Quick Reference Instructions for BD Veritor™ SARS-CoV-2

REF 256082

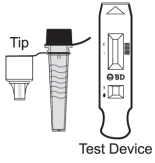
Use of BD Veritor™ System for Rapid Detection of SARS-CoV-2 with the BD Veritor™ Plus Analyzer

In the USA: For use under Emergency Use Authorization (EUA) Only

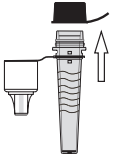
Read the complete test procedure, including recommended QC procedures before performing the test. Refer to the package insert for complete information about the test. Ensure ALL components are at room temperature (15–30 °C) when running the test.

Sample preparation

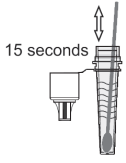
1 Gather test materials and label test device with specimen ID.



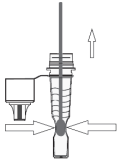
2 Remove cap from extraction reagent tube.



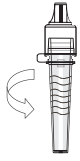
3 Insert patient sample swab and vigorously plunge the swab up and down for 15 seconds.



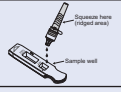
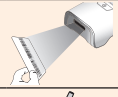
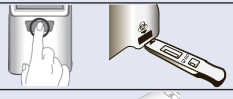
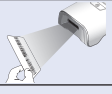
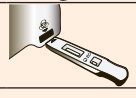
4 Remove swab while squeezing tube to extract liquid. Properly dispose of swab.



5 Press dispensing tip on the tube firmly. Mix the sample by flicking or swirling the bottom of the tube.



Using the BD Veritor Plus Analyzer to read the assay device

ANALYZE NOW MODE		OR	WALK AWAY MODE (instrument must be plugged in)	
6	Add 3 drops of the processed sample to the test device sample well.		Press blue start button once to power on. When prompt appears, **double click** to enter Walk-Away mode. Three minute countdown timer displays time remaining for test device insertion.	
7	Allow test to develop for 15 minutes. CAUTION: Incorrect results may occur if development time is less than 15 minutes. Cover test device if working in a drafty environment.		Optional: If using the barcode scanning accessory, follow screen prompts to scan any required barcodes.	
8	When test is ready, power on instrument by pressing blue start button once. When prompted, insert test device to read.		Add 3 drops of the processed sample to the test device sample well.	
	Optional: If using the barcode scanning accessory, follow screen prompts to scan any required barcodes to start the test analysis.		Confirm timer is visible and Walk Away mode is activated before inserting device. Insert device to start assay timing and analysis. **Do not touch instrument during analysis. Keep level.**	
9	Result will appear on screen. Record result and remove test device. Properly dispose of test device.		Result will appear on the screen after analysis is complete (15 minutes). Record result, remove test device and discard properly. Instrument returns to Analyze Now mode when test device is removed.	

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IVD Rx Only

Display	Interpretation
CoV2: +	Positive Test for SARS-CoV-2 (antigen present)
CoV2: –	Presumptive Negative Test for SARS-CoV-2 (no antigen detected)
CONTROL INVALID	Test Invalid. Repeat the test.

INTERPRETATION OF RESULTS

Test results must **NOT** be read visually. The BD Veritor Plus System Analyzer (purchased separately) must be used for interpretation of all test results. Refer to table above.

Positive Test Results – SARS-CoV-2 antigen present; does not rule out coinfection with other pathogens.

Negative Test Results – Negative results are presumptive. Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with COVID-19, or in those who have been in contact with the virus. It is recommended that these results be confirmed by a molecular testing method, if necessary for patient management.

Invalid Test - If the test is invalid the BD Veritor Plus System Analyzer will display a "CONTROL INVALID" result and the test or control must then be repeated.

EXTERNAL QUALITY CONTROL PROCEDURE

Swab controls are supplied with each kit. These swab controls should be used to ensure that the test reagents work properly and that the test procedure is performed correctly. For kit swab controls, insert the control swab into the extraction reagent tube and vigorously plunge the swab up and down for 15 seconds. Process according to the test procedures on the reverse side of this card beginning at step 4. BD recommends running controls for each new kit lot, each new operator, and each new shipment of test kits or at periodic intervals required by your facility. If the kit controls do not perform as expected, do not report patient results and contact BD Technical Support at 1.800.638.8663.

SPECIMEN COLLECTION AND HANDLING

Proper specimen collection and handling of nasal swabs is required to ensure accurate results (see enclosed specimen collection guide). Additional training or guidance is recommended if operators are not experienced with specimen collection and handling procedures.

WARNINGS AND PRECAUTIONS

1. For *in vitro* Diagnostic use only.
2. All test results must be obtained using the BD Veritor Plus Analyzer.
3. **DO NOT** read the test results visually.
4. Handle all specimens and related materials as if capable of transmitting infectious agents.
5. Dispose of used materials as biohazardous waste in accordance with federal, state and local requirements.
6. **Ensure all components are at room temperature (15–30 °C) when running the test.**
7. Please refer to the package insert for detailed assay instructions, cautions, limitations and warnings.

In the USA, this test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests and at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and, in the USA, this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

US Customers only: For symbol glossary, refer to bd.com/symbols-glossary
Technical Information: In the United States contact BD Technical Service and Support at 1.800.638.8663 or bd.com

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