

UPDATE: Point of Care Antigen Test Use and Interpretation

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TO:	Health Alert Network
FROM:	Rachel Levine, MD, Secretary of Health
SUBJECT:	UPDATE: Point of Care Antigen Test Use and Interpretation
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This transmission is a “Health Update” provides important information for a specific incident or situation; may not require immediate action.

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, NURSING AND LABORATORY STAFF IN YOUR HOSPITAL; **EMS COUNCILS:** PLEASE DISTRIBUTE AS APPROPRIATE; **FQHCs:** PLEASE DISTRIBUTE AS APPROPRIATE **LOCAL HEALTH JURISDICTIONS:** PLEASE DISTRIBUTE AS APPROPRIATE; **PROFESSIONAL ORGANIZATIONS:** PLEASE DISTRIBUTE TO YOUR MEMBERSHIP; **LONG-TERM CARE FACILITIES:** PLEASE SHARE WITH ALL MEDICAL, INFECTION CONTROL, AND NURSING STAFF IN YOUR FACILITY

This Health Update provides recommendations and considerations for point-of-care (POC) antigen testing and replaces the guidance provided in PA-HAN-532.

- The availability and use of point of care (POC) antigen tests to detect SARS-CoV-2 are increasing.
- The main advantage of using these antigen tests is the rapid turnaround time for results; however, these tests are not as sensitive as molecular tests (i.e., PCR).
- Some sites may be new to using these POC tests and, in order to ensure accuracy of results, facilities conducting these tests should become familiar with good laboratory practices. Some laboratory best practices and suggestions for preventing errors are included in this message.
- Individuals using POC tests should understand antigen test performance characteristics in order to recognize potentially false negative or false positive results and to guide patient management.
- Assessment of the person being tested, which would include the likelihood they have the disease or were exposed to COVID-19, should be considered when interpreting antigen test results and assessing the potential need for additional testing.
- The following message is being disseminated to address questions associated with antigen tests and assist with the use and interpretation of POC antigen test results.
- While some information contained in this HAN may be useful for long term care facilities, separate guidance for using antigen tests and the associated public health response in these facilities has been previously disseminated. **Long term care facilities using antigen tests should refer to guidance disseminated in [HAN-547](#).**
- If you have questions about this guidance, please call your local health department or **1-877-PA-HEALTH (1-877-724-3258)**.

The availability and use of antigen tests to detect SARS-CoV-2 are increasing. The main advantage of using these antigen tests is the rapid turnaround time for results; however, these tests are not as sensitive as molecular tests.

This guidance is designed to describe what an antigen test is and how it differs from PCR testing, some best practices for sites conducting these tests, when POC antigen testing should be considered, and circumstances that should be considered when interpreting antigen test results.

DESCRIPTION OF ANTIGEN TESTS

PCR tests look for pieces of nucleic acid from SARS-CoV-2, the virus that causes COVID-19, in the nose, throat, or other areas in the respiratory tract. Antigen tests look for pieces of proteins that make up the SARS-CoV-2 virus. While both tests can be used to determine if a person has an active infection, antigen tests are less sensitive than PCR for detecting COVID-19 infections. The results of these antigen tests are impacted by pretest probability (i.e., the probability of a person having an infection before the test result is known) and need to be carefully interpreted.

Information on available antigen tests can be found at the following websites:

- <https://www.health.pa.gov/topics/disease/coronavirus/Pages/Guidance/Point-of-Care-Testing.aspx>
- <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>
- <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#individual-antigen>

CONSIDERATION FOR USE OF ANTIGEN TESTS

Clinical Laboratory Improvement Amendments (CLIA) Certificate

Any entity utilizing Point-of-Care (POC) tests for COVID-19 must have a Pennsylvania laboratory permit and a CLIA Certificate. If you already have a Pennsylvania laboratory permit and CLIA Certificate, you must notify the Department of your intent to implement COVID-19 antigen testing to ensure that this test is added to the list of tests that you are approved to perform before beginning to perform the testing.

Please see [Understanding Clinical Laboratory Regulation in Pennsylvania](#) for more information. If you have questions about laboratory permits or CLIA certification, please notify RA-DHPACLIA@pa.gov to assure laboratory compliance.

Reporting

All entities conducting testing to identify SARS-CoV-2, the virus that causes COVID-19, are required to report positive, inconclusive/indeterminate, and negative results to PA-NEDSS within 24 hours of test completion. There are a number of mechanisms that have been established to ensure reporters can be compliant in providing the results of POC tests. Details on how to report to PA-NEDSS can be found in [PA-HAN-534](#).

Laboratory Best Practices and Preventing Errors

All testing for SARS-CoV-2, including rapid antigen testing, is directly impacted by the integrity of the specimen, which depends on specimen collection and handling. To reduce the potential for inaccurate results related to testing errors, implement the following:

- Ensure that users are properly trained to complete POC testing.
 - Maintain training records and ensure procedural compliance through routine auditing.
 - CDC provides materials on [good laboratory practice](#) and offers an online training with professional continuing education credits for their [Ready, Set, Test](#) training program.
- Follow manufacturer's instructions for specimen collection, processing, storage, and handling of the specimen. Not following the manufacturer's instructions can cause some swabs to have limited amounts of viral genetic or antigenic material for detection, leading to false negative results.
 - Antigen test manufacturers offer different training modalities for sites to familiarize themselves with the appropriate use of these products. Sites are encouraged to utilize these training opportunities and carefully review these materials prior to antigen test use.
- Wear appropriate PPE when collecting and handling specimens per [PA-HAN-524](#). It is critical that gloves are changed and hand hygiene is performed between each specimen collection and handling. Handling specimens without changing gloves or performing hand hygiene in between creates the potential for cross-contamination.
- Minimize delays between specimen collection and processing. Delays can affect the accuracy of the result.
- Conduct calibration of the machine, if applicable, and ensure positive and negative control procedures are performed as per manufacturer's instructions. Carefully handle positive control solutions. Once control procedures are complete, clean and disinfect hands, work surfaces, and the instrument (if applicable) to assure the positive control does not contaminate clinical specimens.
- For batch testing methods, carefully plan a systematic approach to specimen receipt, labelling, rotation into the instrument (if applicable), removal, and recording the results. For each step of the process, the plan should address ways to minimize contamination and errors in results reporting, such as mixing up specimens from two individuals.

Testing Considerations and Antigen Test Interpretation

The clinical performance of rapid antigen diagnostic tests largely depends on the circumstances in which they are used. Rapid antigen tests perform best when the person is suspected of having COVID-19 or they have been exposed to COVID-19 either individually (e.g., household or close contact) or as part of an outbreak/cluster. Symptomatic individuals should be tested in the early stages of infection with SARS-CoV-2 (i.e., typically within the first 5-7 days of symptoms onset) when viral load is generally highest. Testing of individuals with symptoms or with COVID-19 exposures is recommended to quickly identify COVID-19 infection, isolate these individuals, and identify/quarantine contacts. The results of antigen tests are impacted by pretest probability (i.e., the probability of a person having an infection before the test result is known) and need to be carefully interpreted. Use of antigen tests in symptomatic individuals correlates with a high pre-

test probability which increases the likelihood of true positives but also increases the likelihood of false negatives. For this reason, additional molecular testing (i.e., PCR) should be considered in symptomatic individuals with a presumptive negative result. Additional information about the interpretation of antigen results in these individuals can be found in [Figure 1](#) below.

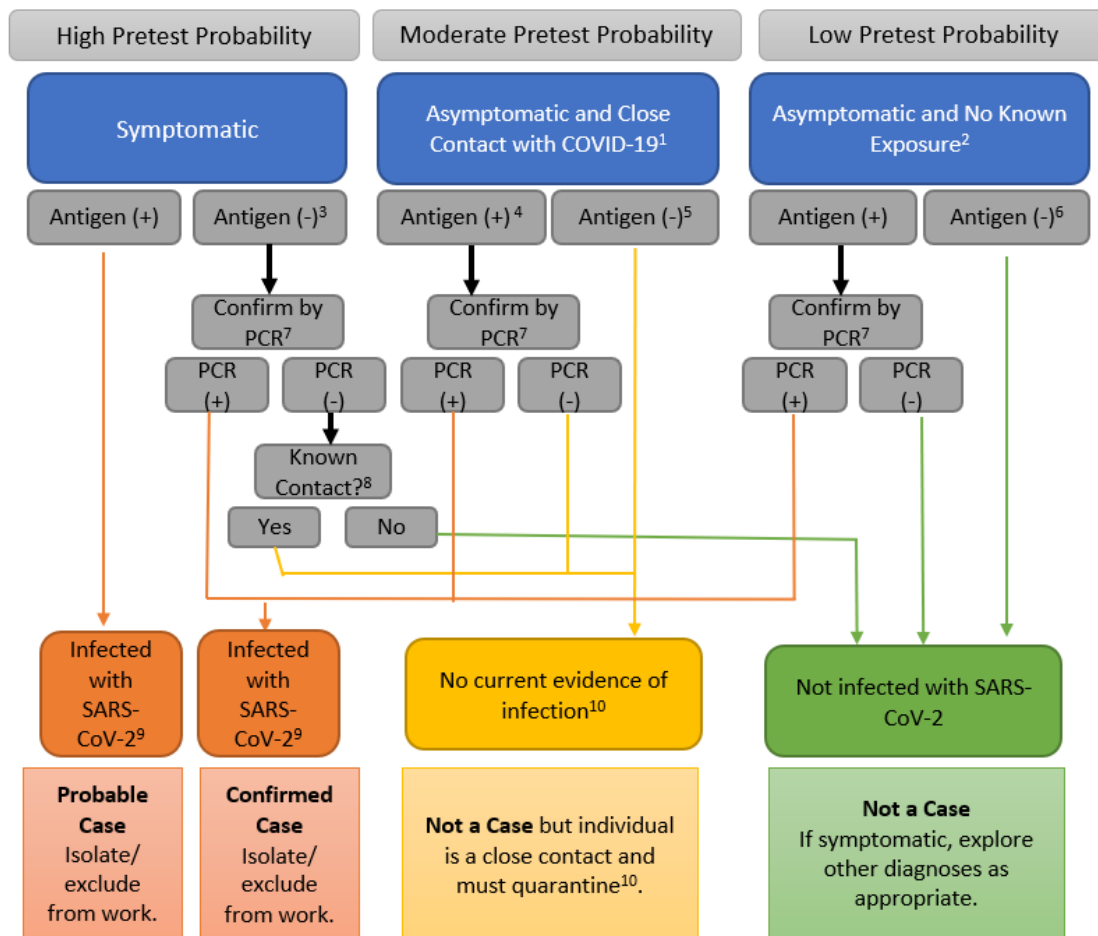
While antigen tests can be performed in individuals who are asymptomatic or who have not been exposed, this can present challenges for test interpretation. Use of antigen tests in asymptomatic individuals who are close contacts with a COVID-19 case correlates with a moderate pre-test probability. Use of antigen tests in asymptomatic individuals who do not have known exposures correlates with a low pre-test probability. In both of these circumstances, additional molecular testing (i.e., PCR) should be considered if antigen test results are positive. Additional information about the interpretation of antigen results in these individuals can be found in [Figure 1](#) below.

Antigen testing of asymptomatic and/or not exposed individuals should be reserved for closed congregate settings, such as a long-term care facility, correctional facilities and shelters, where early identification of COVID-19 introduction into these settings could limit further transmission. [HAN-547](#) details the use, interpretation and response to antigen tests in these long-term care settings. In other congregate care settings (e.g., correctional facilities, shelters), plans should be developed on how to best utilize this type of testing, how to obtain molecular testing when necessary and how best to respond to test results (e.g., cohort, isolate, exclude, quarantine). In addition to testing those who are symptomatic and/or exposed, testing clientele on admission or intermittent scheduled testing could be considered.

FIGURE 1- CONSIDERATIONS FOR ANTIGEN TEST RESULTS INTERPRETATION

The following figure was developed to assist partners with the interpretation of antigen tests. The figure considers additional laboratory results which may be available or the need to request additional laboratory testing. While this information can be used as a guide, there may be additional circumstances (e.g., confidence in laboratory testing procedures, assessment of clinical picture, specimen collection practices, burden of COVID-19 in the surrounding community, etc.) that affect pre-test probability that should be considered and may alter the interpretation from the below table. Separate guidance ([HAN-547](#)) regarding the use of antigen testing in long-term care facilities is available and should be used to guide actions in those settings. This table is subject to change as additional information about antigen testing is learned.

Figure 1



¹Single, multiple, or continuous known exposure to a person with COVID-19 within the last 14 days; perform PCR first if short turnaround time is available, if person cannot be effectively and safely quarantined, or if there are barriers to possible confirmatory testing

²No known exposure to a person with COVID-19 within the last 14 days

³If a symptomatic person has a low likelihood of SARS-CoV-2 infection, clinical discretion should determine if this negative antigen test result requires confirmatory testing. If there is a high likelihood of SARS-CoV-2 infection, confirmatory testing is strongly encouraged. If additional testing is not conducted or alternate diagnosis is not provided, isolation of these individuals is advisable.

⁴In instances of higher pretest probability, such as high incidence of infection in the community, clinical discretion should determine if this positive antigen result requires confirmation

⁵In certain settings, serial antigen testing could be considered for those with a negative antigen test result; serial testing may not require confirmation of negative results. The role of a negative antigen test result in ending quarantine depends upon when it is performed in the quarantine period. See [PA-HAN-538](#).

⁶If prevalence of infection is not low in the community, clinical discretion should consider whether this negative antigen result requires confirmation

⁷Nucleic acid amplification (PCR) test; confirm within 48 hours using a PCR that has been evaluated against FDA's reference panel for analytical sensitivity

⁸Known exposure to a person with COVID-19 within the last 14 days; if unsure, clinical discretion should determine whether isolation is necessary

⁹Isolation is necessary. See [PA-HAN-518](#) for persons in the community and [PA-HAN-517](#) and [PA-HAN-524](#) for persons in healthcare settings.

¹⁰Quarantine is necessary. See [PA-HAN-538](#).

Resources

- PADOH Point of Care Testing
 - <https://www.health.pa.gov/topics/disease/coronavirus/Pages/Guidance/Point-of-Care-Testing.aspx>
- CDC Interim Guidance for Rapid Antigen Testing for SARS-CoV- 2
 - <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>
- CDC COVID-19 Guidance for Shared or Congregate Housing
 - <https://www.cdc.gov/coronavirus/2019-ncov/community/shared-congregate-house/guidance-shared-congregate-housing.html>
- CDC COVID-19 Guidance on Correctional and Detention Facilities
 - <https://www.cdc.gov/coronavirus/2019-ncov/community/correction-detention/index.html>

If you have questions about this guidance, please call your local health department or **1-877-PA-HEALTH (1-877-724-3258)**.

Categories of Health Alert messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for a specific incident or situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

<p>This information is current as of January 22, 2021 but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.</p>
