

BD Veritor Overview

Presented by

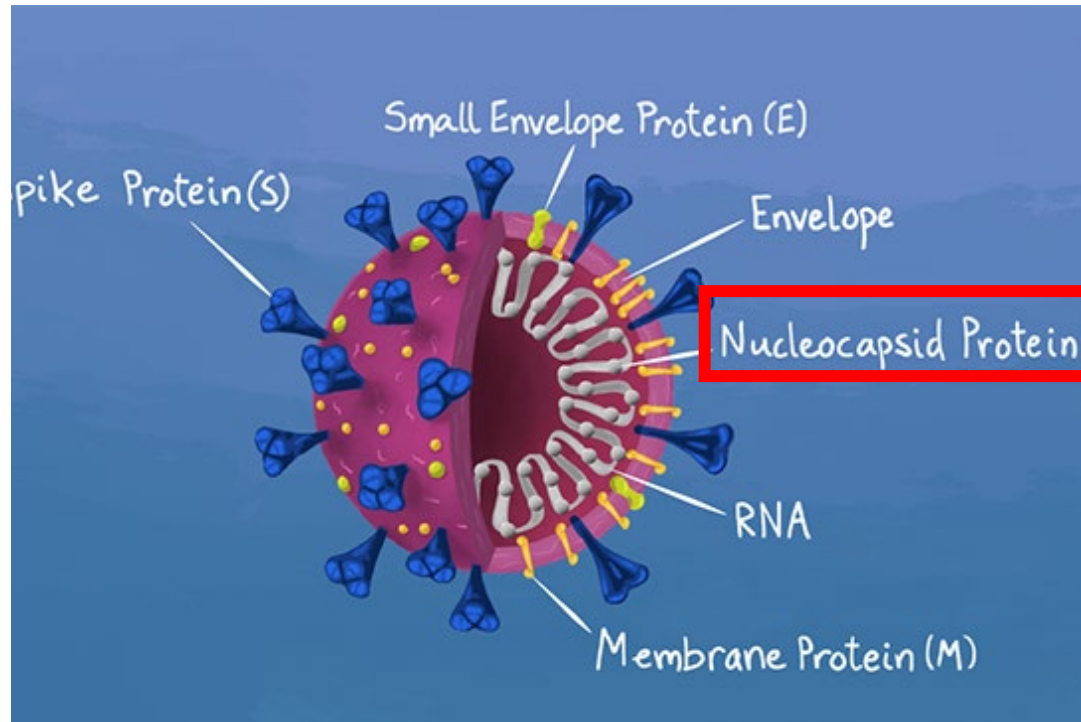
Priscilla Seabourn M.S., Ph.D.
Candidate

APHL-CDC COVID-19 Associate
&

Joanna Kettlewell Ph.D.

APHL-CDC COVID-19 Response
Postdoctoral Fellow



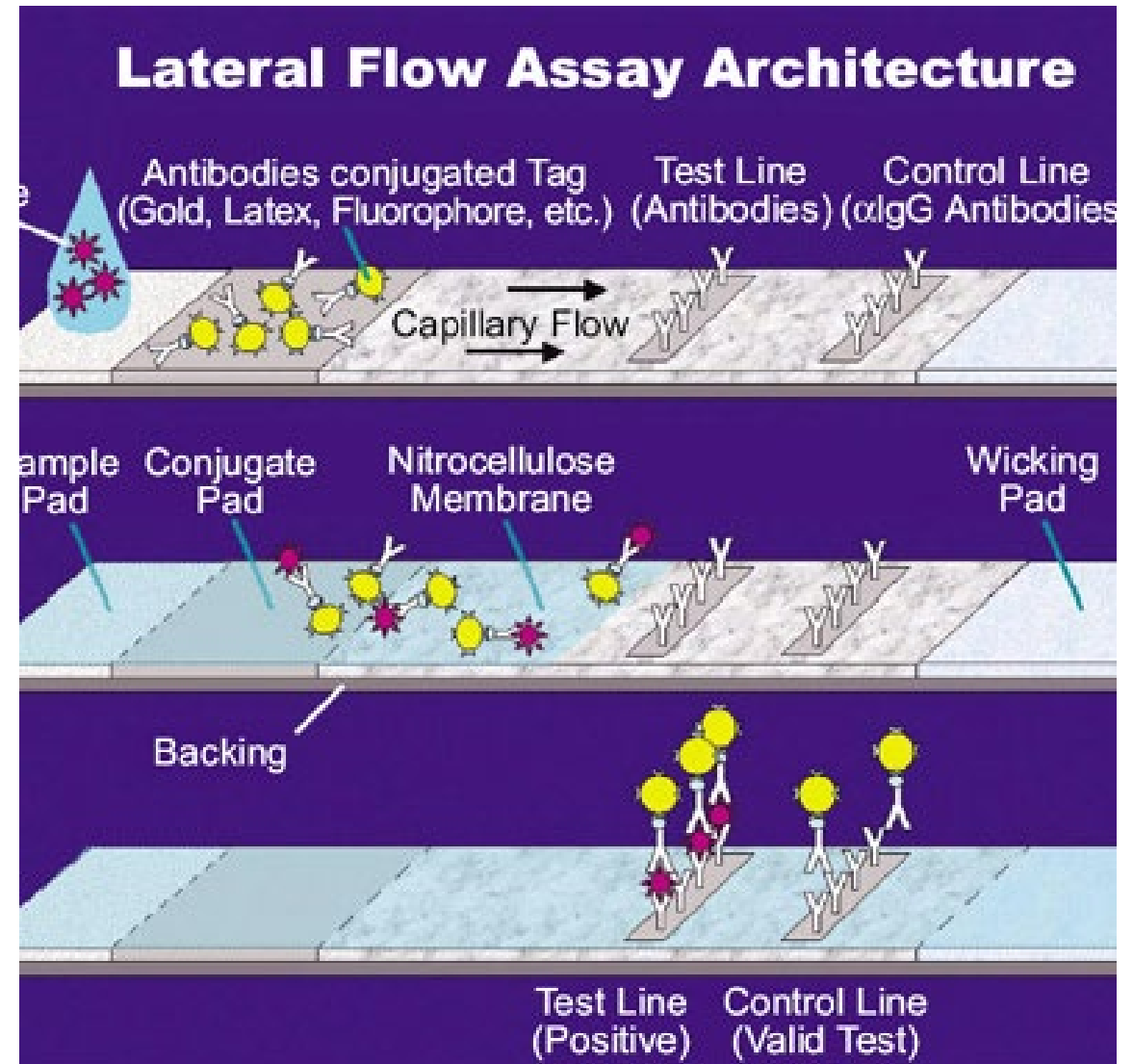


Overview

The BD Veritor System for Rapid Detection of SARS-CoV-2 is a chromatographic digital immunoassay intended for the direct and qualitative detection of SARS-CoV-2 nucleocapsid antigens (red box) in nasal swabs

PRINCIPLES OF THE PROCEDURE

- Detects the presence of nucleocapsid protein (antigen) in the nasal swab specimens.
- The system includes a lateral flow strip that binds to SARS-CoV-2 monoclonal antibodies
- Nucleocapsid antigen (if present) will bind to conjugated antibodies (gold, latex, Fluorophore, etc.).
- Binding will be visualized if nucleocapsid protein is detected.
- The BD instrument will detect this binding and provide **Positive** or **Negative** result.

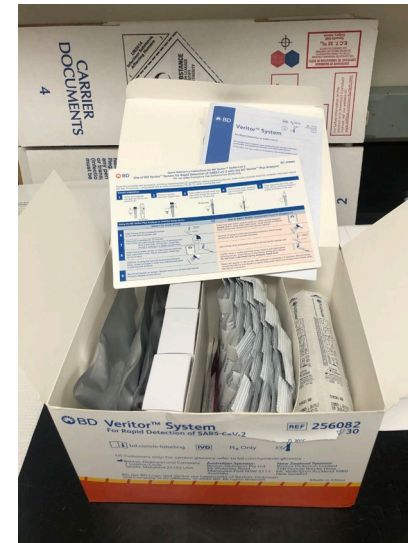


Reagents and Materials Provided

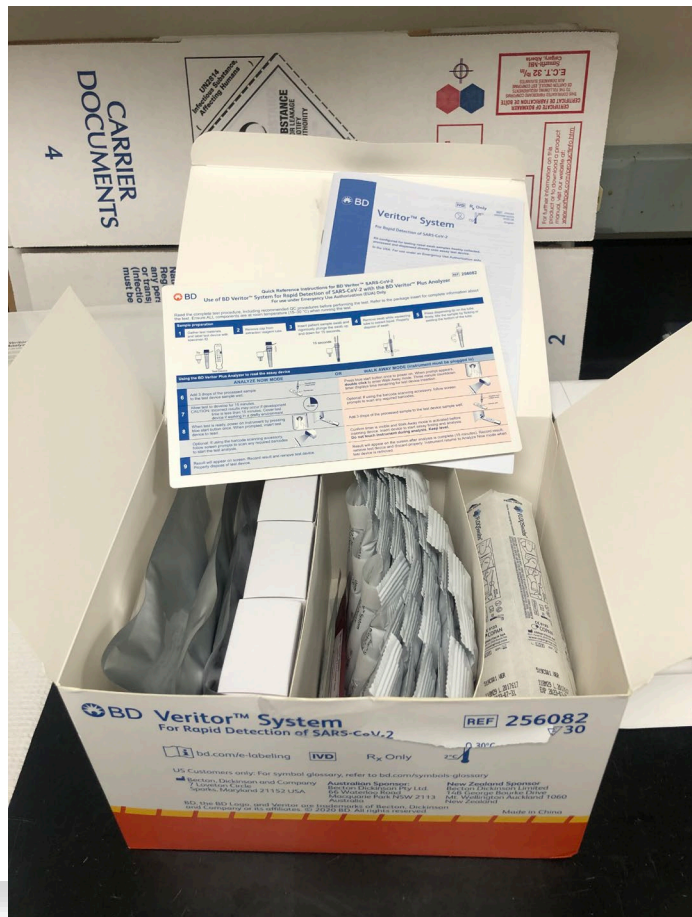
- BD Veritor System Test Devices
- Extraction Reagent
- Sterile Specimen Sampling Swabs
- Positive and Negative Control Swabs
- Tube rack for specimens

Materials not Provided

- BD Veritor Plus Analyzer- **Necessary to display results**
- Timer
- PPE



Included in Kits



Storage

- 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.**



Recommended PPE

- N-95 or Disposable Mask
- Face shield or safety glasses
- Gloves
- Clothing protection
 - Disposable lab coat
 - Disposable gown



First Step: Reader Verification Cartridge



Reader Verification Cartridge

- Perform when opening a brand-new kit
- Perform each day before testing patient specimens



Steps:

1. Press the power button, wait for self test to complete.
2. When screen appears "Self Test Pass" you are ready to proceed.
3. Screen should say "INSERT TEST DEVICE or DOUBLE CLICK for WALK-AWAY MODE".
4. Open reader verification cartridge (orange package).
5. Insert cartridge device into test device slot.
6. Reading should take **3 seconds** and should display **VERIFY PASS**. Ready to test patient samples.

If the system fails, **DO NOT** test patient samples.

Performing the Test



Testing Outline

Prepare Workspace

Collect Nasal Swab

Add Nasal Swab to Extraction Reagent

Performing the Test

Interpreting Results

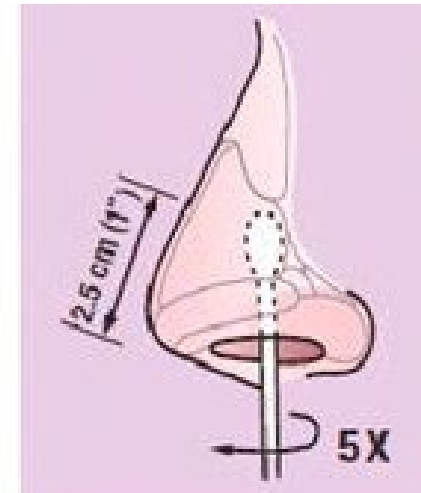
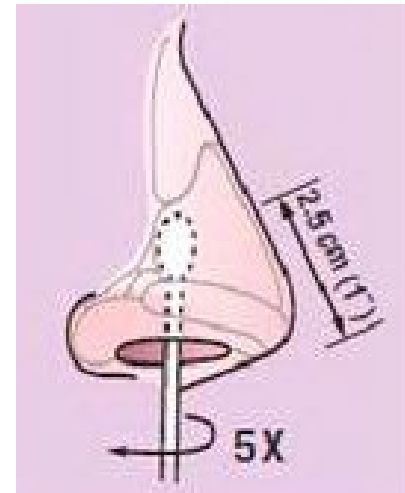
Prepare Workspace

- Remove one extraction reagent tube/tip and one BD Veritor System test device from its foil pouch immediately before testing.
- Label one test device and one extraction reagent tube for each specimen or control to be tested.
- Place the labeled extraction reagent tube(s) in a rack in the designated area of the workspace.



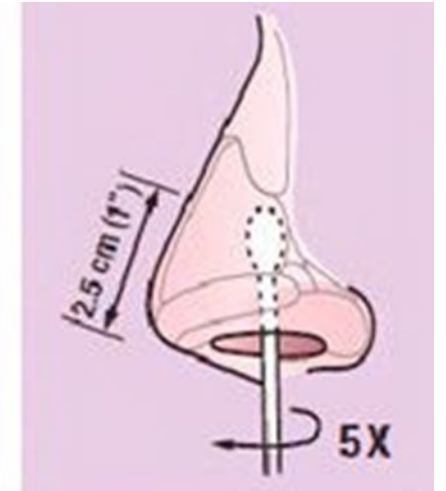
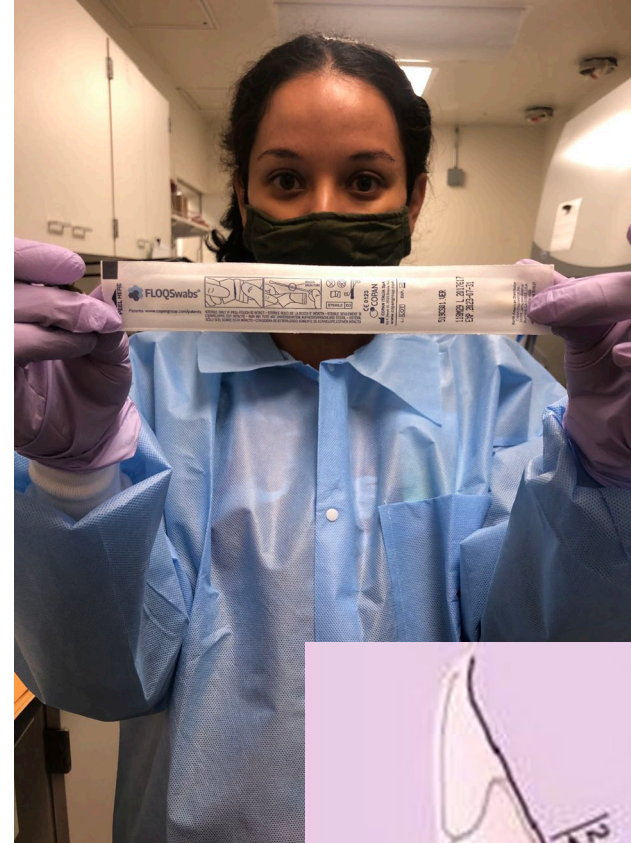
Collecting Nasal Swab

1. Insert the nasal swab about **1-inch** into the nostril with the most visible drainage.
2. Gently rotate the swab until resistance is met.
3. **ROTATE** the nasal swab **5 TIMES** against the nasal wall.
4. Remove the swab.
5. Using the same swab, **REPEAT** the sample collection into the other nostril.
6. **DO NOT** return swab to its original package.



Collecting Nasal Swab

1. ROTATE the nasal swab **5 TIMES** against the nasal wall.
2. Remove the swab.
3. Using the same swab, **REPEAT** the sample collection into the other nostril.





Add Nasal Swab to Extraction Reagent

1. Remove and discard the cap from the extraction reagent tube.
2. Insert the swab into the tube and plunge the swab up and down in the fluid for a minimum of 15 seconds, taking care not to splash contents out of the tube.
3. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.



Adding Extraction Reagent to Test Cartridge

1. Invert the extraction reagent tube and hold it vertically (approximately one inch above the sample well).
2. Gently squeeze the ridged body of the tube, dispensing three (3) drops of the processed specimen into the sample well.
3. The test takes 15 minutes to run

Interpreting Results: “*Analyze Now*” mode

1. The BD Veritor Plus Analyzer will complete a self-test before it is ready for use.
2. After the self-test the display window shows “INSERT TEST DEVICE OR DOUBLE-CLICK BUTTON FOR WALK AWAY MODE”.
3. INSERT THE TEST DEVICE when the 15-minute assay development time is complete.
4. The status of the assay analysis process appears in the display window. Follow the on-screen prompts to complete the procedure. Do not touch the Instrument or remove the test device until the result appears.
5. When analysis is complete, the test result appears in the display window.

Record the Result before removing the test device



Analyze Now Mode

- After 15-minute incubation time, turn the BD Veritor Plus Analyzer on by pressing the blue power button once.
- Insert test cartridge into test slot.

BD Veritor Plus Analyzer in “*Walk Away*” mode

1. Turn the BD Veritor Plus Analyzer on by pressing the blue power button once.
2. When the display window reads: “INSERT TEST DEVICE OR DOUBLE-CLICK FOR WALK AWAY MODE”, Double-click the blue power button.
3. The display window reads “ADD SPECIMEN TO TEST DEVICE AND INSERT IMMEDIATELY”.
4. Invert the tube, holding it vertically (approximately one inch above the BD Veritor System test device sample well).
5. Gently squeeze the ridged body of the tube, dispensing three (3) drops of the processed specimen into the sample well.
6. Insert the test device into the slot on the right side of the BD Veritor Plus Analyzer.



Walk Away Mode

CAUTION: A countdown timer displays the time remaining for test insertion. Walk Away mode must be activated again when this timer expires.

Confirm timer is visible and Walk Away mode is activated before inserting test device.

ATTENTION: TEST Results are NOT maintained in the display window when the device is removed or if the

BD Veritor Plus Analyzer will power off if unattended for more than 15 minutes (60 minutes if AC power adapter is connected).

Interpreting Results

- Using adaptive read technology.
- Test results objective, and digitally displayed.

A digital display with a dark green background showing the text 'CoV2: +' in a white, monospaced font.

Positive

A digital display with a dark green background showing the text 'CoV2: -' in a white, monospaced font.

Negative

A digital display with a light gray background showing the text 'CONTROL' on the top line and 'INVALID' on the bottom line in a black, monospaced font.

Invalid – Repeat test

DISPOSAL

- Test cartridges and PPE are considered biohazard waste.
- Use appropriate disinfectant to clean up test areas.
- Check List N on FDA to see if it is appropriate to kill SARS-CoV-2

[List N How-To - YouTube](#)



External Positive and Negative 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 BD Veritor System Instrument perform as expected. Prepare kit control swabs and test using the same procedure as used for patient specimens.
- BD recommends controls 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.

Testing Controls

Negative Control



Positive Control



Controls Failing?

- If controls fail, **DO NOT USE** for sample testing.
- Report to BD Veritor technical_services@bd.com

Additional Resource and Contact Information



Priscilla Seabourn M.S., Ph.D. Candidate
APHL COVID-19 Laboratory Associate
priscilla.seabourn.nsw@doh.hawaii.gov



Dr. Joanna Kettlewell Ph.D.
APHL COVID-19 Response Postdoctoral Fellow
joanna.kettlewell@doh.hawaii.gov