

Long Term Care Antigen Testing Guidance

10.08.20

Background

On Tuesday, July 14, the U.S. Department of Health and Human Services announced it would be providing rapid point of care testing devices and tests to long term care facilities in COVID-19 hotspots in the U.S. HHS will determine the facilities that will be receiving the testing equipment. It is the Department's understanding at this time that facilities will be receiving either Quidel Sofia 2 Instrument or the BD Veritor Plus system – along with 400 of the associated tests. IDPH and SHL will not be involved in determining which testing equipment each facility receives. Those determinations will also be made by HHS. Following the initial distribution of the testing equipment and test supplies, facilities will be responsible for ordering their own additional testing supplies.

Receipt of the rapid point of care testing devices is contingent upon a facility's possession of a CLIA waiver. Questions about how to obtain a CLIA waiver should be directed to the State Hygienic Lab at (319) 335-4500. Additional information about obtaining CLIA certificates of waiver can also be found on the CMS website.

This document serves to provide guidance on how to use these testing devices in a long term care setting. The guidance may be updated as new information becomes available. Additionally, facilities that receive these testing devices will also be offered training materials from SHL.

Guidance for Use

1. Rapid Testing for Symptomatic Residents and Staff

It is anticipated this equipment will be useful for identifying positive cases quickly in congregate settings, such as long term care facilities. In accordance with manufacturer instructions, this testing equipment can be used for the rapid testing of symptomatic staff or residents.

If a positive result is received using the rapid testing equipment, the appropriate isolation protocols for residents and staff must immediately be followed and the results should be reported to public health.

It is important to know that there is the possibility of a false negative test. If a negative test result is received for a resident or staff member for whom COVID infection is highly suspected, IDPH and SHL recommend conducting a confirmatory diagnostic PCR test. The package insert states: "Negative results should be treated as presumptive and confirmed with an FDA authorized molecular assay, if necessary, for clinical management, including infection control." Confirmatory diagnostic PCR testing supplies can be obtained through the state hygienic laboratory (SHL) or other reference laboratory used by the long term care facility. Instructions for ordering testing supplies from the SHL can be found in Appendix A of the Long-Term Care Facilities Visitation and Testing

Specifications for Use

1. CLIA Certificate of Waiver

To perform this testing the facility must have a current CLIA certificate of waiver. To obtain a certificate of waiver, the facility is required to comply with all CLIA documentation and other requirements. Questions about obtaining a CLIA certificate of waiver should be directed to SHL at (319) 335-4500.

This testing is deemed a waived test for CLIA which means facilities are required to follow manufacturer's instructions when using these test systems.

Positive and negative external quality control is required with each new lot/shipment of cartridges. If you receive a new shipment or new lot number you must perform the external quality control.

2. Effect of Acceptance.

By accepting this instrument and its associated test cartridges and controls you are agreeing and authorized to use the equipment for testing only for your long term care facility, you are not authorized to perform testing for other facilities.

3. Training.

Training to perform this testing using this equipment is an important component of adhering to the CLIA requirements. All testing staff are required to read the package insert and document that they have done so. The procedure detailed in the package insert must be followed exactly and safety guidance should be followed.

4. Results Reporting.

Reporting to IDPH of both positive and negative test results is required. Facilities that receive these machines will be contacted by IDPH to establish a mechanism to electronically report all tests performed (both positive and negative results) to IDPH the same day the testing was performed. Facilities with questions related to reporting should contact John Satre at IDPH by calling (515) 229-0417.

5. Biosafety Risk Assessments.

A biosafety risk assessment must be performed before testing is performed. Use appropriate PPE to perform the test. Clean and disinfect the area around the instrument after each test performance.

FAQs

Clinical:

1. CMS has told us that the two testing systems they plan to distribute to all facilities, Quidel Sofia 2 SARS Antigen FIA and BD Veritor System for Rapid Detection of SARS-CoV-2, and now the Abbot BinaxNOW are intended to be used for surveillance testing in nursing facilities for residents, staff and visitors. What would IDPH's concerns be with these two particular antigen testing POC systems, if any?

A: Recommendations for use of the POC equipment is found above.

This guidance is subject to change as federal guidance is released and clarified, and as additional Iowa-specific data is collected.

2. Can you confirm that facilities with a CLIA Waiver will be able to process these tests without further requirements?

A: Yes, this is correct. Facilities with a CLIA certificate of waiver will be able to receive and use the POC testing equipment sent.

3. How will IDPH view POC testing accuracy? Will positive tests require subsequent PCR confirmation testing? What about symptomatic residents who test negative? Could a facility rerun the test, or would a PCR confirmation be required?

A: As indicated in the above guidance, Iowa Department of Public Health recommends that positive tests from the POC testing equipment be treated as an infection. If an individual is symptomatic and suspected to have COVID but receives a negative test result from the POC equipment provided, it is recommended that the individual is retested by PCR to ensure that it is not the result of a false . negative

Operations:

4. Who will be allowed to collect the specimens? Who will be allowed to run the lab testing equipment?

A: Any medical professional that has received training and is documented as competent will be considered allowed to collect specimens. Individuals must have documented training to run the lab testing equipment but do not require specific medical license or education.

5. What types of control testing and logs will be required?

A: Materials related to quality control testing and necessary logs will be provided to the facility based on the type of POC equipment that was received.

Reimbursement:

6. It appears that Medicare will pay for this testing for residents. If a resident does not have Medicare coverage, may the facility bill Medicaid for testing and how will that be billed?

A: Yes, the facility may bill Medicaid but should confirm that they are appropriately enrolled with the Iowa Medicaid Enterprise and applicable managed care organizations to bill for lab services.

7. Will the state cover the costs of staff testing with these POC systems? If so, how would we bill this?

A: The state is working with federal partners to understand the intended use of federal COVID provider relief funds. More information will be provided when available.

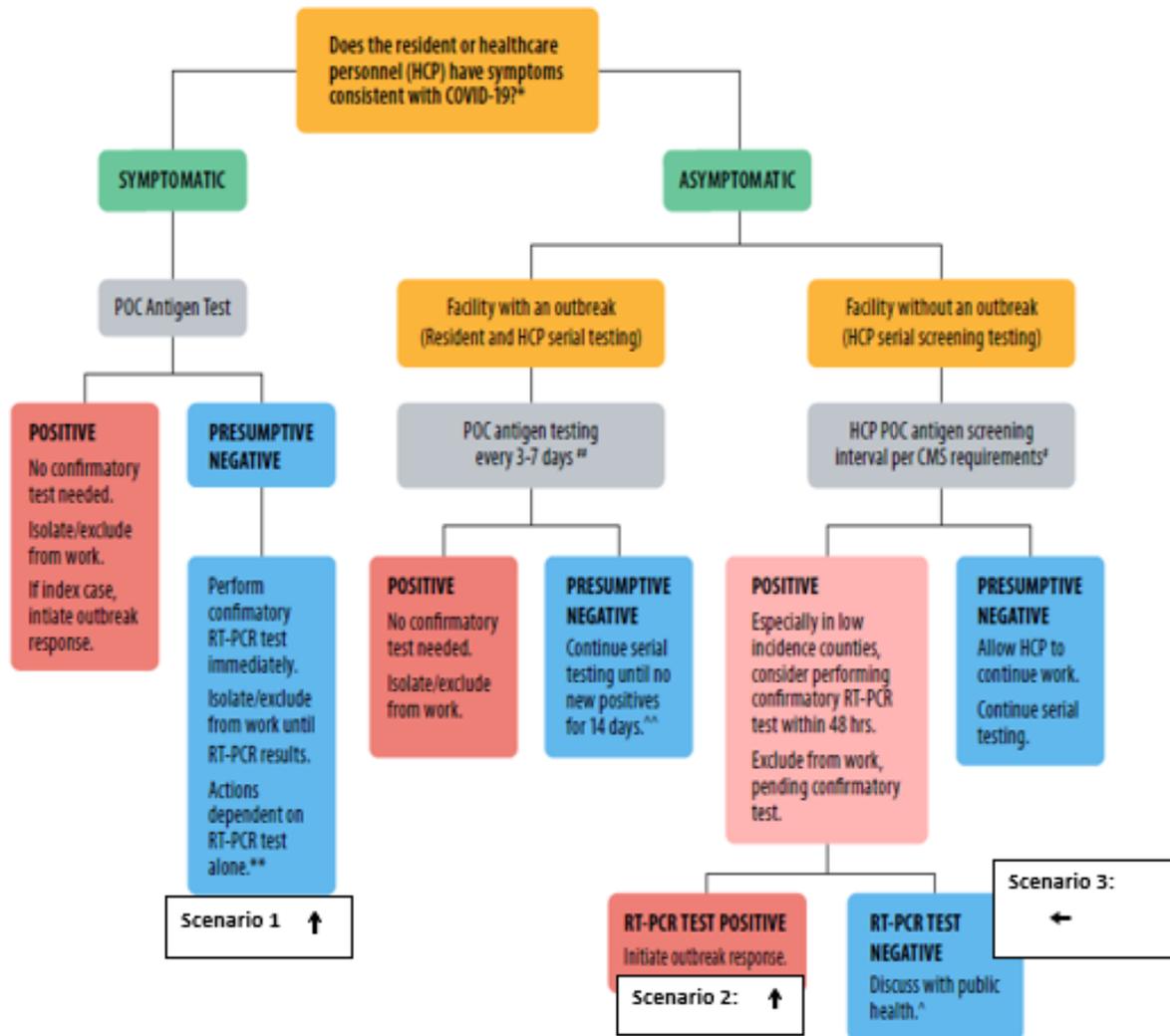
8. How will facilities be able to cover the cost of visitor testing?

A: The Iowa Department of Human Services does not recommend that the POC testing equipment provided to facilities be used for screening visitors at this time. Standard protocols for screening should continue to be followed.

Guidance for Long Term Care Facilities Concerned About False Positive or False Negative Antigen Testing Results as Part of CMS Required Repeat Testing Protocols

This guidance is subject to change as federal guidance is released and clarified, and as additional Iowa-specific data is collected.

CONSIDERATIONS FOR INTERPRETING ANTIGEN TEST RESULTS IN NURSING HOMES



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
 POC: point-of-care
 HCP: healthcare personnel
 Index case: a newly identified case of SARS-CoV-2 infection in a resident or HCP in a nursing home facility with no known infections of SARS-CoV-2 infection in the previous 14-day period.
 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.

* 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, alternative diagnoses should be considered prior to retesting for SARS-CoV-2.

** Some antigen platforms have higher sensitivity when testing individuals within 5 days of symptom onset. Clinical discretion should be utilized to determine if retesting by RT-PCR is warranted.

† CMS recommendations for testing asymptomatic HCP in facilities without a case

‡ CDC guidance on testing residents of nursing homes. CDC guidance on testing HCP

^ In discussion with the local health department, community incidence and time between antigen test and RT-PCR test can be utilized to interpret discordant results and determine when HCP can return to work.

** If an antigen test is presumptive negative in a facility with an outbreak, residents should be placed in transmission-based precautions or HCP should be allowed to continue working while monitoring for symptoms.

This guidance is subject to change as federal guidance is released and clarified, and as additional Iowa-specific data is collected.

If a Long Term Care (LTC) facility suspects false positive antigen results in ASYMPTOMATIC staff or ASYMPTOMATIC residents AND the long term care facility is NOT currently experiencing an outbreak (defined as at least three positive residents), the following procedures can be considered:

The ASYMPTOMATIC staff or ASYMPTOMATIC resident can be re-tested twice using confirmatory PCR testing,

- The first PCR specimen must be collected within 48 hours of when the positive antigen specimen was collected.
- The second PCR specimen must be collected at least 24 hours after the first PCR specimen was collected.
- If BOTH PCR specimens test NEGATIVE, the original antigen result should be considered a false positive result.

When PCR results are pending, the ASYMPTOMATIC staff member should be isolated and public health will advise close contacts to quarantine. If the ASYMPTOMATIC staff member is determined to have a false positive antigen result (in accordance with the guidance above) the ASYMPTOMATIC staff member can stop isolation and return to work. Close contacts in quarantine will be released by public health.

When PCR results are pending in ASYMPTOMATIC residents, the long term care facility should transfer the ASYMPTOMATIC resident to a single room if there is a roommate, implement use of Transmission-Based Precautions, and dedicate staff. The LTC facility should not transfer the ASYMPTOMATIC resident to a COVID-19 unit or place them in another shared room with new roommates. Close contacts will be identified by public health and quarantined. If the ASYMPTOMATIC resident is determined to have a false positive antigen result (in accordance with the guidance above) COVID-19 precautions should be discontinued in the LTC facility. Close contacts in quarantine will be released by public health.

This confirmatory testing strategy should only be applied in a long term care setting. At this time, this strategy DOES not apply to antigen testing occurring in the community.

Confirmatory PCR testing for ASYMPTOMATIC staff and ASYMPTOMATIC residents previously testing positive on antigen tests, can be performed at the State Hygienic Laboratory (SHL) at the discretion of the LTC facility.

If a Long Term Care (LTC) facility suspects false negative antigen results in SYMPTOMATIC staff or SYMPTOMATIC residents, the SYMPTOMATIC staff or SYMPTOMATIC residents can be re-tested using confirmatory PCR testing. This testing can be performed at the SHL at the discretion of the LTC facility.

When PCR results are pending, the SYMPTOMATIC staff member should isolate themselves and be excluded from working. Public health will not perform an investigation or contact trace unless the PCR results are positive. If the SYMPTOMATIC staff member tests negative on PCR, they can return to work 24 hours after symptoms resolve in accordance with the facility's established procedures. If the SYMPTOMATIC staff member tests positive on PCR, they should continue to be excluded in accordance with COVID-19 procedures and public health will perform an investigation or contact trace.

When PCR results are pending in SYMPTOMATIC residents, the LTC facility should transfer the SYMPTOMATIC resident to a single room if there is a roommate, implement use of Transmission-Based Precautions, and dedicate staff. The LTC facility should not transfer the SYMPTOMATIC resident to a COVID-19 unit or place them in another shared room with new roommates. Public health will not perform an investigation or contact trace unless the PCR results are positive. If the SYMPTOMATIC resident tests negative on PCR, follow the facility's established procedures for isolating ill residents. If the SYMPTOMATIC resident tests positive on PCR, they should continue to be isolated in accordance with COVID-19 procedures and public health will perform an investigation or contact trace.

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LTC facilities should consider reporting false positive and false negative antigen results through FDA's medwatch (in addition to public health): www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

Scenario 1: If a LTC facility suspects false negative antigen results in SYMPTOMATIC staff or SYMPTOMATIC residents, the SYMPTOMATIC staff or SYMPTOMATIC residents can be re-tested using confirmatory PCR testing. This testing can be performed at the SHL at the discretion of the LTC facility. Please see additional guidance above.

Scenario 2: If a Long Term Care (LTC) facility suspects false positive antigen results in ASYMPTOMATIC staff or ASYMPTOMATIC residents AND the long term care facility is NOT currently experiencing an outbreak (defined as at least three positive residents), the following procedures can be considered:

The ASYMPTOMATIC staff or ASYMPTOMATIC resident can be re-tested twice using confirmatory PCR testing,

- The first PCR specimen must be collected within 48 hours of when the positive antigen specimen was collected.
- The second PCR specimen must be collected at least 24 hours after the first PCR specimen was collected.

If EITHER PCR is positive, accept the positive result. Please see additional guidance above.

Scenario 3: If a Long Term Care (LTC) facility suspects false positive antigen results in ASYMPTOMATIC staff or ASYMPTOMATIC residents AND the long term care facility is NOT currently experiencing an outbreak (defined as at least three positive residents), the following procedures can be considered:

The ASYMPTOMATIC staff or ASYMPTOMATIC resident can be re-tested twice using confirmatory PCR testing,

- The first PCR specimen must be collected within 48 hours of when the positive antigen specimen was collected.
- The second PCR specimen must be collected at least 24 hours after the first PCR specimen was collected.

If BOTH PCR specimens test NEGATIVE, the original antigen result should be considered a false positive result. Please see additional guidance above.

This guidance is subject to change as federal guidance is released and clarified, and as additional Iowa-specific data is collected.