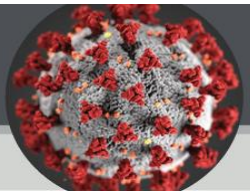

POINT OF CARE ANTIGEN TESTING FOR COVID-19

Revised: July 28, 2020

PART I: BACKGROUND & LOGISTICAL INFORMATION

Background

The U.S. Department of Health & Human Services (HHS) has announced that it will supply rapid point-of-care antigen testing instruments and tests to nursing homes throughout the country to aid in identification and mitigation of COVID-19. Each nursing home will receive one shipment that includes supplies to facilitate baseline testing among nursing home residents and staff, and enable a pathway to conduct ongoing testing according to public health guidelines.

The U.S. Food & Drug Administration (FDA) has granted emergency use authorization to two antigen detection tests: (1) the Sofia SARS Antigen FIA manufactured by Quidel Corporation (Quidel) and (2) the Veritor System for Rapid Detection of SARS-CoV-2 manufactured by Becton, Dickenson and Company.

These antigen tests quickly detect fragments of proteins found on or within the virus by testing samples collected from the nasal cavity using swabs. This test is authorized for use in high and moderate complexity laboratories certified by Clinical Laboratory Improvement Amendments (CLIA), as well as for point-of-care testing by facilities operating under a CLIA Certificate of Waiver. Antigen tests are different from:

- Polymerase chain reaction (PCR) tests, a molecular diagnostic testing technique that detects the genetic material from the virus and can help diagnose an active COVID-19 infection; and
- Serological tests that look for antibodies to the virus, which can help identify individuals who have developed an adaptive immune response to the virus, as part of either an active infection or a prior infection (serological, or antibody, tests should not be used to diagnose active infection).

Who will receive the testing platforms and U.S. Food and Drug Administration (FDA)-authorized antigen diagnostic tests?

Nursing homes will receive either a Quidel Sofia 2 Instrument or Becton, Dickinson and Company (BD) Veritor™ Plus System over the coming months along with the associated FDA-authorized antigen diagnostic tests. Each facility will receive a system from one or the other manufacturer, not both.

To be eligible, nursing homes must have a current CLIA Certificate of Waiver AND meet certain epidemiological criteria. (See below for additional information about CLIA Certificates of Waiver.) Nursing homes mean facilities that are certified as a Medicare Skilled Nursing Facility (SNF) and/or Medicaid Nursing Facility (NF).

Can nursing homes keep the testing platforms?

Yes. Upon receipt, the instrument(s) become the property of the nursing home and can be used in accordance with the conditions of authorization for the test.

How many COVID-19 test kits will nursing homes receive?

Allotments of instruments and test kits are determined by the estimated volume of tests needed for the facility to test all staff and residents at least once and enable a pathway to conduct ongoing testing according to public health guidelines. This estimated volume is based on the average number of weekly staff, and the average resident census for each facility reported by CMS. All facilities will receive at least one instrument. A second instrument will be allocated to facilities that were identified to receive 900 tests (facilities identified as major outliers).

Nursing homes were categorized into 5 groupings based on their estimated testing needs:

- Small facilities – 150 tests, 1 instrument;
- Small-medium facilities – 240-250 tests,* 1 instrument;
- Medium facilities – 325-330 tests,* 1 instrument;
- Large facilities – 600 tests, 1 instrument;
- Major outlier facilities – 900+ tests, 2 instruments.

*Note: The range accounts for variations in kit size between BD and Quidel. Tests for the BD Veritor™ Plus come in kits of 30 and those for the Quidel Sofia 2 in kits of 25.

Will HHS be providing more tests after the initial shipment?

No. After the initial shipment of instruments and tests, nursing homes will be responsible for procuring their own tests directly from the manufacturer or medical device distributor.

According to a July 15 Skilled Nursing News account, the cost should be approximately $25/test, and HHS hopes to have 15 million to 20 million tests available each month by September.

Who will provide training to nursing home staff? In what format will the training be provided in?

Quidel and BD will provide training materials to nursing home staff. Training documentation will be made widely available for all nursing homes that are receiving supplies. Quidel training information can be found at quideltogetheragain.com. BD is offering training services through their Learning Management System (LMS) platform to all BD Veritor System customers at no additional cost. The eLearning training platform is available online.

Note: As of July 28 some facilities across the country have reported to LeadingAge national that they received instruments and tests, but without training materials. Manufacturers may ship materials and follow-up separately with education, training and support materials.

When will my nursing home receive the shipment of testing platforms and FDA-authorized antigen diagnostic tests? Will these devices be sent directly to the nursing homes or to states for distribution?

Devices will be sent directly to nursing homes to ensure that nursing homes can begin testing as soon as they receive the devices and complete the requisite training. Supplies will arrive in a single shipment directly from the manufacturer and/or distributor.

Instruments and tests will be shipped on a weekly basis directly to CMS-prioritized nursing homes. Instruments and tests will begin shipping the week of July 20. Shipping schedules are based on the availability of instruments and test kits (i.e. production is still ramping up). Facilities that have been prioritized to receive early shipments (within the first 3 weeks) are located in CDC epidemiological hotspot counties (see the next question below). Most shipments will occur in the first 4 weeks, although it may take up to 14 weeks for all nursing homes to receive their shipment due to supply availability.

How is distribution of the testing platforms and FDA-authorized antigen diagnostic tests being determined? How were nursing homes prioritized to receive a testing platform and FDA-authorized antigen diagnostic tests?

The prioritization is based on CDC epidemiological hotspot data, as well as nursing homes that reported the following information to the CDC by July 5th (i.e. indicating to CMS an elevated risk for COVID-19 transmission):

- Current CLIA Certificate of Waiver;
- Three or more confirmed or suspected new cases of COVID-19 in the last 7 days;
- At least one new COVID-19 case in the last 7 days after having zero previous COVID-19 cases;
- Inadequate access to testing in the last 7 days;
- At least one new resident death due to COVID-19 in the last 7 days;
- At least one new confirmed or suspected COVID-19 case among staff in the last 7 days.

Note: As of July 28 some facilities across the country have reported to LeadingAge national that they received instruments and tests despite, by their reckoning, not falling into these prioritized categories.

Which nursing homes will receive instruments and tests in the first wave of shipments?

CMS has prioritized > 3,900 nursing homes to receive instruments and tests in the coming weeks. Once those shipments are complete, HHS will continue a phased distribution of antigen testing supplies to nursing homes with a current CLIA Certificate of Waiver and based on updated epidemiological data.

The list of nursing homes receiving instruments and tests in the first wave of 635 facilities is available on this Nursing Home Data - Point of Care Device Allocation webpage. There were not Minnesota facilities included in the first wave. This list will be updated as the phased distribution progresses and new shipments go out.

PART II: CLIA CERTIFICATE OF WAIVER REQUIREMENT

Nursing homes must have a CLIA Certificate of Waiver both to ***receive*** the instruments and tests HHS will be distributing and to ***perform*** the tests. Here is some additional information about this aspect of the program. CMS has also noted that facilities should use the instrument in a location associated with a current CLIA certificate.

We have a CLIA Certificate of Waiver, but our facility received an email from the Minnesota Department of Health (MDH) indicating that we don't have one. What's going on?

CMS provided MDH with a list of 54 Minnesota nursing homes that do not have a CCOW, according to CMS records. On July 27th MDH pushed an email out to all of those facilities noting that there is not a waiver in place, and advising facilities to submit a Certificate of Waiver application if you wish to be included in the HHS initiative.

If you have a Certificate of Waiver, but still received that MDH communication, here are two possible reasons why:

Hospital-Attached: MDH recently received guidance from CMS indicating each nursing home facility must have its own CLIA Certificate of Waiver if it wishes to be included in the initiative.

Note: Participation in the initiative is not mandatory. It is acceptable for hospital attached/associated facilities to continue using the hospital laboratory for their COVID-19 testing if that is their preference and the laboratory is able to accommodate the volume.

Laboratory Type: The CLIA Application for Certification (CMS-116) includes a section to designate the type of laboratory (i.e. facility type). One issue MDH has identified is that some facilities' certificates are categorized under a catch-all category called "Other". According to MDH, the facility will need to submit a CMS-116 to change the lab type to #27 – Skilled Nursing Facility/Nursing facility if it wishes to be included in the initiative.

Note: This potentially also could be an issue if a nursing home and assisted living setting on the same campus are covered by a Certificate of Waiver that is recorded under the "Assisted Living Facility" laboratory type.

If you wish to participate in the HHS initiative, work directly with MDH to identify the specific reason why its records show you do not have a Certificate of Waiver. Contact the Minnesota Department of Health CLIA Program: health.clia@state.mn.us or 651-201-4120. MDH will identify to CMS facilities that have contacted MDH to make changes to their certificates.

Related note: If your facility has a CLIA waiver, check to confirm that it has not expired. The waivers are valid for two years, then need to be renewed. MDH did not identify expirations as an issue, but it would be worthwhile for you to confirm. And, if your certificate renewal date is approaching soon, be sure to complete the renewal in a timely way.

Our organization has more than nursing home site grouped under a Certificate of Waiver. Will those individual sites also need to obtain a specific waiver if they wish to participate in the CMS initiative?

MDH has have asked CMS this question, but CMS has not yet provided an official answer. If you are in this situation, we recommend that you contact MDH proactively to ask about it:
email health.clia@state.mn.us or call 651-201-4120. MDH shared that there were several nursing homes in the CMS list of facilities without a Certificate of Waiver that did have CLIA coverage as a secondary sites on a Certificate of Waiver. From this, it appears to MDH that each nursing home currently covered as a multiple site must have its own Certificate of Waiver to be included in the HHS initiative.

What should we do if our facility does not have a CLIA Certificate of Waiver?

If you wish to participate in this initiative, we recommend you begin the application process right away. Refer to this MDH webpage and this guidance from CMS for information on how to apply.

MDH recommends that facilities ensure the information below is included when completing an application form:

- In Section III Laboratory Type, please select #27 – Skilled Nursing Facility/Nursing facility.
- HHS does not know which diagnostic instrument will be sent to your facility. Therefore, in Section VI Waived Testing, please include the following information:
  - Quidel Sofia and Sofia 2 Instrument SARS Antigen FIA

- BD Veritor Plus System Rapid Detection of SARS-CoV-2
- If you intend to do tests other than COVID-19 under your Certificate of Waiver, include those too.
- You must indicate an annual estimated test volume in Section VI as well.
- The laboratory director must sign the application form.

How long does the application process take?

MDH will expedite your application and provide your CLIA Certificate of Waiver number via email within a few days of receipt.

If a nursing home has an existing Certificate of Waiver (e.g. obtained for blood glucose), does it need to amend the Certificate to receive the antigen testing instruments or to perform the COVID-19 tests?

No. MDH has advised LeadingAge Minnesota that this is not necessary.

Who should we contact with questions or to resolve issues?

Contacting MDH will likely be the fastest way to resolve issues relating to your CLIA Certificate of Waiver:

Minnesota Department of Health CLIA Program
3333 West Division Street, Suite 212, St. Cloud, MN 56301-4557
Email: health.clia@state.mn.us or Phone: 651-201-4120

CMS has established an email address specifically for this initiative, which may also contact with questions, comments or concerns: cliacovidinquiries@cms.hhs.gov. This CMS CLIA lookup page may also be a resource.

PART III: CLINICAL/OPERATIONAL ISSUES AND CONSIDERATIONS

Clinical Issues and Considerations:

Introductory Note: No sooner did HHS announce plans to distribute antigen testing platforms, than questions arose about the accuracy of the tests, and when and how long-term care providers should use them. In a teleconference tied to the announcement of this initiative, HHS indicated these tests are in the neighborhood of 85-90% accurate. While positive results are 99% accurate, said HHS, there is a higher chance of a false negative with this type of testing vs. lab-based testing. **The Minnesota Department of Health is developing guidance on these questions, and we will add that information here as soon as it is available.** In the meantime, we are presenting initial information from FDA, CMS, and CDC on these questions.

The FDA Emergency Use Authorization issued to Quidel Corporation for the Sofia 2 SARS Antigen FIA (May 9) comments:

This latest FDA authorization is for an antigen test, which is a new type of diagnostic test designed for rapid detection of the virus that causes COVID-19. Each category of diagnostic test has its own unique role in the fight against this virus. PCR tests can be incredibly accurate, but running the tests and analyzing the results can take time. One of the main advantages of an antigen test is the speed of the test, which can provide results in minutes. However, antigen tests may not detect all active infections, as they do not work the same way as a PCR test. Antigen tests are very specific for the virus, but are not as sensitive as molecular PCR tests. This means that positive results from antigen tests are highly accurate, but there is a higher chance of false negatives, so negative results do not rule out infection. With this in

mind, negative results from an antigen test may need to be confirmed with a PCR test prior to making treatment decisions or to prevent the possible spread of the virus due to a false negative.

The CDC's Overview of Testing for SARS-CoV-2 (July 17) notes:

CDC recommends using authorized nucleic acid or antigen detection assays that have received an FDA EUA to test persons with symptoms when there is a concern of potential COVID-19. Tests should be used in accordance with the authorized labeling; providers should be familiar with the tests' performance characteristics and limitations.

CMS provides this information in a Questions & Answers document (July 23):

What are antigen tests? Is it required to retest negative results with a PCR test?

Antigen diagnostic tests quickly detect fragments of proteins found on or within the virus by testing samples collected from the nasal cavity using swabs.

Negative results should generally be treated as presumptive, do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. If necessary, confirmation with a molecular assay for patient management may be performed. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Why is the federal government sending antigen testing supplies to nursing homes if they cannot be used to rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment?

Fighting this global pandemic requires an array of different technologies, including antigen testing. In areas of high prevalence or for patients with known risk factors, positive results from an antigen test can be considered confirmatory and used for diagnostic purposes. In areas of high prevalence, confirming negative results using an alternate form of testing is recommended. In low-prevalence areas where the patient is asymptomatic, results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management.

Operational Issues and Considerations:

How many tests can be conducted with the Quidel Sofia 2 Instrument and the BD Veritor™ Plus System testing platforms?

Each test takes about 20 minutes to perform from start to finish. However, it is possible to run tests in an assembly line fashion to test 20 – 30 samples per hour. To use this strategy, the start time for each test is staggered by a few minutes. Next, at the end of the test incubation period, each test is read one by one every few minutes. Instructions for using batch mode are included with the Instructions for Use and vendor training.

How should facilities handle indeterminate results?

Quidel Sofia 2: If the test does not flow correctly, Sofia or Sofia 2 will indicate that the result is invalid. Should this occur, review the procedure and repeat the test with a new patient sample and a new Test Cassette.

BD Vertior: The test results could be 'positive', 'negative', or 'invalid'. If the test is invalid, the BD Veritor System Instrument will display "CONTROL INVALID" and the test (or control) must then be repeated. Do not report results. Repeat the test.

Do facilities need a provider order to conduct the test?

These are prescription use tests under the Emergency Use Authorization and must be ordered by a healthcare professional licensed under the applicable state law or a pharmacist under HHS guidance.

How should the materials be stored when they arrive?

For BD, kits may be stored at 2 to 30°C. Reagents and instruments must be at room temperature (15 to 30 °C) when used for testing. DO NOT FREEZE.

For Quidel, kits may be stored at room temperature, 59°F to 86°F (15°C to 30°C), out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box. DO NOT FREEZE.

Are nursing homes required to report results of any COVID-19 tests?

Yes. All laboratories must have a CLIA Certificate and report the results of the COVID-19 tests that they conduct to the appropriate federal, state, or local public health agencies.

Laboratories must report data for all testing completed, for each individual tested. This data must be reported within 24 hours of test completion, on a daily basis, to the appropriate state or local public health department, based on the individual's residence. Testing sites must report all diagnostic test data in accordance with the HHS Lab Data Reporting Guidance for COVID-19 issued June 4, 2020 and meet these reporting requirements by August 1, including providing your facility name and CLIA number when reporting results. Please visit the CDC website for more information about data reporting requirements.

The following links from CDC and HHS provide additional information on this critical operational issue:

- CDC laboratory reporting website
- HHS laboratory reporting guidance
- HHS FAQs

What safety precautions are required when performing these tests?

CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (*https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html#decentralized*) are outlined below:

- For providers collecting specimens or within 6 feet of patients suspected to be infected with SARS-CoV-2, maintain proper infection control (*https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Finfection-control%2Fcontrol-recommendations.html*) and use recommended personal protective equipment (PPE), which includes an N95 or higher-level respirator (or facemask if a respirator is not available), eye protection, gloves, and a gown, when collecting specimens.
- Use the instrument in a location associated with a current CLIA certificate.
- Perform a site-specific and activity-specific risk assessment to identify and mitigate safety risks.
- Train staff on the proper use of the instrument and ways to minimize the risk of exposures. Follow manufacturer recommended procedures for decontamination after use.

- Follow Standard Precautions when handling clinical specimens, including hand hygiene and the use of PPE, such as laboratory coats or gowns, gloves, and eye protection. If needed, additional precautions can be used, such as a surgical mask or face shield, or other physical barriers, such as a splash shield to work behind.
- When using patient swabs, minimize contamination of the swab stick and wrapper by widely opening the wrapper prior to placing the swab back into the wrapper.
- Change gloves after adding patient specimens to the instrument.
- Decontaminate the instrument after each run by using an EPA-approved disinfectant for SARS-CoV-2. Following the manufacturer's recommendations for use, such as dilution, contact time, and safe handling.

States may have more stringent requirements, so CMS advises consultation with state officials for further guidance. The Minnesota Department of Health is developing guidance on these questions, and we will add that information here as soon as it is available.

REFERENCES:

- Trump Administration Announces Initiative for More and Faster COVID-19 Testing in Nursing Homes (https://www.hhs.gov/about/news/2020/07/14/trump-administration-announces-initiative-more-faster-covid-19-testing-nursing-homes.html)
- CMS FAQ: COVID-19 Testing at Skilled Nursing Facilities/ Nursing Homes (https://www.leadingagemn.org/assets/docs/CMS_FAQ_on_Point_of_Care_Testing_Instruments_Distribution_and_Use_07.23.2020.pdf)
- Coronavirus (COVID-19) Update: FDA Authorizes First Antigen Test to Help in the Rapid Detection of the Virus that Causes COVID-19 in Patients (https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-antigen-test-help-rapid-detection-virus-causes)

- CDC's Overview of Testing for SARS-CoV-2 (https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html).