Covid Antigen testing using the BD Veritor system		Page **1** of **5**
Doc#: CHEM 6010	**Section:** Small Inst/Manual	**Effective Date:** June 16, 2021

PURPOSE: This document provides instructions for performing the Becton Dickinson Rapid Covid Antigen immunochromatographic assay using the BD Veritor optical reader.

SCOPE: This procedure pertains to UPMC Hanover.

PRINCIPLE: 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 patients with signs and symptoms of infection who are suspected of COVID-19. 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.

EQUIPMENT AND MATERIALS:

- Standard laboratory PPE
- BD Veritor Plus Analyzer
- BD Veritor System test device
  Single use, foil pouched test device containing one reactive strip.
- Extraction Reagent
  Single use reaction tubes each with 325 µL extraction reagent and with integral dispensing tip.
- Specimen Sampling Swabs: Sterile, single use
- Positive Control Swab (1): SARS-CoV-2 (+) Control Swab (non-infectious)
- Negative Control Swab: SARS-CoV-2(-) Control Swab
- Miscellaneous Manual Worksheet (patient result log)

STORAGE/HANDLING OF SUPPLIES: Kits may be stored at 2-30ºC. DO NOT FREEZE. Reagents and devices must be at room temperature (15-30ºC) when used for testing.

QUALITY CONTROL:

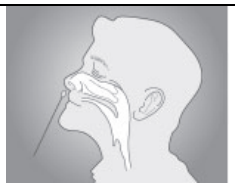
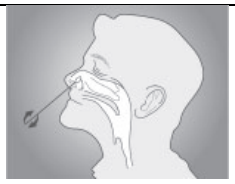
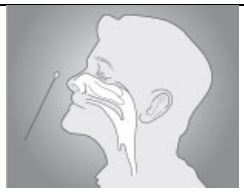
- External Positive and Negative controls (provided with each kit) will be tested with each new kit lot and/or each new kit shipment.
- External QC results are manually recorded in the Unity RealTime QC software.
- Internal procedural Positive and Negative controls are integral to each test cartridge and interpreted by the system reader device. Failed internal QC generates a test result of INVALID and repeat testing with a new cartridge is required.

SPECIMEN:

- Fresh, nasal specimen using only the nasal swab provided within the BD Veritor kit. Nasal swab specimens must be obtained by the dual nares collection method.
- Freshly collected specimens should be processed immediately, within 60 minutes of collection; specimens older than 60 minutes must be discarded and recollected.

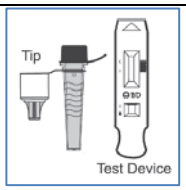
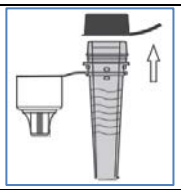
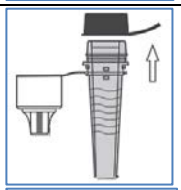
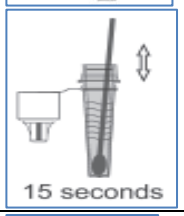
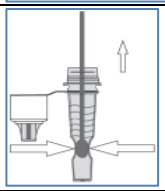
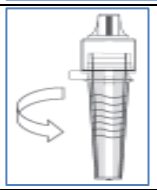
SPECIMEN COLLECTION:

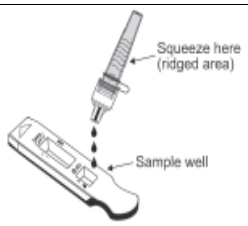
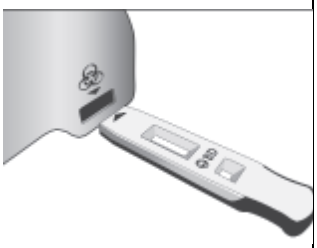
NOTE**:** Specimen collection will not routinely be performed by Laboratory testing personnel. Collection instructions are provided for informational purposes.

Peform positive patient identification using 2 patient identifiers.	
Initiate the collection process in the LIS and print labels.	
Open the testing swab packaging and remove swab.	
Insert the swab into one nostril of the patient. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected.	
Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.	
Withdraw the swab from the nasal cavity. Place the swab into the transport tube provided with the media collection kit. Break the swab off and cap the tube.	
Label the transport tube with the LIS test label.	
Transport the specimen to the laboratory immediately. DO NOT send through the pneumatic tube system.	

PROCEDURE:

Patient testing will be performed the Core Lab biological cabinet. All testing supplies are located in/at the cabinet. Additional supply inventory is maintained in the POC/Resource office.

Print an additional patient label.	
Obtain 1. 1 extraction reagent tube/tip 2. 1 BD Veritor System test device (to remain in foil packaging until time of testing)	
Remove test device from foil wrapper.	
Verify the patient identification sticker from the transport tube and apply a demographic label to the test device.	
Affix an additional barcode label to the manual result log sheet.	
Remove and discard the cap from the extraction reagent tube.	
• Remove nasal swab from transport tube • Insert the swab into the extraction tube • Plunge the swab up and down in the fluid for a **minimum of 15 seconds**, taking care not to splash the contents out of the tube.	 
Remove the swab **while squeezing the sides** of the tube to extract the liquid from the swab.	
Press the attached tip firmly onto the extraction reagent tube containing the processed sample. Mix thoroughly by swirling or flicking the bottom of the tube.	

Add the specimen to the sample well of test device by squeezing the body of the tube, dispensing 3 drops of processed specimen into the well.	
Analyzing using "**Walk Away**" mode (preferred): • Turn on the BD Veritor Plus Analyzer by pressing the blue power button once. • Double-click the blue power button. • The display window reads "ADD SPECIMEN TO TEST DEVICE AND INSERT IMMEDIATELY" • Insert the test device into the slot on the right side of the analyzer. o "DO NOT DISTURB TESTING IN PROGRESS" appears in the display window. o The display window shows the remaining analysis time. **Do not touch the Analyzer or remove the test device during this process. Doing so will abort the assay analysis.**	
• When the analysis is complete, the result appears in the display window. • Leaving test device inserted in the analyzer, verify the patient label information on the test device and record the sample result and name of person who performed the test on the manual result log sheet.	**ATTENTION:** Test results are NOT maintained on the display window when the device is removed. Results will disappear from display after 60 minutes if analyzer plugged in (15 minutes on battery power).
Discard test device and extraction tube into biohazard waste container.	
Manually enter test results into LIS. Note reagent lot# and expiration date in Lab Comments.	

In the event an analyzer is not available for immediate testing in the "Walk Away" mode, the operator may utilize the "Analyze Now" process. • Perform all specimen collection and preparation steps as listed above. • After applying sample to the test device, set a timer for **15 minutes.** • Leave testing cartridge in horizontal position, undisturbed during incubation. • At the indicated completion time: o Power on analyzer (if necessary) o Insert test device when display screen reads "INSERT TEST DEVICE OR DOUBLE CLICK BUTTON FOR WALK AWAY MODE" o Record results as indicated above.	

Document History

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Medical Director or Designee Approval:	**I have reviewed this document and approve it for use** ___ pending approval of Medical Director of record. ___ change in Medical Director of record. _____ Date:_____ Cindy Sturtz, MD Medical Director