Frequently Asked Questions: COVID-19 Testing at Skilled Nursing Facilities/ Nursing Homes

1. **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. To be eligible, nursing homes must have a current CLIA Certificate of Waiver AND meet certain epidemiological criteria. The list of nursing homes is posted on the Centers for Medicare & Medicaid Services (CMS) COVID NHSN data page and will be updated as new shipments go out. The U.S. Department of Health and Human Services (HHS) will distribute the testing platforms and FDA-authorized antigen diagnostic tests to all nursing homes with a CLIA Certificate of Waiver over the next few months.

   Nursing homes mean facilities that are certified as a Medicare Skilled Nursing Facility (SNF) and/or Medicaid Nursing Facility (NF), otherwise referred to a Long Term Care Facility or nursing home.

2. **How is distribution of the testing platforms and FDA-authorized antigen diagnostic tests being determined? Will these devices be sent directly to the nursing homes or to states for distribution?**

   Distribution of instruments and tests are prioritized for facilities based on Centers for Disease Control and Prevention (CDC) epidemiological hotspot data and facilities whose data indicate an elevated risk for COVID-19 transmission. 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.

   Shipping schedules are based on the availability of instruments and test kits. Facilities that have been prioritized to receive early shipments (within the first 3 weeks) are located in CDC epidemiological hotspot counties. 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.

3. **When will the testing platforms and authorized point-of-care tests be distributed?**

   Instruments and authorized diagnostic antigen tests will begin shipping the week of July 20 and shipments will continue over the course of 14 weeks. Supplies will arrive in a single shipment directly from the manufacturer and/or distributor.

4. **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.

5. **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.

6. **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:

   - 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.

7. **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.

8. **Are nursing homes required to have a CLIA Certificate of Waiver to perform these tests?**

   Yes. Nursing homes are required to have a CLIA Certificate of Waiver to perform these tests. If you would like to apply for a CLIA Certificate of Waiver, please refer to the brochure, How to Apply for CLIA Certificate of Waiver and submit your application form (CMS Form 116) to the state (CLIA State Agency Contacts) where the laboratory is located.

9. **What safety precautions are required when performing these tests?**

   CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 are outlined below. States may have more stringent requirements, so you may need to consult with your State Agency (SA Contacts) for further guidance.

   - For providers collecting specimens or within 6 feet of patients suspected to be infected with SARS-CoV-2, maintain proper infection control 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.

10. Will every nursing home receive a point-of-care instrument and associated tests?

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.

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

The list of nursing homes receiving instruments and tests in the first wave is available on the CMS COVID NHSN data page. This list will be updated as the phased distribution progresses.

12. When will my nursing home receive the shipment of testing platforms and FDA-authorized antigen diagnostic tests?

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 and shipments will continue over the course of 14 weeks. 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.

13. How will states be made aware that nursing homes within their states will receive instruments and supplies?

Facilities will be made aware of shipments directly from the manufacturers. States can refer to the CMS COVID NHSN data page to see which nursing homes in your state is receiving supplies.

14. 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.

15. **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.

16. **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.

17. **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.

18. **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.

19. **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.

20. 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.

21. 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.