Point-of-Care Antigen Testing Guidance for Skilled Nursing Facilities

COVID-19

The Tennessee Department of Health has created a resource booklet for skilled nursing facilities (SNFs) to use for guidance on using rapid COVID-19 point-of-care antigen testing devices

TN Department of Health

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Contents

Background:

The Department of Health and Human Services (HHS) is distributing rapid COVID-19 antigen point-of-care (POC) testing devices and tests to all skilled nursing facilities (SNFs) in the United States. The FDA has granted Emergency Use Authorization (EUA) to three antigen detection tests: (1) the Sofia SARS Antigen (Ag) FIA manufactured by Quidel Corporation (Quidel),(2) the Veritor™ System for Rapid Detection of SARS-CoV-2 manufactured by Becton, Dickenson and Company (BD) and the BinaxNOW™ COVID-19 Ag Card by Abbott. These assays are approved for detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal (both devices) and nasopharyngeal (Sofia SARS Antigen FIA only) swab specimens. These tests are authorized for use at the point of care, *e.g.,* inpatient care settings such as SNFs operating with a CLIA Certificate.

Each SNF with a CLIA Certificate of Waiver may receive one diagnostic instrument – either the Quidel Sofia 2 Instrument or the BD Veritor™ Plus system – along with the associated test kits. Following the initial distribution, **skilled nursing facilities (SNFs) are responsible for procuring additional tests using two options.** All SNFs must have the capability to screen and test residents at baseline, and test staff on a weekly basis according to specific guidance issued by the Centers for Medicare and Medicaid Services (CMS) and the state and local health departments. This procurement will also enable testing of visitors if appropriate for that facility. Separately, SNFs may receive BinaxNOW Cards directly from HHS or may request supplies from the state directly.

FAQs:

1. Who is expected to receive a point-of-care COVID-19 instrument?
    - In Tennessee, skilled nursing facilities (SNFs) that have a CLIA Certificate of Waiver (CoW).
2. What will this include?
    - One rapid COVID-19 point-of-care testing instrument and testing supplies.
    - HHS is offering two different instruments from different manufacturers (Quidel or BD), but each facility will receive only one instrument.
3. What is an antigen test[1]?
    - Antigen tests can quickly detect fragments of proteins found on the surface of the virus. These protein fragments are known as antigens (Ag).

Executive Summary
Important Testing Recommendations

- POC Ag testing **will be allowed** to satisfy the CMS requirement for weekly staff testing at SNFs (see page 20 for CMS guidelines for testing).

- POC Ag testing is not as sensitive as polymerase chain reaction (PCR) based tests, therefore, there is the potential for a higher rate of false negative results when using this testing type.

- Ag testing is most **effective** for **symptomatic** persons.

- Facilities should decide whether a PCR confirmation test is warranted based on the:
    - **Type of test conducted** (*i.e.* diagnostic versus screening)
    - **Clinical** (presence or absence of symptoms) and **epidemiological** context of the person who has been tested
    - **Number of cases** in the facility over the course of the previous 7-10 days

- Read CDC's Interim Guidance for Rapid Antigen Testing for SARS-CoV-2[2] and Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes[3].

- It is encouraged that facilities utilize this testing platform for rapid test results among **symptomatic** staff or residents to allow for the prompt initiation of comprehensive infection control measures for newly identified cases.

Definitions

Diagnostic Testing:

Diagnostic testing is used to identify an active/current infection in an individual with signs or symptoms consistent with COVID-19, or when an individual is asymptomatic but has confirmed or suspected exposure to SARS-CoV-2[2].

Screening Testing:

Screening testing is intended to identify infected persons who are asymptomatic and without known or suspected exposure to SARS-CoV-2. Screening testing is performed to identify persons who may be contagious so that measures can be taken to prevent further transmission[2]. An example of this type of testing may be weekly testing of asymptomatic staff members without suspected exposures to SARS-CoV-2.

Pretest Probability:

Pretest probability is impacted by the prevalence of COVID-19 in the community as well as the clinical context (symptomatic vs asymptomatic) of the individual receiving the test. It is important to know the number of positive cases in a facility over the previous 7–10 days. For example, if a specific testing site, such as a SNF, has had zero cases within the past 7-10 days, this should be used to help determine pretest probability[2].

Interpretation of results:

- **Positive Result**
  - **Diagnostic Testing:**
    A positive test result indicates antigens from SARS-CoV were detected, and the patient is infected with the virus and presumed to be contagious. Laboratories and testing sites should follow the instructions for use and the package insert that are specific for the test system that they are using[2].

  - **Screening Testing:**
    When used in congregate settings, test results for SARS-CoV-2 should be considered presumptive. Confirmatory molecular testing (ex. PCR) following a positive antigen test may not be necessary when the pretest probability is high.
    - A high pretest probability is when on your facility has had at least one COVID-19 positive result within the past 7-10 days
    - When the pretest probability is low (*i.e.* facility has had zero cases in the past 7-10 days), those persons who receive a positive antigen test should isolate until they can be confirmed by a molecular test[2]. A confirmatory molecular test may not be pursued if conducting serial testing on individuals (see page 20 for CMS routine staff testing).

    **** Please note***, false positive results are possible with antigen tests, especially if testing procedures are not closely followed.

- **Negative Result**
  - **Diagnostic Testing**
    In most cases, negative antigen diagnostic test results are considered presumptive. A negative test result means that antigens from SARS-CoV were not detected from the collected specimen. However, a negative result ***does not*** definitively rule out COVID-19 and should never be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results of symptomatic persons that were tested after 5 days from symptom onset should be confirmed with PCR testing within two days. Confirmation using a molecular test like PCR should also occur when the pretest probability is relatively high, especially if the patient is

symptomatic or has a known exposure to a person confirmed to have COVID-19[2]. A confirmatory molecular test may not be pursued if conducting serial testing on individuals (*i.e.* twice a week, weekly, monthly).

- **Screening Testing:**
  When used in congregate settings, test results for SARS-CoV-2 should be considered presumptive. However, confirmatory molecular testing following a negative antigen test when used for screening may not be necessary if the pretest probability is low, the person is asymptomatic or has no known exposures, or is part of a cohort that will receive rapid antigen tests on a recurring basis[2]. A confirmatory molecular test may not be pursued if conducting serial testing on individuals (see page 20 for CMS routine staff testing).

Action Following Results: Diagnostic Testing

- **Positive and Symptomatic OR Positive and Asymptomatic:**
  - **Staff** members should discontinue working immediately and isolate[4-5] at home for a minimum of 10 days.
  - **Residents** should be placed in a single room on contact and droplet isolation precautions[6] for a minimum of 10 days. Cohorting of positive residents is an option in case of a limited number of rooms. Cohorting should never occur with a positive and negative resident.
  - Generally, clinicians can rely upon a positive diagnostic antigen test result because the specificity of current FDA-authorized antigen tests is high. However, false positive results are possible, especially if testing procedures are not closely followed.

- **Negative and Symptomatic**
  - **Staff** members should discontinue working immediately and isolate at home while additional testing and clinical evaluation is ongoing.
  - **Residents** should be placed in a single room on contact and droplet isolation precautions while additional testing and clinical evaluation is ongoing.
  - In most cases, negative antigen diagnostic test results are considered presumptive. It is recommended to confirm with a PCR test when the pretest probability is high, especially if the patient is symptomatic. Ideally, confirmatory molecular (PCR) testing should take place **within two days** of the initial antigen testing. If PCR testing is not available, clinical discretion can be used in whether to recommend the patient isolate[2].

- **Negative and Asymptomatic with a Confirmed COVID-19 Exposure:**
  - **Staff** members can continue working and must wear a surgical/procedural mask and use eye protection for all direct resident encounters, consistent with quarantine procedures for critical infrastructure workers.
  - **Residents** should be placed in a single room on contact and droplet isolation precautions (consistent with quarantine requirements) while additional testing and clinical evaluation is ongoing.
  - In most cases, negative antigen diagnostic test results are considered presumptive. It is recommended to confirm with a molecular test when the pretest probability is relatively high, especially if the patient

has a known exposure to a person confirmed to have COVID-19. Ideally, confirmatory PCR testing should take place **within two days** of the initial antigen testing. If PCR testing is not available, clinical discretion can be used in whether to recommend the patient isolate[2].

Action Following Results: Screening Testing

Using an Ag test on an asymptomatic individual for a weekly screen may warrant confirmatory testing, therefore, review the following recommendations. A confirmatory molecular test may not be pursued if conducting serial testing on individuals (*i.e.* twice a week, weekly, monthly). Please note, if a confirmatory molecular test is negative, treat as a negative result regardless of the Ag test result. If the confirmatory molecular test is positive, treat as a positive result regardless of the Ag test result.

- **Positive and Asymptomatic:**
  - **Staff** members are recommended to isolate[4-5] at home for 10 days from the date of specimen collection.
  - **Residents** should be placed in a single room on contact isolation and droplet precautions[6] for a minimum of 10 days from the date of specimen collection. Cohorting of positive residents is an option in case of a limited number of rooms. Cohorting should never occur with a positive and negative resident.
  - Confirmatory molecular testing may not be necessary when the pretest probability is high[2] or if conducting serial testing (see page 20 for CMS routine staff testing).
  - If pretest probability is low those individuals should isolate until they can be confirmed with a molecular test. Confirmatory molecular testing should take place **within two days** of the initial antigen testing[2].

- **Negative and Asymptomatic:**
  - **Staff** members should work as normal with a surgical/procedural mask and eye protection for all direct resident encounters**.**
  - Confirmatory molecular testing may not be necessary if the pretest probability is low, the individual has no known exposures or is part of a cohort that will receive rapid antigen tests on a recurring basis (see page 20 for CMS routine staff testing).
  - Persons **should be confirmed** with a molecular PCR result if they meet at least one of the following situations:
    - The person has a known exposure to a person confirmed to have COVID-19
    - The pretest probability is high (ex. based on your facility COVID-19 prevalence within the past 7-10 days)

Quidel Sofia 2

PRINCIPLE OF THE TEST The Sofia SARS Antigen FIA employs immunofluorescence technology in a sandwich design that is used with Sofia and Sofia 2 to detect nucleocapsid protein. This test allows for the detection of SARS-CoV-2. This test detects, but does not differentiate, between the SARS-CoV and SARS-CoV-2 viruses. The patient sample is placed in the Reagent Tube, during which time the virus particles in the sample are disrupted, exposing internal viral nucleoproteins. After disruption, the sample is dispensed into the Test Cassette sample well. From the sample well, the sample migrates through a test strip containing various unique chemical environments. If SARS-CoV or SARS-CoV-2 viral antigen is present, they will be trapped in a specific location.

Reagents, storage, warnings/precautions:
Read the manufacturer's guide for more information on the reagents and warnings/precautions. Store the kit 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.

How to get started:

- Before using the instrument, please read the entire manufacturer's instructions for use document that accompanies the kit. This can also be found here[7]
- Prior to use, read the manufacturer's guidance regarding quality controls. Positive and negative control swabs are supplied with each kit. These controls provide additional quality control material to assess that the test reagents and instrument perform as expected. Prepare kit control swabs and test using the same procedure as used for patient specimens. Controls must be run once for, each new kit lot, each new operator, as required by internal quality control procedures and in accordance with local, state and federal regulations or accreditation requirements. This ensures each instrument is working properly and has been calibrated to

industry standards. This quality testing should be performed by personnel at your facility with clinical/ laboratory experience.

- Prior to use, read the manufacturer section on calibration checks for the instrument and follow instructions.

Sample Collection:

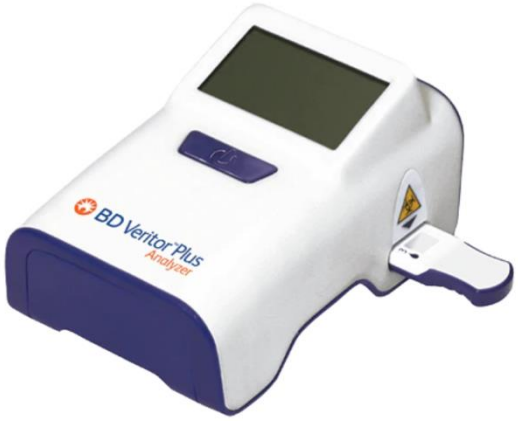
1.) Nasal Swab Sample: Use the nasal swab supplied in the kit.
2.) Nasopharyngeal Swab Sample: Use a nylon flocked nasopharyngeal swab, not supplied.

Sample Transport and Storage: Samples should be tested as soon as possible after collection. Based on data generated with the SARS-CoV-2 Antigen FIA, nasal or nasopharyngeal swabs are stable for up to 48-hours at room temperature or 2° to 8°C.

Ordering Supply Kits:

- For those that already have a Quidel Sofia instrument, additional testing supplies can be ordered online through TEMA's Survey123
- Follow the guidance here: https://www.tn.gov/content/dam/tn/health/documents/cedep/novelcoronavirus/Request_Binax_Supplies.pdf

BD Veritor™ Plus



The BD Veritor™ System consists of a dedicated opto-electronic interpretation instrument and immunochromatographic assays for the qualitative detection of antigens from pathogenic organisms in samples processed from respiratory specimens. The BD Veritor™ System for Rapid Detection of SARS-CoV-2 is designed to detect the presence or absence of SARS-CoV-2 nucleocapsid proteins in respiratory samples from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms. When specimens are processed and added to the test device, SARS-CoV-2 antigens present in the specimen bind to antibodies conjugated to detector particles in the test strip. The antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line of antibodies bound on the membrane. A positive result is determined by the BD Veritor™ Plus Analyzer when antigen-conjugate is deposited at the Test "T" position and the Control "C" position on the assay device. The instrument analyzes and corrects for non-specific binding and detects positives not recognized by the unaided eye to provide an objective result.

Reagents, storage, warnings/precautions:
Read the manufacturer's guide for more information on the reagents and warnings/precautions. Kits may be stored at 2–30 °C. DO NOT FREEZE. Reagents and devices must be at room temperature (15–30 °C) when used for testing.

How to get started:

- Before using the instrument, please read the entire manufacturer's instructions for use document that accompanies the kit. This can also be found here[8]
- Prior to use, read the manufacturer's guidance regarding quality controls. Positive and negative control swabs are supplied with each kit. These controls provide additional quality control material to assess that the test

reagents and the instrument perform as expected. Prepare kit control swabs and test using the same procedure as used for patient specimens. Controls must be run once for, each new kit lot, each new operator, as required by internal quality control procedures and in accordance with local, state and federal regulations or accreditation requirements. This ensures each instrument is working properly and has been calibrated to industry standards. This quality testing should be performed by personnel at your facility with clinical/laboratory experience.

Sample Collection:

1.) Nasal Swab Sample: This BD Veritor™ System assay kit is **only** intended for nasal swab specimens that are collected and tested directly (*i.e.,* swabs that have NOT been placed in transport media). Use the nasal swab supplied in the kit.

Sample Transport and Storage: Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection. Specimens must be at room temperature (15–30 °C) for testing.

Ordering Supply Kits:

- The state of TN does not maintain any test kits for BD Veritor ™ System. Supplies must be ordered directly from the manufacturer.

Abbott BinaxNOW™

The BinaxNOWTM COVID-19 Ag Card is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasal swabs from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.

The U.S. Department of Health and Human Services (HHS) and the Department of and Defense (DOD) awarded a contract for $760 million to Abbott for delivery of 150 million rapid, Abbott BinaxNOW™ COVID-19 Ag Cards, a point of care (POC) SARS-CoV-2 diagnostic test, to expand strategic, evidence-based testing in the United States.

The Federal Government has already begun distributing tests to SNFs in counties with a medium or high prevalence (page 20).

Reagents, storage, warnings/precautions:
Read the manufacturer's guide for more information on the reagents and warnings/precautions. Store kit at 2-30°C. The BinaxNOW™ COVID-19 Ag Card kit is stable until the expiration date marked on the outer packaging and containers. Ensure all test components are at room temperature before use.

How to get started:

- Before using the instrument, please read the entire manufacturer's instructions for use document that accompanies the kit. This can also be found here[9]
- Prior to use, read the manufacturer's guidance regarding quality controls. Positive and negative control swabs are supplied with each kit.
- Kits contain a Positive Control Swab and Sterile Swabs that can be used as a Negative Control Swab. These swabs will monitor the entire assay. Test these swabs once with each new shipment received and once for each untrained operator.
- BinaxNOW™ COVID-19 Ag Card has built-in procedural controls. For daily quality control, Abbott suggests that you record these controls for each test run.

Sample Collection and Storage:

1.) Nasal Swab Sample: The BinaxNOW™ COVID-19 Ag Card is **only** intended for nasal swab specimens that are collected and tested directly (*i.e.,* swabs that have NOT been placed in transport media). Use the nasal swab supplied in the kit and do not return the nasal swab to the original packaging.
   - For best performance, direct nasal swabs should be tested as soon as possible after collection. If immediate testing is not possible, and to maintain best performance and avoid possible contamination, it is highly recommended the nasal swab is placed in a clean, unused plastic tube labeled with patient information, preserving sample integrity, and capped tightly at room temperature (15-30°C) for up to (1) hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed. If greater than 1-hour delay occurs, dispose of sample. A new sample must be collected for testing.

Ordering Supply Kits:

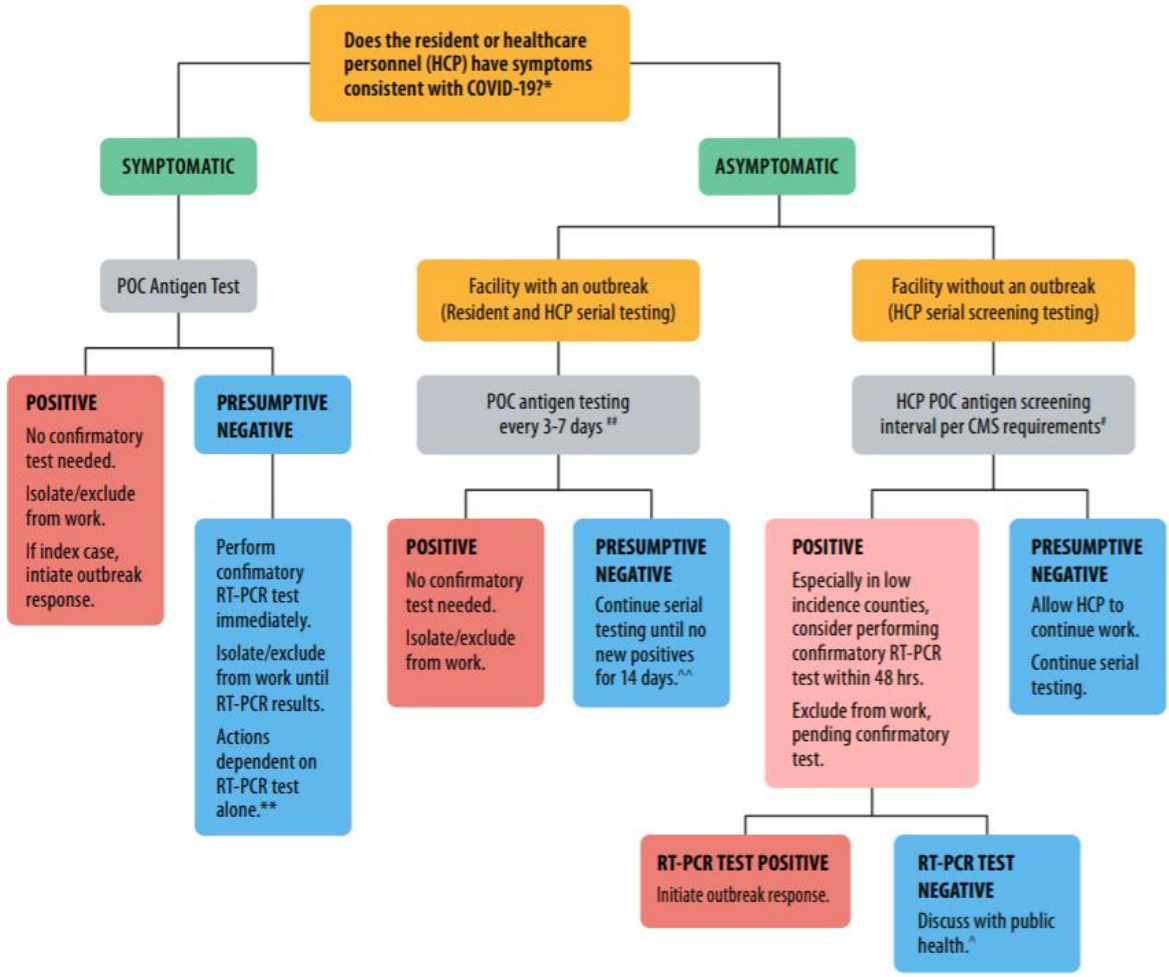
- Additional test cards can be ordered online through TEMA's Survey123
- Follow the guidance here: https://www.tn.gov/content/dam/tn/health/documents/cedep/novelcoronavirus/Request_Binax_Supplies.pdf

Reporting Results

All laboratory results for COVID-19 are reportable to TDH.

1) **Report the results to TDH, following the guidance for reporting Point of Care Results posted here:** https://www.tn.gov/content/dam/tn/health/documents/cedep/novelcoronavirus/POC-Reporting-Guidance.pdf
2) **General reporting guidance (for testing that is not conducted at the Point of Care) is available here: https://www.tn.gov/content/dam/tn/health/documents/cedep/novel-coronavirus/CaseReportingGuidance.pdf**

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.

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cdc.gov/coronavirus

Table 2: Routine Testing Intervals Vary by Community COVID-19 Activity Level

Community COVID-19 Activity	County Positivity Rate in the past week	Minimum Testing Frequency
Low	<5%	Once a month
Medium	5% - 10%	Once a week*
High	>10%	Twice a week*

*This frequency presumes availability of Point of Care testing on-site at the nursing home or where off-site testing turnaround time is <48 hours.

Considerations for Interpreting Antigen Test Results in Nursing Homes

	Positive Test	Negative Test	Additional Information
Testing of Symptomatic Residents or Healthcare Professionals (HCP):	If an antigen test is positive, no confirmatory test is necessary.	If an antigen test is presumptive negative, perform RT-PCR immediately (e.g., within 48 hours).	
Testing of Asymptomatic Residents or Healthcare Professionals (HCP) in Nursing Homes as part of an Outbreak Response	If an antigen test is positive, no confirmatory test is necessary.	If an antigen test is presumptive negative, residents should be placed in appropriate precautions. HCP should be allowed to continue to work with continued symptom monitoring. The facility should continue serial viral testing (antigen or RT-PCR) every 3-7 days until no new cases are identified for a 14-day period.	The FDA has granted Emergency Use Authorizations (EUA) to certain antigen tests for testing specimens from individuals who are **suspected of COVID-19 by their healthcare provider** within a number of days after the onset of symptoms, specific to each authorized test's validated performance. **Facilities need to have a CLIA Certificate of Waiver to perform testing**
Testing of Asymptomatic HCP in Nursing Homes without an Outbreak per CMS Recommendations	If an antigen test is positive, perform confirmatory RT-PCR test within 48 hours of the antigen test, especially in counties with low prevalence. If confirmatory test is performed, HCP should be excluded from work until confirmatory test results are completed.	If an antigen test is presumptive negative, allow HCP to continue to work. The HCP should continue to monitor for symptoms, and serial testing should continue per CMS recommendations.	CMS recommends initial testing of all HCP as part of the nursing home reopening process and serial testing of HCP at an interval based on local incidence of COVID-19.

Courtesy of Centers for Medicare and Medicaid (CMS)

Resources:

1) Considerations for Implementation of SARS-CoV-2 Rapid Antigen Testing. Association of Public Health Laboratories (APHL) [https://www.aphl.org/programs/preparedness/Crisis-Management/Documents/APHL-SARSCov2-Antigen-Testing-Considerations.pdf]

2) Interim Guidance for Rapid Antigen Testing for SARS-CoV-2. Centers for Disease Control and Prevention (CDC) https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

3) Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes. Centers for Disease Control and Prevention (CDC) https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html

4) Releasing Cases and Contacts from Isolation and Quarantine. Tennessee Department of Health (TDH) [https://www.tn.gov/content/dam/tn/health/documents/cedep/novel-coronavirus/Isolation-QuarantineRelease.pdf]

5) Ending Home Isolation Interim Guidance. Centers for Disease Control and Prevention (CDC) [https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html]

6) Discharging COVID-19 Patients. Centers for Disease Control and Prevention (CDC) [https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html]

7) Sofia SARS Antigen Intended for Use (IFU) [https://www.fda.gov/media/137885/download

8) BD Veritor ™ System Intended for Use (IFU) [https://www.fda.gov/media/139755/download]

9) Abbott BinaxNOW™ Intended for Use (IFU) [https://www.fda.gov/media/141570/download]