

DATE:	1/22/2021
TO:	Health Alert Network
FROM:	Rachel Levine, MD, Secretary of Health
SUBJECT:	UPDATE: Point-of-Care Antigen Testing for SARS-CoV-2 in Long-term Care Facilities
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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 for SARS-CoV-2 in long-term care facilities and replaces the guidance provided in PA-HAN-526.

Key changes to the guidance include:

- Generally, a positive antigen test in an asymptomatic person (resident or HCP) should be followed by a confirmatory molecular test within 48 hours;
- Generally, a negative antigen test in a symptomatic person (resident or HCP) should be followed by a confirmatory molecular test within 48 hours;
- When awaiting results of confirmatory testing, individuals should be treated as potentially infectious (Transmission-Based Precautions for residents and work exclusion for HCP);
- A positive antigen test followed by a negative viral test collected within 48 hours using adequate technique should be treated as a false positive, regardless of the outbreak status of the facility.

For more information about POC testing in general, please visit our [POC testing website](#). If you have questions about this guidance, please contact DOH at **1-877-PA-HEALTH (1-877-724-3258)** or your local health department.

This Health Update provides recommendations and considerations for use of SARS-CoV-2 (the virus that causes COVID-19) point-of-care antigen testing in nursing homes. The advisory focuses on the use and interpretation of results **and represents a change in the way test results are interpreted. This guidance replaces PA-HAN-526.** For more information about point-of-care testing in general, including reporting requirements, test machine specifics, and links to resources, please visit DOH POC COVID-19 testing website available [here](#).

If you have questions about this guidance, please contact DOH at **1-877-PA-HEALTH (1-877-724-3258)** or your local health department. This guidance is not intended for healthcare facilities that are not long-term care residential settings or for non-healthcare settings (e.g., schools).

This advisory contains the following sections:

- A. Background
- B. When to use antigen testing in nursing homes
- C. Laboratory best practices and preventing errors
- D. Reporting requirements for SARS-CoV-2 tests
- E. When a confirmatory molecular test should be used
- F. Considerations for interpreting antigen test results in nursing homes
- G. Figure: Algorithm for interpreting antigen test results in nursing homes

A. BACKGROUND

Antigen tests are available as point-of-care (POC) diagnostics for SARS-CoV-2. They have a rapid turnaround time, which is critical in the identification of SARS-CoV-2 infection and rapid implementation of infection prevention and control strategies. These tests can augment other testing efforts, especially in settings where reverse-transcriptase polymerase chain reaction (RT-PCR) testing capacity is limited or testing results are delayed (e.g., >48 hours). In general, these POC antigen tests have a lower sensitivity, but similar specificity, for detecting SARS-CoV-2 compared to RT-PCR tests. However, false positives have been identified, particularly when users do not follow the instructions for use of the antigen tests or perform testing in low-prevalence populations (e.g., screening asymptomatic healthcare personnel (HCP) in non-outbreak settings). See [FDA's letter to clinical laboratory staff and healthcare providers on potential false positives with use of antigen tests for detection of SARS-CoV-2](#).

This update pertains to antigen tests that have been granted a US Food and Drug Administration's Emergency Use Authorization (FDA EUA) to detect SARS-CoV-2. Antigen tests perform best when the person is tested within the first days of symptom onset when viral load is generally highest. There are limited data on antigen test performance in asymptomatic persons. Preliminary reports suggest that antigen tests have lower percent positive agreement with RT-PCR test results when performed in asymptomatic individuals compared to symptomatic individuals. However, given the transmission of SARS-CoV-2 from asymptomatic and presymptomatic nursing home residents and healthcare personnel (HCP) with SARS-CoV-2 infection, DOH and CDC are providing considerations for the use of antigen tests for asymptomatic persons during this public health emergency. More information is available from the [Department of Human Services](#) regarding PREP Act coverage and use of antigen testing for asymptomatic persons.

B. WHEN TO USE ANTIGEN TESTING IN NURSING HOMES

This advisory guides the interpretation of results when antigen tests are used in the following circumstances:

- Testing of symptomatic residents and HCP,
- Testing of asymptomatic residents and HCP as part of a COVID-19 outbreak response in the facility, or testing of asymptomatic residents or HCP who are known close contacts of persons with COVID-19, and
- Testing of asymptomatic HCP in facilities without a COVID-19 outbreak as required by DOH and CMS recommendations.

Testing in other circumstances are likely to occur, such as testing asymptomatic residents and HCP who were exposed to persons with COVID-19 outside of the nursing home (e.g., recent hospitalization or outpatient services) or through other screening activities. The principles described here can be used to guide the interpretation of antigen test results in those situations.

Antigen tests should not be utilized to determine the duration of Transmission-Based Precautions nor when HCP can return to work following infection. Follow the guidance in [PA-HAN-517](#) and [PA-HAN-516](#), respectively for these situations. Test-based strategies are not generally recommended to determine duration of transmission-based precautions, nor to determine when HCP may return to work following infection. If used, test-based strategies should rely only on RT-PCR.

C. 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:

- Assure that users are properly trained to complete POC testing; assure competency by using teach-back methods and checklists. Maintain training records and assure procedural compliance through routine auditing. CDC offers an online training with professional continuing education credits for their [Ready, Set, Test POC 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 negatives.
- 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 positive and negative control procedures 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.

D. REPORTING REQUIREMENTS FOR SARS-COV-2 TESTS

Every COVID-19 testing site is [required to report](#) to the appropriate state or local public health department every diagnostic and screening test performed to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 as mandated by the Coronavirus Aid, Relief, and Economic Security (CARES) Act.

In Pennsylvania, reporting of positive, negative, inconclusive, and indeterminate results for SARS-CoV-2 to the electronic disease surveillance system ([PA-NEDSS](#)) is mandated by law within 24 hours. Do not report "invalid" results; repeat testing as per the IFU. Please refer to [PA-HAN-534](#) for specifics about reporting test results for point-of-care SARS-CoV-2 testing.

E. CONSIDERATIONS FOR INTERPRETING ANTIGEN TEST RESULTS IN NURSING HOMES

As the sensitivity of antigen tests is generally lower than RT-PCR, [FDA EUA](#) recommends that negative POC antigen tests be considered presumptive. Confirmatory RT-PCR testing might be needed prior to making clinical decisions, cohorting residents, or excluding HCP from work. **See Figure at the end of this HAN.** When interpreting the results of antigen tests, test characteristics and probability of infection should be considered.

- Test sensitivity might vary between antigen testing platforms. Facilities should be aware of which platform is being used and the sensitivity of the test for the patient population to be tested. For example, the first two antigen tests to receive [FDA EUA](#) ranged in sensitivity from 84% to 97% when used within 5 days of symptom onset. This may result in some false negative results.
- Factors that increase the probability of infection include the presence of symptoms in the person being tested, recent exposure to someone diagnosed with COVID-19, and whether testing is being conducted in a nursing home with an outbreak or within a high-prevalence community. These factors inform the decision of whether confirmatory testing by RT-PCR is indicated following an antigen test.

If a confirmatory RT-PCR test is collected within 48 hours (preferably collect within 24 hours), **individuals should be assumed infectious until the confirmatory test results are completed.** For example, if a symptomatic resident tests presumptive negative on antigen test and a RT-PCR is collected within 48 hours, the resident should remain in Transmission-Based Precautions per [PA-HAN-524](#) until the RT-PCR test results are received. Similarly, if an asymptomatic HCP working in a LTCF without an outbreak tests antigen positive, they should be excluded from work until a negative molecular test is available.

1. Testing of symptomatic residents or HCP

- If an antigen test is positive, and no quality assurance issues are identified, no confirmatory test is necessary.
 - Residents should be placed in Transmission-Based Precautions or HCP should be excluded from work. Follow the guidance in [PA-HAN-517](#) and [PA-HAN-516](#), respectively for these situations.
 - Conduct contact tracing, notifications and quarantine/isolation of exposed persons.
 - If the resident or HCP is the first positive test for SARS-CoV-2 within the facility in the previous 14 days (i.e., an index case), an [outbreak response](#) should be initiated immediately per [PA-HAN-509](#).*
 - Confirmatory testing may be considered in some situations, including if there are other unexpected positive results from testing performed on specimens collected from other persons that were run on the same day or if the person has a low likelihood of SARS-CoV-2 infection (e.g., non-respiratory systemic symptoms soon after SARS-CoV-2 vaccine administration in a HCP or LTCF resident with no known exposures in a non-outbreak facility).
- If an antigen test is presumptive negative, collect a confirmatory RT-PCR test immediately (e.g., within 48 hours, but preferably within 24 hours).
 - Symptomatic residents and HCP should be kept in transmission-based precautions per [PA-HAN-524](#) or excluded from work until RT-PCR results return.
 - Some antigen platforms have higher sensitivity when testing individuals within the first few days of symptom onset. Clinical discretion should be utilized to determine if

individuals who test negative on such platforms should be retested with RT-PCR. In some instances, confirmatory testing may not be necessary if the individual has a low likelihood of SARS-CoV-2 infection (e.g., non-respiratory systemic symptoms soon after SARS-CoV-2 vaccine administration in a HCP or LTCF resident with no known exposures in a non-outbreak facility).

- Facilities should test for both influenza and SARS-CoV-2 if influenza and SARS-CoV-2 are circulating in the community. Refer to [PA-HAN-537](#).
- If antigen and confirmatory tests are negative and the person is a known contact, residents should remain in quarantine for 14 days from exposure and HCP should follow [PA-HAN-510](#).
- Symptomatic HCP who test negative for SARS-CoV-2 on both antigen and confirmatory testing should continue work exclusion and return to work per institutional policy.
- Note: if an individual has recovered from SARS-CoV-2 infection in the past 3 months and develops new symptoms suggestive of COVID-19, they should be evaluated and may need to be retested if an alternate illness etiology cannot be identified.

2. Testing of asymptomatic exposed or potentially exposed residents or HCP in nursing homes as part of an outbreak response per [PA-HAN-530*](#)

- If an antigen test is **positive**, perform confirmatory RT-PCR test immediately (e.g., within 48 hours, but preferably within 24 hours).
 - Residents should be placed in transmission-based precautions per [PA-HAN-524](#) in a single room or, if single rooms are not available, remain in their current room pending results of confirmatory testing. They should **not** be transferred to a COVID-19 unit or placed in another shared room with new roommates. HCP should be excluded from work.
 - In situations where the pre-test probability is high (e.g., facility with large outbreak, such as prevalence >20%, and the person resided with another infected person), the antigen positive test might not require confirmation and the individual should be treated as infectious.
 - If confirmatory NAAT is positive, then resident should transfer to COVID-19 unit. HCP should remain excluded from work until they meet return to work criteria. Conduct contact tracing, notifications and quarantine/isolation of exposed persons.
- If an antigen test is **presumptive negative** OR if the antigen test is positive but the confirmatory NAAT (performed within 2 days) is negative, exposed residents should be placed in transmission-based precautions in Yellow zones as described in [PA-HAN-530](#). HCP should be allowed to continue to work with continued symptom monitoring. The facility should continue serial viral testing (antigen or RT-PCR) at least weekly until no new cases are identified for a 14-day period.
 - Note: the Yellow zones as described in [PA-HAN-530](#) are a form of quarantine following exposure. Testing during the 14-day quarantine period does not eliminate the need for quarantine in the Yellow zone, even if results are negative.
 - Note: asymptomatic individuals who have recovered from SARS-CoV-2 infection in the past 3 months and live or work in a nursing home performing facility-wide testing should not be tested for SARS-CoV-2.

3. Testing of asymptomatic residents or HCP in nursing homes without an outbreak, and with no known exposure, per DOH and CMS recommendations

[DOH](#) and [CMS guidance](#) for skilled nursing facilities require serial testing of residents or HCP at intervals based on local incidence of COVID-19.

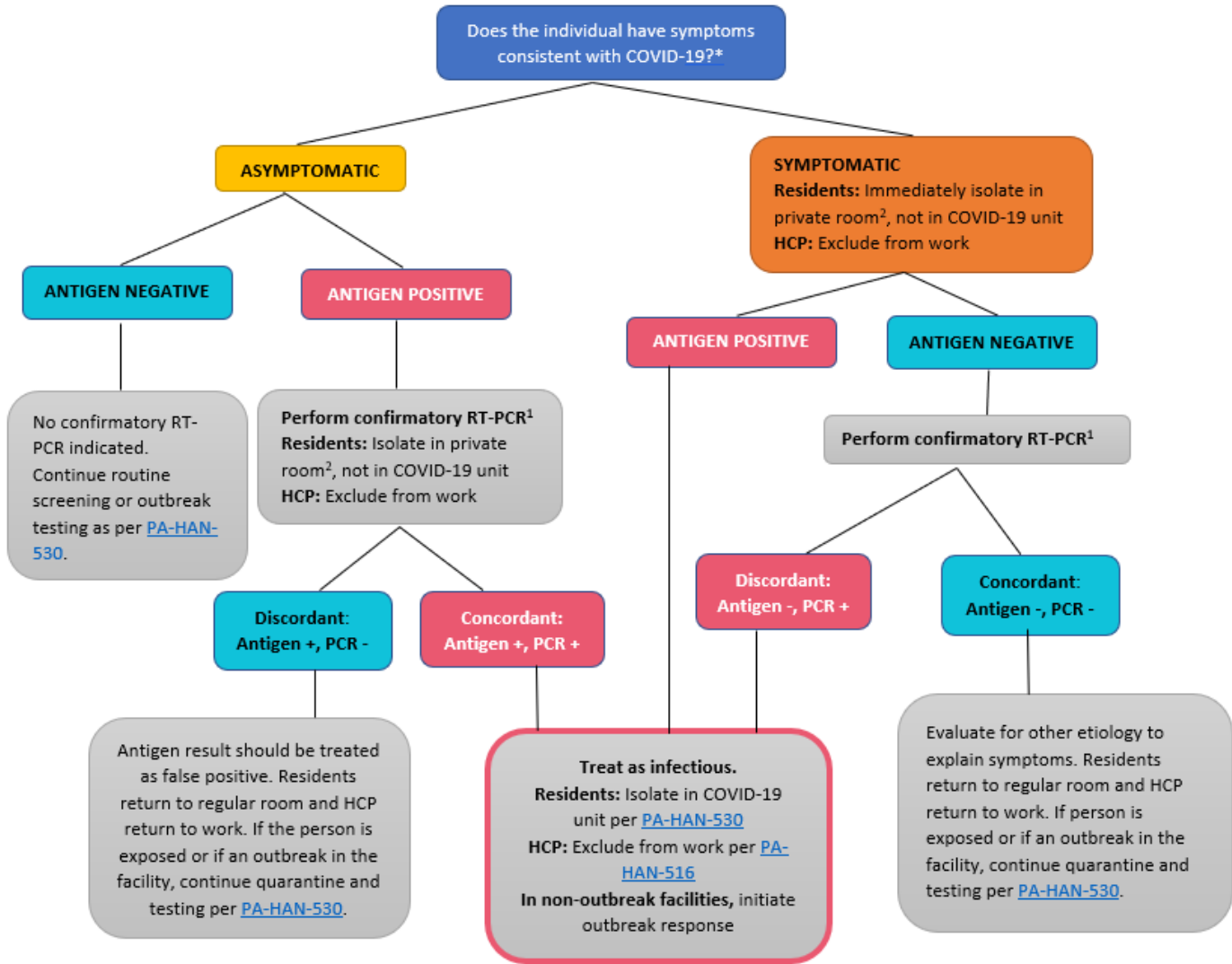
- If an antigen test is **positive**, collect a confirmatory RT-PCR test within 48 hours of the antigen test (preferably within 24 hours). A resident or HCP should be kept in transmission-based precautions or excluded from work until RT-PCR results return. However, outbreak response, including facility-wide testing, can be delayed until confirmatory test results are completed.
 - If the confirmatory test is **positive**, residents should continue Transmission-Based Precautions or HCP should be excluded from work. Follow the guidance in [PA-HAN-517](#) and [PA-HAN-516](#), respectively for these situations and initiate an outbreak response including facility-wide testing of all residents and HCP per [PA-HAN-530](#).
 - If the confirmatory test is **negative**, the antigen test should be considered a false positive and the HCP should return to work.
- If an antigen test is **negative**, allow HCP to continue to work. Continue to monitor for symptoms, and serial testing should continue per [DOH](#) and [CMS recommendations](#).
- Note: Asymptomatic residents and HCP who have recovered from SARS-CoV-2 infection in the past 3 months should not be tested for SARS-CoV-2.

Notes:

*A new COVID-19 outbreak response in a nursing home is triggered when a single resident or HCP tests positive for SARS-CoV-2, following the conclusion of any previous outbreaks as described in PA-HAN-530. An index infection in a resident should include SARS-CoV-2 infections that originated in the nursing home and should not include:

- Residents who were known to have COVID-19 on admission to the facility and were placed into [Transmission-Based Precautions](#).
- Residents who were placed into Transmission-Based Precautions on admission and developed SARS-CoV-2 infection within the 14-day period after admission.

F. FIGURE: ALGORITHM FOR INTERPRETING ANTIGEN TEST RESULTS IN NURSING HOMES



* Asymptomatic individuals who have recovered from SARS-CoV-2 infection in the past 3 months and live or work in a nursing home performing facility-wide testing do not need to be retested. If an individual has recovered from SARS-CoV-2 infection in the past 3 months and develops new symptoms suggestive of COVID-19, they should be evaluated and may need to be retested if an alternate illness etiology cannot be identified.

¹Asymptomatic people who test antigen positive may not need confirmatory testing if they have high pre-test probability (e.g., person resided with another infected individual in a facility with a large outbreak, such as prevalence >20%).

²If a single room is not available, keep the resident in the same room with transmission-based precautions. Do not transfer to a room with a new roommate.

This algorithm should be used as a guide, but clinical decisions may deviate from this guide if indicated. Contextual factors including community incidence, characteristics of different antigen testing platforms, as well as availability and turnaround times of RT-PCR, further inform interpretation of antigen test results.

RT-PCR: reverse-transcriptase polymerase chain reaction
HCP: healthcare personnel

COVID-19 outbreak response in a nursing home is triggered when one nursing home-onset SARS-CoV-2 infection in a resident or one HCP SARS-CoV-2 infection.

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.

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.