



COVID-19 RAPID ANTIGEN TESTING GUIDANCE

The State of Delaware has identified point-of-care lateral flow immunoassays (“rapid antigen tests”) as useful diagnostic tools for COVID-19 and subsequently developed guidance for use of these tests. Use of rapid antigen tests is contingent upon implementation in appropriate clinical scenarios. Guidance is described and diagrammed herein.

Only rapid antigen tests that have received an Emergency Use Authorization (EUA) from the FDA **OR** that have been independently verified by a CLIA certified laboratory may be used. As of September 22, 2020, four separate assays have been awarded an EUA through the FDA: **LumiraDx, BD Veritor, Abbott BinaxNOW, and Quidel Sofia.**

All testing must be performed in compliance with standards set forth by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). All antigen tests that currently hold an EUA are authorized for use in a patient care setting that is operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Testing may only be performed under the direction and order of an independently licensed medical practitioner (MD/DO, DMD/DDS, PA, or APRN). For the purposes of this guidance, pharmacists (based on the state’s scope of practice) may also be considered independently licensed medical practitioners and may direct and order testing for COVID-19.

The ultimate clinical decision making from, implementation of, interpretation of, and reporting of COVID-19 antigen tests are the ultimate responsibility of the licensed practitioner (MD/DO, DMD/DDS, PA, APRN, or pharmacist) by whom the tests are administered and who is listed as the ordering practitioner for the testing procedure. DPH guidance for test implementation and interpretation is listed below (See Appendix A).

Use of point-of-care COVID-19 antigen testing is contingent upon reporting of results to the Delaware Division of Public Health via the results logging portal, access to which can be requested by emailing Dhss_Dph_RedcapAccess@delaware.gov (note underscores). COVID-19 remains a reportable disease and failure to report may result in adverse action.

All patients undergoing testing must be provided with detailed instructions on test interpretation and subsequent care and isolation instructions (See Appendix B).

Antigen Tests

Antigen tests are relatively inexpensive and can be used at the point-of-care. The currently authorized devices return results in approximately 15 minutes. Antigen tests for SARS-CoV-2 are generally less sensitive than viral tests that detect nucleic acid using reverse transcription polymerase chain reaction



(RT-PCR). Proper interpretation of antigen test results is important for accurate clinical management of patients with suspected COVID-19, or for identification of potentially infected persons when used for screening.

The sensitivity of rapid antigen tests is generally lower than RT-PCR. The first two antigen tests that received FDA EUAs (Sofia and Veritor) demonstrate sensitivity of 84% and 97%, respectively, compared to RT-PCR. Studies have shown that antigen levels in some patients who have been symptomatic for more than five days may drop below the limit of detection of the test. Scant data are available regarding performance in asymptomatic individuals.

The specificity of rapid antigen tests is generally as high as RT-PCR. The first two antigen tests that received FDA EUAs (Sofia and Veritor) have specificity of 100% – this means that false positive results are unlikely. While all published datasets reflect specificities of 100%, cases of false positives have been reported. It is unclear at this time whether these incidents represent actual false positives, contamination, or test performance failure (false positives are a known phenomenon when certain transport media [e.g. Remel M4 or M4RT] are used. Positive and negative predictive values of all in vitro diagnostic tests vary depending upon the pretest probability of the patient being tested. Pretest probability is impacted by the prevalence of the target infection in the community as well as the clinical context of the recipient of the test.

Definition of Diagnostic Testing

Diagnostic testing for SARS-CoV-2 is intended to identify current infection in individuals and is performed when a person has signs or symptoms consistent with COVID-19, or when a person is asymptomatic but has recent known or suspected exposure to SARS-CoV-2. Examples of diagnostic testing include testing symptomatic persons, testing persons identified through contact tracing efforts, and testing those who indicate that they were exposed to someone with a confirmed or suspected case of COVID-19.

Use of Antigen Tests for Diagnostic Testing

The use of antigen tests for symptomatic or exposed persons to SARS-CoV-2 permits rapid detection at the point-of-care and early initiation of critical contact tracing and case investigation efforts. Implementation of point-of-care testing has previously been demonstrated to assist in outbreak control, mitigate disease spread, and play an irreplaceable role in quickly identifying persons at risk for carrying SARS-CoV-2.¹

¹ Pescatore, R.M., Henry, L.M., Walker, R.D., Chasanov, W., Gaeta, C.M., Webb, C.M., Moreno-Gorrin, C., Eggers, P., Franze, F.P., Huerta, S. and Pleasanton, C., Validation and Use of Point-of-Care Lateral Flow Chromatographic Immunoassays for Early Diagnostic Support During the COVID-19 Pandemic.



Definition of Screening Testing

Screening testing for SARS-CoV-2 is intended to identify infected persons who are asymptomatic and without known or suspected exposure to SARS-CoV-2. Screening testing is performed to identify persons who may be contagious so that measures can be taken to prevent further transmission. Examples of screening include testing in congregate settings, such as a long-term care facility or a correctional facility, a workplace testing its employees, or a school testing its students, faculty, and staff.

Use of Antigen Tests for Screening Testing

Modeling studies have convincingly demonstrated that point-of-care or self-administered screening tests with fast turnaround time or frequent testing have high epidemiological value, and can attenuate surges of infection in highly congregate settings, such as military bases and centers of education.² Universal high-frequency testing holds significant promise in stopping the spread of disease.³ In testing of asymptomatic individuals, however, community prevalence significantly influences test utility. Bayesian analysis of the diagnostic performance of antigen tests, using conservative measures (85% sensitivity, 99% specificity), indicates that where community prevalence is 5% or less, a negative antigen test lowers the post-test probability in an asymptomatic individual to less than 1%. A positive result correlates with a 70-90% likelihood of disease.⁴ In higher prevalence settings, diagnostic performance remains acceptable for significant risk shifting.

Use of Antigen Tests in Congregate Settings

In settings where large groups of individuals are expected to repeatedly congregate and social distancing may be hard to maintain (e.g., long-term care facilities, schools, correctional institutions, shelters), the accessibility, frequency, and sample-to-answer time of antigen tests offer profound logistical benefits. Analytical limits of detection should remain a consideration, however, and the implementation of antigen testing should be considered additive to PCR strategies.

Standard Operating Procedure

I. Purpose

Standard Operating Procedure (SOP) will establish procedure for Rapid, Point-of-Care Antigen Testing for the following populations (Appendix A):

² Larremore, D.B., Wilder, B., Lester, E., Shehata, S., Burke, J.M., Hay, J.A., Tambe, M., Mina, M.J. and Parker, R., 2020. Test sensitivity is secondary to frequency and turnaround time for COVID-19 surveillance. *MedRxiv*.

³ Peto, J., Alwan, N.A., Godfrey, K.M., Burgess, R.A., Hunter, D.J., Riboli, E., Romer, P., Buchan, I., Colbourn, T., Costelloe, C. and Smith, G.D., 2020. Universal weekly testing as the UK COVID-19 lockdown exit strategy. *The Lancet*, 395(10234), pp.1420-1421.

⁴ <http://araw.mede.uic.edu/cgi-bin/testcalc.pl?DT=43&Dt=7&dT=10&dt=940&2x2=Compute>



- Long-term and post-acute care facilities
- Schools and educational settings
- Emergency and homeless shelters
- Patients evaluated at primary care offices and other ambulatory settings

II. Concept of Operations

DPH will provide guidance to organizations, offices, and agencies who are strategically positioned to reach the target populations for whom antigen testing is prioritized.

III. Scope

This SOP will apply to trained personnel working to identify COVID-19 infection within the target populations and settings.

IV. Procedure

1. Preparatory information

- a) Trained personnel would screen individual to determine if the person needs a COVID-19 test (PCR, point-of-care, etc.)
- b) All testing must be performed in compliance with OSHA and CLIA regulations or if conducted in a clinical laboratory setting, in accordance with standards set forth by the Commission on Office Laboratory Accreditation (COLA).
- c) All providers or testing sites must report data and results for all diagnostic and screening testing completed, which includes point-of-care antigen testing, for each individual tested. These data must be reported within 24 hours of test completion to DPH.
 1. Additional information regarding reporting, including a link to the point-of-care test reporting portal, can be requested by emailing:
dhss_dph_RedcapAccess@delaware.gov.

2. Screening for Symptoms

- a) Trained staff determines if person is asymptomatic or symptomatic
 1. Symptomatic persons may include those with fever $\geq 100.4^{\circ}\text{F}$, shaking chills, severe sore throat, loss of taste or smell, shortness of breath, cough, or muscle aches.
 2. Alternate symptoms including headache, nausea, vomiting, and diarrhea, and others have been identified as potential COVID-19 symptoms and may prompt further screening, action, or investigation.
- b) Trained personnel may refer to Appendix A - SOP for Rapid COVID-19 Antigen Testing

3. Testing Protocol



- a) Trained personnel perform rapid point-of-care antigen test and provides patient with results. Testing must be performed in accordance with manufacturer's instructions for use (IFU) and FDA EUA.
- b) Trained personnel obtain subsequent sample for PCR testing if indicated.
- c) Prior to ending visit with person, trained personnel reiterate protective measures and provide patients with instructions after testing (Appendix B).

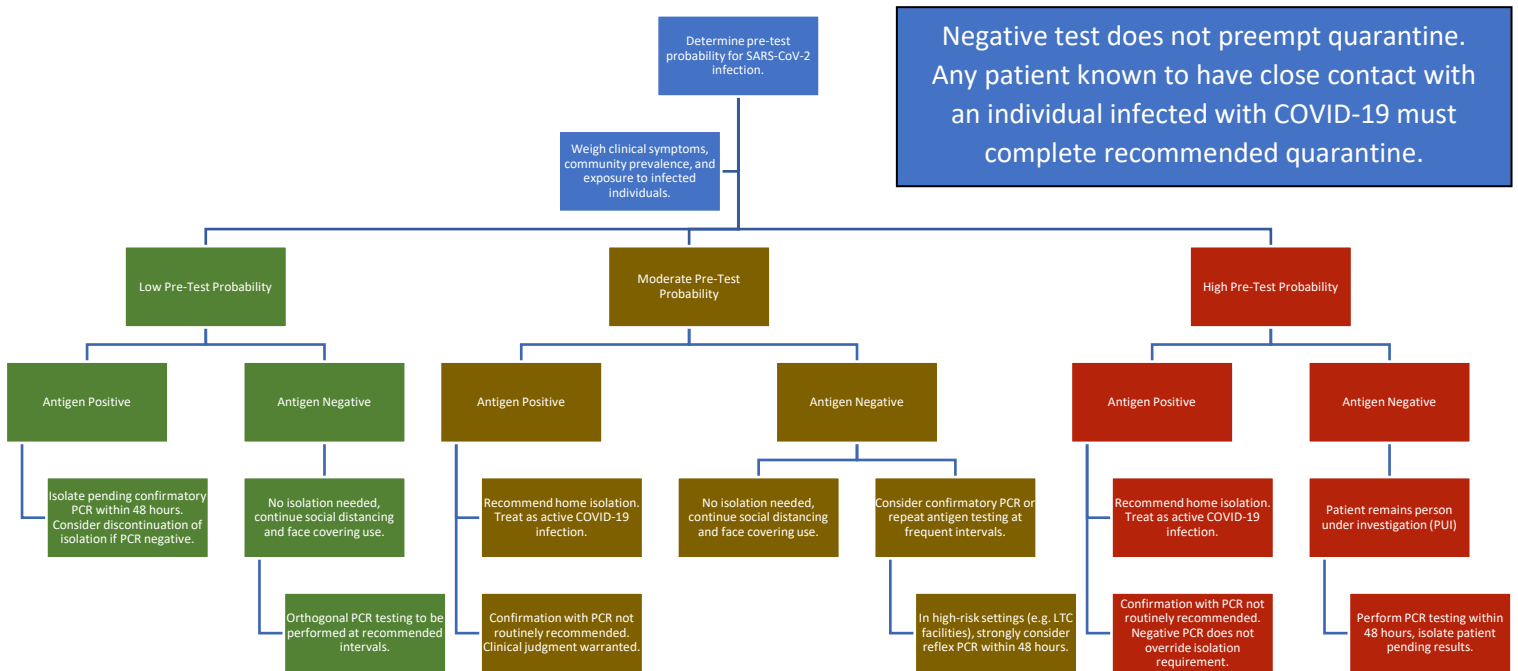
4. Follow-up/closure

- a) Staff ensures that results are submitted for each rapid, point-of-care antigen test performed for COVID-19 to the Division of Public Health within 24 hours.
 - 1. For information regarding the submittal of point-of-care test results to DPH, and to obtain a link to DPH reporting portal, email dhss_dph_RedcapAccess@delaware.gov.
- b) Negative cases should continue with recommended PCR cadence previously promulgated by DPH based on pre-test probability of disease.
 - 1. Ordering clinician may send confirmatory PCR as deemed appropriate.
- c) Confirmatory testing with PCR may be recommended for positive cases—clinical judgment is warranted and encouraged.



– APPENDIX A –

SOP for Rapid COVID-19 Testing



Antigen Testing Frequency

- Long-term and post-acute care facilities
 - All residents and staff should be tested at intervals as deemed appropriate by DPH Office of Infectious Diseases Epidemiology in consultation with LTC/PAC Task Force.
- Schools and educational settings
 - Primary and secondary education (K-12) and higher education testing cadence should occur at intervals and frequency sustainable by facility medical personnel. A target of 25-50% of the student and staff population weekly is encouraged.
 - Antigen testing does not influence or alter PCR testing related to these settings, which may be monthly or at other intervals as deemed appropriate by DPH Office of Infectious Diseases Epidemiology in consultation with Department of Education.



- Emergency and homeless shelters
 - All persons should be tested prior to facility admission, and at weekly intervals if indicated. Antigen-positive asymptomatic individuals (“suspected positives”) may not be cohorted with other individuals until confirmatory PCR has resulted.

- Patients evaluated at primary care offices and other ambulatory settings
 - At the discretion of ordering provider.



– APPENDIX B –

Patient Instructions

Today you had a rapid antigen test performed by your doctor. This “rapid test” looks directly for presence of the virus that causes COVID-19. The test is fast and accurate, however it may not pick up as many cases as tests that are processed in a laboratory.

Patients who had symptoms (fever, cough, shortness of breath) at time of testing

- Your test was **NEGATIVE** – **this does not mean that you are not infected with COVID-19**. Follow-on testing is usually performed. You **must** continue to isolate yourself at home, away from others, and should **consider yourself to be infected** until results are available from a follow-up test or your health care provider gives you further instructions.
- Your test was **POSITIVE** – **you are infected with COVID-19**. Follow your health care provider’s directions. You **must** isolate from others for at least **10 days** since you first noticed you were sick, and at least 24 hours following your fever going away.

For patients without symptoms at time of testing

- Your test was **NEGATIVE** – **this does not mean that you are not infected with COVID-19**. Your healthcare provider or DPH may recommend additional testing, and you should consider visiting community testing sites at least once a month for additional laboratory testing for COVID-19. You may not notice symptoms for up to 2 weeks following exposure to the virus that causes COVID-19. You **must** continue to wear a face covering, practice social distancing and follow any other appropriate instructions. *If you were previously advised to quarantine for 14 days due to being a close contact of someone with COVID-19, you must still complete the full 14 days of quarantine.*
- Your test was **POSITIVE** – **you are infected with COVID-19**. Follow your health care provider’s directions. You **must** isolate from others for at least **10 days** since your first test. If you live with others, isolate in a private room and use a private bathroom, if possible. Interact with others as little as possible. If you develop symptoms, notify your healthcare provider immediately for further instructions.

RESOURCES FOR MORE INFORMATION

For more information, visit coronavirus.delaware.gov.

Individuals with questions about COVID-19 should call Delaware 2-1-1, individuals who are deaf or hard of hearing can text their ZIP code to 898-211. Hours of operation are 8:00 a.m. to 9:00 p.m. Monday through Friday; 9:00 a.m. to 5:00 p.m. Saturday and Sunday. Medically related questions regarding testing, symptoms, and health-related guidance can be submitted by email at DPHCall@delaware.gov.