BD Veritor™ Plus System

This document is a supplement to the manufacturer’s instructions and is intended to provide helpful testing tips when using the BD Veritor™ Plus System for Rapid Detection of SARS-CoV-2. To ensure accurate performance of this test, please refer to the package insert or Instructions for Use for complete details on how to perform the test. Additional instructions can be found at https://www.fda.gov/media/139755/download.

For information on the BD Veritor™ system please view the manufacturer’s website here https://www.bdveritor.com./.*

* Use of trade names and commercial sources is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention, the Public Health Service, or the U.S. Department of Health and Human Services.
Before the Test

Acceptable specimens are nasal swab obtained by collection from both nostrils. Do not use nasal swabs other than those provided with the kit.

The kit is not intended for testing liquid specimens, such as wash or aspirate specimens, or swabs in transport media. Results can be compromised by over dilution.

Label specimens correctly to avoid recordkeeping issues.

Transport specimens carefully from the collection area to the testing area. Time from sample collection to testing should be minimized, and the temperature of the specimen during this time must be controlled.

Store kits at 2–30°C (35.6–86°F). Do not freeze. Reagents and devices must be at room temperature (15–30°C or 59–86°F) when used for testing.

**Do not use:**

- Expired reagents or damaged test devices.
- Reagents other than those provided in the kit.

Add specimens to the extraction reagent no later than one hour after collection.

Use the test devices immediately after opening the foil pouch. The user should never open the foil pouch exposing the test device to room temperature until ready for immediate use. Use caution when opening the test device during batch testing. The timing of opening the test devices for multiple specimens and processing the specimens is important.
During the Test

Gloves should be changed before collecting, handling, and processing a new specimen. Discard used gloves in a biohazardous waste container. If handling multiple specimens (batch testing), change gloves after collecting specimen and placing the swab in sample tube for each individual. It is not necessary to change gloves between pipetting steps for multiple test devices when batch testing.

Keep the test device in a flat position when in use.

Add reagent to the appropriate area on the test device and insert into the device as shown below.

Test devices used in a laminar flow hood or in areas with high air flow should be covered during test development to ensure proper sample flow.

Allow the test to incubate for 15 minutes. Incorrect results may occur if less time is provided for development. Some lines may appear on the test device sooner. Do not read the test device visually.

Keep track of and follow proper timing for reading the results from each test when testing multiple specimens (one specimen per test device) at the same time.

The BD Veritor™ Plus Analyzer automatically interprets the internal controls when reading each test device and presents a CONTROL INVALID message to the user in the case of failure.*

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After the Test

Multiple sequential specimens with unexpected results inconsistent with clinical indications may indicate errors have occurred and the individuals should be retested. Disinfect the area, change gloves, rerun controls, and then retest those specimens.

To avoid cross contamination, CDC recommends decontamination of the instrument and workspace between specimen processing. If handling multiple specimens, cleaning and disinfection may be performed after batch testing has been completed. Follow the manufacturer's recommendations for using an approved disinfectant, including proper dilution, contact time, and safe handling.