Long Term Care Antigen Testing Guidance

8.24.20

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 C of the Long Term Care Reopening Guidance.
2. **Routine Testing**

Routine, ongoing testing should be conducted in accordance with the testing guidance found in Appendix A of the Long Term Care Reopening Guidance.

**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*, are intended to be used for

   *This guidance is subject to change as federal requirements are modified.*
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.

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 positive.

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.

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Facilities Getting First Round of Equipment:

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<tr>
<th>Facility Name</th>
<th>Address</th>
<th>City</th>
<th>Zip Code</th>
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<tr>
<td>TOUCHSTONE HEALTHCARE COMMUNITY</td>
<td>1800 INDIAN HILLS DRIVE</td>
<td>SIOUX CITY</td>
<td>IA 51104</td>
<td>Woodbury</td>
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<td>THOMAS REST HAVEN</td>
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<td>IA 50058</td>
<td>Carroll</td>
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<td>COUNCIL BLUFFS</td>
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<td>1512 ZENITH AVENUE</td>
<td>SPIRIT LAKE</td>
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<td>IOWA MASONIC HEALTH FACILITIES</td>
<td>2500 GRANT STREET</td>
<td>BETTENDORF</td>
<td>IA 52222</td>
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<tr>
<td>BURLINGTON CARE CENTER</td>
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