February 2, 2021

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

SUMMARY

As of February 1st, 2021, there have been 37,138 laboratory-confirmed cases of COVID-19, and 921 deaths in DC residents. The District of Columbia is now in Phase 2 of re-opening and continues to experience moderate to substantial community spread. This Health Notice provides guidance and reporting guidelines for SARS-CoV-2 antigen testing in the setting of moderate to substantial community spread.

BACKGROUND

The FDA has issued over 200 Emergency Use Authorizations (EUA) for SARS-CoV-2 diagnostic tests since the beginning of the pandemic. The two main categories of tests to use for diagnosing a current COVID-19 infection are: nucleic acid tests (also known as RT-PCR tests, molecular tests) and antigen tests. As of January 18, 2021, the FDA has issued 13 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 can be performed as a rapid point of care test with results available in approximately 15 minutes. Antigen assays are less sensitive compared to RT-PCR. As a result, antigen testing is prone to more false negative results. Antigen tests have generally been considered to share the high specificity of RT-PCR tests, producing few false positives. However, a recent study of the Sofia SARS Antigen FIA assay (the first antigen test approved for an EUA) found poorer test accuracy than was reported in its FDA EUA, with higher rates of false positives as well as false negatives.[1] False positives are unlikely in the setting of a symptomatic patient with a high pretest probability for infection, such as moderate-to-substantial levels of community spread.

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 an individual is asymptomatic but has a known exposure to a confirmed case of COVID-19. The use of antigen testing in asymptomatic patients who do not have a known exposure to a confirmed case of COVID-19 is an off-label use, and should be only used in situations where highly sensitive (PCR) tests are not feasible, such as lack of availability or prolonged turnaround time. Antigen testing must not be used as a substitute for daily staff symptom screening procedures or any mandated testing as directed by DC Health. The CDC does not currently recommend use of antigen testing to make decisions about discontinuing isolation.

Result Interpretation

DC is currently experiencing moderate to substantial community spread. Below are requirements for

[1] cdc.gov/mmwr/volumes/69/wr/mm695152a3.htm

confirmatory testing based on the local epidemiology.

- Confirmatory RT-PCR testing is not required when:
  - Testing a **symptomatic individual** who receives a positive antigen test result.
  - Testing an **asymptomatic person with a known exposure** to a confirmed case of COVID-19 who receives a positive result.
- Confirmatory testing with an FDA authorized RT-PCR test is required when:
  - Testing **symptomatic or exposed individuals** who receive a negative antigen test result (a negative test result is more likely to be a false negative in this scenario).
  - Testing **asymptomatic individuals with no exposure** who receive a positive antigen test result (a positive test result is more likely to be a false positive in this scenario).
- Samples for confirmatory RT-PCR testing should be collected immediately or as soon as possible after a preceding antigen test is resulted, but no later than 48 hours.
- Confirmatory RT-PCR testing should be performed by a commercial laboratory.
- **Patients who require confirmatory testing should be instructed to quarantine until RT-PCR test results return.**
- Patients who test positive should be informed to expect to receive a call from the DC Health Contact Trace Force, and should be provided guidance on isolating and quarantine at home (see guidance documents at coronavirus.dc.gov/phasetwo).

Laboratory/Site 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. Facilities will ensure only trained staff will perform antigen 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 as follows:
  - Submit a "COVID-19 Reporting Form" on the DC Health COVID-19 Reporting website: dchealth.dc.gov/page/covid-19-reporting-requirements.
    - **ALL** positive results should be submitted at the time the test is resulted.
    - **ALL** negative results may be batched and reported daily.

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