regarding COVID-19 at:
Phone: 202-576-1117 Fax: 202-442-8060 | Email: coronavirus@dc.gov