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**Updated Interpretation of CLIA-Certified Point-of-Care Antigen Test for COVID-19
Diagnosis in School Entities in Montgomery County**

Release: October 11, 2021

Effective: October 11, 2021

Antigen testing in Montgomery County is a powerful tool for controlling the spread of COVID-19. Montgomery County Office of Public Health (MCOPH) continues to strive to reduce the risk of in-school COVID-19 transmission through the use of multiple mitigation strategies to support safe, in-person learning opportunities. MCOPH has previously utilized guidance provided by the Pennsylvania Department of Health (PADOH) for Point of Care Antigen Testing Use and Interpretation, [PADOH 548-01-22-UPD](#). This Public Health Advisory provides revised recommendations specific to laboratory-based POC antigen testing for school entities within Montgomery County.

Background:

Research and assessment of the sensitivity and specificity of Point of Care (POC) antigen testing for the detection of the SARS-CoV-2 infection has been ongoing. The Centers for Disease Control and Prevention (CDC) identifies the sensitivity (meaning a true positive is more likely) is generally moderate to high at times of peak viral load, when individuals with a COVID-19 infection are most likely to transmit the virus to others.

Further, the CDC has identified that specificity of antigen testing is high, which means that a false positive test result is less likely as long as testing is completed according to manufacturer's instructions. Specificity increases when individuals are symptomatic or have known exposure.

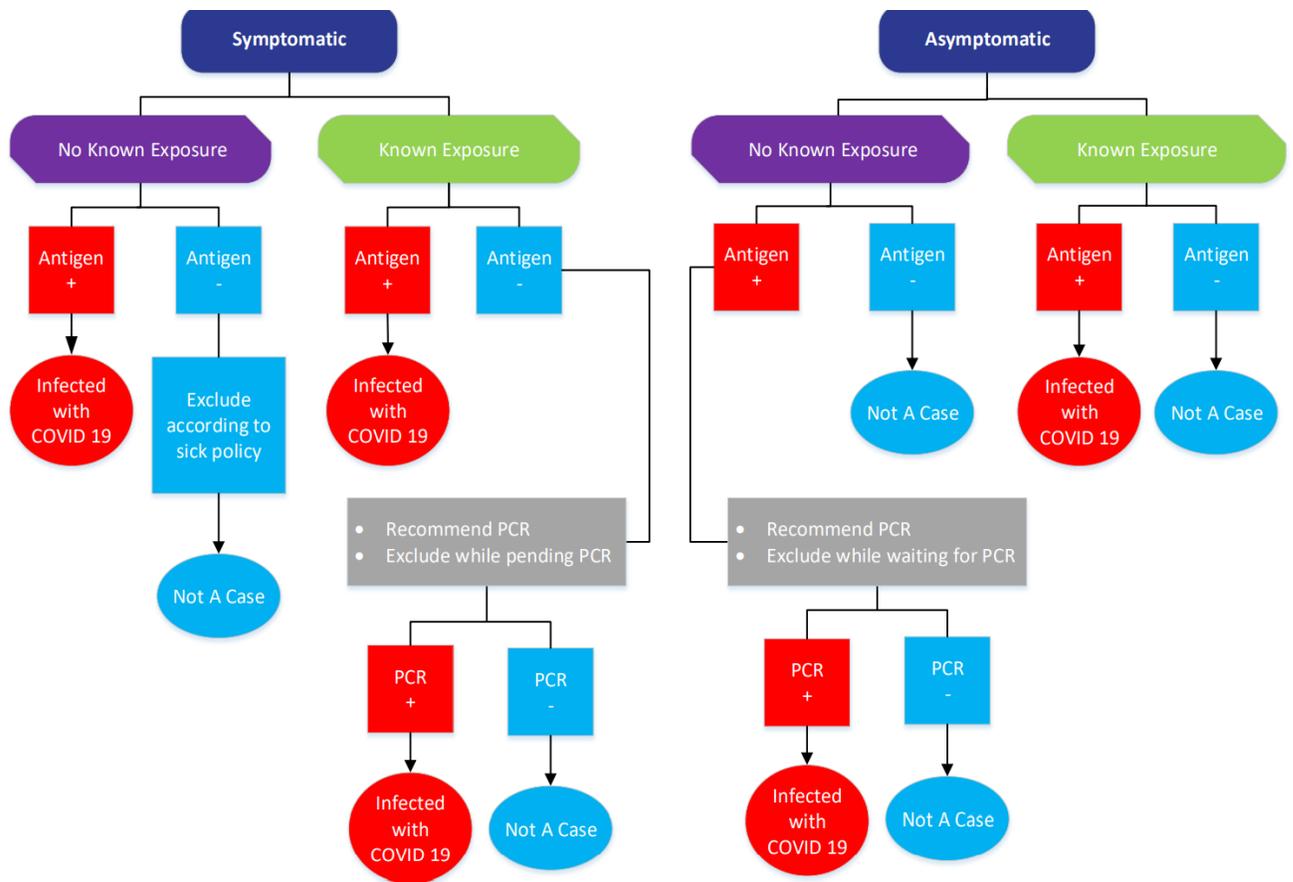
Interpretation: The following diagram outlines updates to recommendations for interpretation of CLIA Certified Point of Care antigen testing in K-12 school entities. CLIA Certified Point of Care (POC) Antigen Testing is antigen testing performed under an oversight laboratory using their CLIA certificate. This includes Project ACE-IT, Physicians' Offices, Urgent Care facilities, and pharmacies. At-home antigen testing is not accepted as CLIA Certified POC antigen testing.

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Separation of Symptomatic by Exposure Type: Multiple respiratory illnesses, such as the common cold and Respiratory Syncytial Virus (RSV), can cause symptoms similar to COVID-19. Thus, it is important when assessing the likelihood of COVID-19 to differentiate between individuals who have had **a known exposure** to COVID-19 in the 14 days before symptom onset and **no known exposure** in the 14 days before symptom onset.

Known exposure is an individual who has been in close contact with someone who is infected with COVID-19.

Close contact is defined as being within 6ft for 15 minutes or more consecutively or living in a household with someone infected with COVID-19.

Symptomatic, No Known Exposure (within 14 days) and Antigen Negative: MCOPH recommends that when an individual has COVID-19-like symptoms (see [CDC Symptoms of COVID-19](#)), but has no known exposure to COVID-19 in that 14 days before obtaining an antigen test, the that a negative antigen test result is acceptable to rule out COVID-19. Individuals are no longer recommended to follow-up with PCR testing when symptomatic, no known exposure and antigen negative. For individuals who experiencing symptoms and receive a negative antigen test, schools should continue to exclude symptomatic individuals from school according to the school’s sick policy. Symptomatic individuals should remember to **STAY HOME WHILE SICK**.

If COVID-like symptoms persist after the initial negative antigen result, individuals should be assessed by a health care provider or serial antigen testing should be considered. Serial antigen testing includes frequent antigen testing two to three times a week to manage risk and provide convenient and quick prevention of the spread of COVID-19.

Overall, a negative antigen test in an individual who is symptomatic has a low probability of false negative. When a negative antigen is obtained early in the onset of symptoms (within 7 days) it increases the likelihood that an individual has a detectable viral load which would cause an antigen test to be positive.

Asymptomatic, Known Exposure (within 14 days), and Antigen Positive: MCOPH recommends that an individual who is not having symptoms but has a known exposure within 14 days before obtaining an antigen test, a positive antigen test result is accepted as a diagnosis for COVID-19. Individuals will no longer be recommended to follow-up with PCR testing when they have an antigen-positive result. This individual should be considered infected with COVID-19 and school entities should immediately exclude and isolate the positive individual and initiate contact tracing.

Overall, an asymptomatic individual, with known exposure to a case of COVID in the last 14 days, who tests antigen-positive has a higher likelihood of a true positive and diagnosis with COVID-19. Research has found that a range of up to 50% of those infected with COVID-19 are carriers that show no symptoms.

References:

Center for Disease Control. COVID-19 Science Update. Edition 2020-06-12.

https://www.cdc.gov/library/covid19/pdf/public_pdfs/2020-06-12-Science-Update_FINAL_public.pdf

Food and Drug Administration. BinaxNOW COVID-19 Ag card (PN 195-000)—instructions for use. 2020 Dec [cited 2021 Mar 15]. <https://www.fda.gov/media/141570/download> External Link

Evaluation of Abbott BinaxNOW Rapid Antigen Test for SARS-CoV-2 Infection at Two Community-Based Testing Sites - Pima County, Arizona, November 3-17, 2020 <https://pubmed.ncbi.nlm.nih.gov/33476316/>

Effectiveness of Abbott BinaxNOW Rapid Antigen Test for Detection of SARS-CoV-2 Infections in Outbreak among Horse Racetrack Workers, California, USA: https://wwwnc.cdc.gov/eid/article/27/11/21-1449_article

Longitudinal Assessment of Diagnostic Test Performance Over the Course of Acute SARS-CoV-2 Infection, June 20, 2021 <https://academic.oup.com/jid/article/224/6/976/6311835>

Order of the Secretary of the P Pennsylvania Department of Health Authorizing the Use of Satellite Testing Locations for COVID-19, <https://policylab.chop.edu/sites/default/files/SOH-Order-Satellite-Testing-Locations.pdf>

Severe Acute Respiratory Syndrome Coronavirus 2 Infections Among Children in the Biospecimens from Respiratory Virus-Exposed Kids (BRAVE Kids) Study. November 2, 2020. <https://pubmed.ncbi.nlm.nih.gov/33141180/>

Montgomery County Office of Public Health COVID-19 School Isolation and Quarantine
For the update, COVID-19 school exclusion requirements and recommendations visit www.montcopa.org/schoolguidance

Testing Locations throughout Montgomery County:

For Montgomery County Office of Public Health COVID-19 testing locations visit: www.montcopa.org/testing

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For additional COVID-19 testing locations throughout the county visit PADOH COVID-19 symptoms and testing: <https://www.health.pa.gov/topics/disease/coronavirus/Pages/Symptoms-Testing.aspx>

COVID-19 (SARS CoV-2) is reportable to the OPH under Chapter 3 of the [Montgomery County Public Health Code](#) and PA Code, Title 28, Chapter 27. School entities and health care providers can report cases of COVID-19 to MCOPH's Division of Communicable Disease Control and Prevention at **610-278-5117**.

For MCOPH after-hours: evenings, weekends, and holidays contact: Montgomery County Police Radio at **(610) 275-1222** and ask to speak to the person on-call for the OPH.

For additional information on General Disease Reporting: www.montcopa.org/DiseaseReporting