Policy and Procedure

Title: Utilizing the BD Veritor System

Policy

Facility will conduct COVID-19 antigen testing with the BD Veritor system as outlined by the manufacture, CMS, CDC and FDA.

Procedure

Specimen Collector Competencies

Specimen Collectors are required to complete the following competencies to ensure they have a basic understating of antigen testing and the BD Veritor System:

1. Register and complete manufacture training at https://www.bdveritor.com/long-term-care-facilities/training/
    A. The completion certificate for all specimen collectors are to be kept in the COVID Binder
2. Review manufacturers manual
3. Review CDC guidance for antigen testing https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html
4. Review CDC guidance for Collecting, Handling, and Testing Clinical Specimens for COVID-19. https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html
5. Complete attached competencies 'Testing Procedure Competency'

Set up / Preparation

1. Unpack machine
2. Inspect for damages
    A. If damages are present contact BD Technical Services
3. Place machine on a flat, dry ,stable surface away from direct sunlight or a bright light
4. Charge machine with power cord
5. Preform verification test:
    A. Insert the supplied verification test cartridge into the right side of the machine
        i. A click indicates when the test device is fully inserted
    B. After a quick 3 second reading and analysis, "Verify Pass" will appear on the screen
        i. If "Verify Fail" appears the analyzer may not be used for testing
            a. Refer to the troubleshooting section of the operation manual
    C. Remove the verification cartridge and place it back into the original packaging
6. Verification test will be conducted once per day when analyzer is being used

Prep and Sample Collection

Specimen collector should be wearing, at minimum, a surgical mask, face shield, gown, and gloves. A fit-tested N-95 mask is not required since this procedure should not result in the test subject coughing or sneezing; however, if this equipment is available, it can be used for extra protection.

1. Label the tube and the BD Veritor test devise for the specimen that is being tested (individuals initials)
2. Place tube(s) in the rack until you are ready to process the sample
3. Collect the sample
    A. Insert the swab about 1 inch in to the nostril of the patient
    B. Roll the swab 5 times along the mucosa inside nostril to ensure both mucus and cells are collected
    C. Using the same swab repeat the process with the other nostril
    D. Remove the swab from the nasal cavity the sample is now ready for processing
4. Hold the tube in one and twist and pull straight up to remove the tube cap
5. Fully insert the swab into the tube ensure it is fully immersed into the solution
6. Plunge the swab up and down in the fluid for a minimum of 15 seconds
    A. Be careful to splash contents out of the tube
7. Remove the swab while squeezing the middle of the tube to capture the optimum amount of sample
8. Snap fit the tip onto the tube (twisting is not required)

Analyze Now Mode

1. Add the specimen to the testing device:
    a. Invert the tube an inch away from the sample well (small well next to the teardrop mark)
    b. Squeeze the half of the tube that is furthest away from the tip to dispense 3 drops into the well
        i. Squeezing the part of the tube closest to the tip can result in the tip to eject
        ii. Ensure full drops are released and do not contain bubbles
    c. Wait 15 minutes
    d. Power on the analyzer. Machine will conduct a self-test. Wait for screen to display “Insert Test Device or Double Click for Walk-Away Mode”
    e. When prompted insert the testing device into the right side of the analyzer
    f. Follow the prompts on the screen to complete the procedure and obtain result
    g. Document test result

Walk-Away Mode

1. Ensure analyzer is connected to the power supply (necessary for Walk-Away mode)
2. Power on the analyzer. Machine will conduct a self-test. Wait for screen to display “Insert Test Device or Double Click for Walk-Away Mode”
3. Double click the power button
4. The display will show “Add specimen to test device and insert immediately”
5. Add the specimen to the testing device:
    A. Invert the tube an inch away from the sample well (small well next to the teardrop mark)

B. Squeeze the half of the tube that is furthest away from the tip to dispense 3 drops into the well
    i. Squeezing the part of the tube closest to the tip can result in the tip to eject
    ii. Ensure full drops are released and do not contain bubbles
6. Insert the testing device into the right side of the analyzer
7. The display will show "Do Not Disturb Test In Progress"
8. A count down timer will show the time remaining
9. Once the incubation period is complete the analyzer will progress through a reading and analyzing step and the test result will be displayed
    A. Test results will be displayed for one hour (when connected to a power source) or until the testing device is removed
10. Document test results

Cleaning

1. The outer case and display may be wiped with a clean towel moistened with 70% isopropyl alcohol or a 10% bleach solution
2. Do not introduce the cleaning solution or any other liquid directly into the unit

Attachments: Testing Procedure Competency
U.S. Department of Health and Human Services PREP Act Coverage Letter

** PREP Act coverage encompasses licensed health-care practitioners prescribing or administering FDA authorized COVID-19 tests, including for off-label (outside the authorization) use to screen asymptomatic individuals in congregate facilities. CMS will temporarily exercise enforcement discretion for the duration of the COVID-19 public health emergency under CLIA for the use of SARS-CoV-2 POC antigen tests on asymptomatic individuals. Specifically, CMS will not cite facilities with a CLIA Certificate of Waiver when SARS-CoV-2 POC antigen tests are performed on asymptomatic individuals, as described by the FDA.

BD Veritor Testing Procedure Competency

Team Member Name: _____ Date: _____

Evaluator Name: _____

Date that Team Member completed the BD Veritor Training Modules: _____

Procedure Step	Done Correctly	Not Done Correctly
Sample Collection Procedure		
1. Perform Hand Hygiene and don gloves, N-95/KN-95, gown, and face shield. Explain procedure of Nasal Swab Sample to the Resident/Team member..		
2. Insert the swab into one nostril of the resident/team member. The swab tip should be inserted to 1 inch from the edge of the nostril. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucous and cells are collected.		
3. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.		
4. Withdraw the swab from the nasal cavity. The sample is now ready for processing.		
Sample Transport and Storage		
5. Swabs should be tested as soon as possible after collection. Use only swabs provided with the kit.		
6. Swab packaging will be identified with resident/team members last name and first initial.		
7. Once swabbing Sample Collection Procedure is completed, swab will be returned to clean and dry original packaging. Place swab in packaging in Ziplock bag for transport and processing.		
8. Remove gloves and perform hand hygiene. Apply a new set of gloves prior to next sample collection.		
Test Procedure		
9. Perform hand hygiene and don gloves, N-95/KN-95, gown, and eye protection.		
10. Gather test materials and label test device with specimen ID.		
11. Remove cap from extraction reagent tube.		
12. Insert patient sample swab and vigorously plunge the swab up and down for 15 seconds.		

13. Remove swab while squeezing tube to extract liquid. Properly dispose of swab in Sharps Biohazard Container.		
14. Press dispensing tip on the tube firmly. Mix the sample by flicking swirling bottom of the tube.		
15. Add 3 drops of the processed sample to the test device sample well.		
16. Allow test to develop for 15 minutes. ***Incorrect results may occur if development time is less than 15 minutes.**		
17. When test is ready, power on instrument by pressing blue start button once. When prompted, insert test device to read result.		
18. Result will appear on screen.		
19. Record result on the BD Veritor COVID Testing Log and remove test cassette. Properly dispose of test cassette in Sharps Biohazard Container.		
20. If the test results come back as INVALID, a new patient sample will need to be collected and a new test kit will need to be utilized.		
21. At the completion of testing cycle, remove gloves and perform Hand Hygiene.		
Disinfecting the BD Veritor Device		
22. Clean device thoroughly with disinfectant wipes using proper procedure. Do not spray disinfectant directly on the device.		
23. Clean bench/work surfaces with spray or disinfecting wipe		

Office of the Assistant Secretary for Health
Washington, D.C. 20201

U.S. Department of Health & Human Services
Office of the Assistant Secretary for Health
August 31, 2020

Guidance for PREP Act Coverage for COVID-19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities

On January 31, 2020, the Secretary of Health and Human Services declared that the 2019 novel coronavirus (COVID-19) is a public-health emergency for the United States.[1] The United States Department of Health and Human Services (HHS) is the lead agency for the federal government's response to the COVID-19 pandemic.

A key component of that response is rapidly expanding COVID-19 testing across America. Within HHS, the Office of the Assistant Secretary for Health leads federal efforts to support that expansion. Enhancing the safety of nursing homes, assisted-living facilities, long-term-care facilities, and other facilities where people congregate to receive care or education or to work (collectively, "congregate facilities") is critical for our Nation's response to the COVID-19 pandemic. Testing for COVID-19, including those who are asymptomatic, is a key part of that effort.[2]

[1] The Secretary's declaration of a public health emergency was retroactively effective on January 27, 2020.

[2] *See, e.g.*, Interim SARS-CoV-2 Testing Guidelines for Nursing Home Residents and Healthcare Personnel, available at https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html (last visited Aug. 29, 2020) (explaining that, in addition to nursing homes, "testing residents with signs or symptoms of COVID-19 and testing asymptomatic close contacts should also be applied to other long-term care facilities (e.g., assisted living facilities, intermediate care facilities for individuals with intellectual disabilities, institutions for mental disease, and psychiatric residential treatment facilities)"); Testing in Institutions of Higher Education, available at https://www.cdc.gov/coronavirus/2019-ncov/community/colleges-universities/ihe-testing.html (last visited Aug. 29, 2020) ("In areas with moderate to substantial community transmission where resources allow, local health officials and [institutions of higher learning] may consider testing some or all asymptomatic students, faculty, and staff who have no known exposure (e.g., students in congregate housing such as residence halls) to identify outbreaks and inform control measures."); Testing asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification in special settings, available at https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/testing-non-healthcare-workplaces.html#testing-3 (last visited Aug. 29, 2020) ("Viral testing of workers without symptoms may be useful to detect COVID-19 early and stop transmission quickly, particularly in areas with moderate to substantial community transmission.").

Both the Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) have issued guidance and provided other information regarding screening asymptomatic individuals, including in congregate settings.

According to FDA,

> For health care providers who are ordering an authorized SARS-CoV-2 diagnostic test to be used off-label (outside the authorization) to screen asymptomatic individuals not suspected of having COVID-19, we recommend they consider the information below. Although the current available literature suggests that symptomatic individuals with COVID-19 and asymptomatic individuals without known exposure may have similar levels of viral genetic material, there is limited data on the distribution of viral loads in individuals with and without symptoms across demographics, different settings, and specimen types. Therefore, when screening asymptomatic individuals, health care providers should consider using a highly sensitive test, especially if rapid turnaround times are available. If highly sensitive tests are not feasible, or if turnaround times are prolonged, health care providers may consider use of less sensitive point-of-care tests, even if they are not specifically authorized for this indication (commonly referred to as "off-label"). For congregate care settings, like nursing homes or similar settings, repeated use of rapid point-of-care testing may be superior for overall infection control compared to less frequent, highly sensitive tests with prolonged turnaround times.[3]

CMS has concluded that

> [it] requires facilities with a CLIA Certificate of Waiver to follow the manufacturer's instructions (Instructions For Use) when performing laboratory testing. 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. The FDA has provided recommendations for health care providers who are ordering authorized tests outside their authorization (e.g., antigen tests for asymptomatic individuals)—see FDA's FAQ on Testing for SARS-CoV-2 ("Q: Does the FDA have recommendations for health care providers using SARS-CoV-2 diagnostic tests for screening asymptomatic individuals for COVID-19?") for further information.
>
> CMS will temporarily exercise enforcement discretion for the duration of the COVID-19 public health emergency under CLIA for the use of SARS-CoV-2 POC antigen tests on asymptomatic individuals. Specifically, CMS will not cite facilities with a CLIA Certificate of Waiver when SARS-CoV-2 POC antigen tests are performed on asymptomatic individuals, as described in the FDA FAQ.[4]

Therefore, as an Authority Having Jurisdiction under the Secretary's March 10, 2020 declaration under the Public Readiness and Emergency Preparedness Act (PREP Act),[5] Assistant Secretary for

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[3] General FAQs, Q: Does the FDA have recommendations for health care providers using SARS-CoV-2 diagnostic tests for screening asymptomatic individuals for COVID-19?, available at https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2#general, (last visited Aug. 29, 2020).

[4] What is CMS's policy regarding laboratories performing antigen tests authorized by the Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA) for use at the point of care (POC) or in patient care settings operating under a Clinical Laboratory Improvement Amendments of 1988 (CLIA) Certificate of Waiver on asymptomatic individuals?, available at https://www.cms.gov/files/document/clia-poc-ag-test-enforcement-discretion.pdf (last visited Aug. 29, 2020).

[5] Declaration Under the Public Readiness and Emergency Preparedness Act for Medical

Health, Admiral Brett P. Giroir, M.D., extends coverage under the PREP Act to licensed health-care practitioners prescribing or administering point-of-care COVID-19 tests, using anterior nares specimen collection or self-collection, for screening in congregate facilities across the Nation. Such tests must be authorized, approved, or cleared by the FDA (collectively, FDA-authorized COVID-19 tests).

PREP Act coverage encompasses licensed health-care practitioners prescribing or administering FDA-authorized COVID-19 tests, including for off-label (outside the authorization) use to screen asymptomatic individuals in congregate facilities.[6]

In addition to the requirements set forth herein, licensed health-care practitioners must comply with the requirements of the PREP Act and the conditions of the Secretary's declaration under the PREP Act in order to receive PREP Act coverage.[7]

This PREP Act coverage preempts any State or local provision of law or legal requirement that prohibits or effectively prohibits such licensed health-care practitioners from administering or prescribing FDA-authorized COVID-19 tests to symptomatic or asymptomatic individuals at congregate facilities.[8]

Countermeasures Against COVID–19, 85 Fed. Reg. 15,198 (Mar. 17, 2020).

[6] FDA determines the scope of on-label authorization.

[7] *See, e.g.*, Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, available at https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-hhs-ogc.pdf (last visited Aug. 29, 2020).

[8] *See, e.g.*, Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, available at https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf (last visited Aug. 29, 2020).