



R_x Only



REF 256082
500048916(01)
2020-07
English

Veritor™ System

For Rapid Detection of SARS-CoV-2

Kit configured for testing nasal swab samples freshly collected, processed and dispensed directly onto assay test device.

For use under an Emergency Use Authorization only.

30

Determinations

For Rapid Detection of SARS-CoV-2

For In Vitro Diagnostic Use

For use with the BD Veritor™ Plus Analyzer running firmware version 5.4 or later

For use under an Emergency Use Authorization only

Please read these instructions completely before beginning testing of specimens.

INTENDED USE

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 in nasal swabs from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high, or waived complexity tests. This test is authorized for use 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.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. This antigen is generally detectable in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results should be treated as presumptive, do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management.

The BD Veritor System for Rapid Detection of SARS-CoV-2 is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of in vitro diagnostic procedures, and proper infection control procedures and individuals similarly trained in point of care settings. In the United States, the BD Veritor System for Rapid Detection of SARS-CoV-2 is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION OF THE TEST

A novel coronavirus (2019-nCoV) was identified in December 2019,¹ which has resulted in hundreds of thousands of confirmed human infections worldwide. Cases of severe illness and deaths have been reported. On February 11, 2020 the International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.²

The median incubation time is estimated to be approximately 5 days with symptoms estimated to be present within 12 days of infection.³ The symptoms of COVID-19 are similar to other viral respiratory diseases and include fever, cough, shortness of breath.

The BD Veritor System for Rapid Detection of SARS-CoV-2 is a rapid (approximately 15 minutes) chromatographic digital immunoassay for the direct detection of the presence or absence SARS-CoV-2 antigens in respiratory specimens taken from patients with signs and symptoms who are suspected of COVID-19. The test is intended for interpretation in both laboratory and near patient testing environments only with the BD Veritor Plus Analyzer Instrument. The test is not intended to be interpreted visually. Procedures to evaluate test devices depend on the BD Veritor Plus Analyzer workflow configuration chosen. In **Analyze Now mode**, the instrument evaluates assay devices after manual timing of their development. In **Walk Away mode**, devices are inserted immediately after application of the specimen, and timing of assay development and analysis is automated. Additionally, connection of a BD Veritor Plus Analyzer to a printer or IT system is possible if desired. Additional result documentation capabilities are possible with the integration of a BD Veritor InfoScan ("InfoScan") module. Please refer to the BD Veritor Plus Analyzer Instructions for Use for details on how to implement these features.

PRINCIPLES OF THE PROCEDURE

The BD Veritor System consists of a dedicated opto-electronic interpretation instrument and immunochromatographic assays for the qualitative detection of antigens from pathogenic organisms in samples processed from respiratory specimens. 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.

REAGENTS

The following components are included in the BD Veritor System for Rapid Detection of SARS-CoV-2 kit.

Materials Provided:

Kit Component	Quantity	Description
BD Veritor System Test Devices	30 single use test devices	Foil pouched test device containing one reactive strip. Each strip has one line of murine anti-SARS coronavirus monoclonal antibody on the test line, and one of biotin coupled to bovine protein on the positive control line. Murine and Leporine anti-SARS coronavirus and anti-biotin monoclonal antibodies conjugated to detector reagents are bound in the sample delivery area.
Extraction Reagent	30 single use reaction tubes, each with 325 µL extraction reagent and having an integral dispensing tip	Detergent solution with less than 0.1% sodium azide (preservative).
Specimen sampling swabs	30 sterile, single use specimen sampling swabs	For sample collection and transfer.
SARS-CoV-2 (+) Control Swab	1 each – individually wrapped for single use	Non-infectious, recombinant viral protein antigen with less than 0.1% sodium azide.
SARS-CoV-2 (–) Control Swab	1 each – individually wrapped for single use	Buffer with less than 0.1% sodium azide.
Assay documentation	1 each - Instructions for use 1 each - Quick reference instruction card 1 each - Nasal sampling instructions	

Materials Required but not provided:

- BD Veritor™ Plus Analyzer (Cat. No. 256066)
- timer
- tube rack for specimens
- any necessary personal protective equipment

Optional Equipment:

- BD Veritor InfoScan Module (Cat. No. 256068)
- USB Printer cable for BD Veritor Plus Analyzer (Cat. No. 443907)
- Epson Printer model TM-T20 II
- BD Veritor Plus Connect (contact BD Technical Services for details).

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use. In the USA, only for use under an Emergency Use Authorization.
2. 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.
3. 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.
4. Do not use this kit beyond the expiration date printed on the outside carton.
5. Do not use the kit to evaluate patient specimens if either the positive control swab or negative control swab fail to give expected results.
6. Test results are not meant to be visually determined. All test results must be determined using the BD Veritor Plus Analyzer.
7. To avoid erroneous results, specimens must be processed as indicated in the assay procedure section.
8. Do not reuse any BD Veritor System test device or kit components.
9. When collecting a nasal swab sample, use the nasal swab supplied in the kit. Use of alternative swabs may result in false negative results.
10. Proper specimen collection, storage and transport are critical to the performance of this test.

11. Specific training or guidance is recommended if operators are not experienced with specimen collection and handling procedures. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated.
12. Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. Standard precautions and institutional guidelines should always be followed in handling, storing, and disposing of all specimens and all items contaminated with blood or other body fluids.
13. The SARS-CoV-2 positive control swabs have been prepared from recombinant viral proteins and do not contain infectious material.
14. Dispose of used BD Veritor System test devices as biohazardous waste in accordance with federal, state and local requirements.
15. Reagents contain sodium azide, which is harmful if inhaled, swallowed or exposed to skin. Contact with acids produces very toxic gas. If there is contact with skin, wash immediately with plenty of water. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.
16. 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.
17. For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at bd.com.

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.**

SPECIMEN COLLECTION AND HANDLING

Specimen Collection and Preparation

Acceptable specimens for testing with this kit include nasal swab specimens obtained by the dual nares collection method. It is essential that correct specimen collection and preparation methods be followed. Specimens obtained early during symptom onset will contain the highest viral titers; specimens obtained after five days of symptoms are more likely to produce negative results when compared to an RT-PCR assay. Inadequate specimen collection, improper specimen handling and/or transport may yield a falsely negative result; therefore, training in specimen collection is highly recommended due to the importance of specimen quality for generating accurate test results.

Specimen Transport and Storage

Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection. It is essential that correct specimen collection and preparation methods be followed.

Nasal Swab Specimen Collection

1. The BD Veritor System Kit includes swabs for nasal specimen collection.
2. 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.
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 using the BD Veritor System SARS-CoV-2 kit.



DOs and DON'Ts of Sample Collection

- Do collect sample as soon as possible after onset of symptoms.
- Do test sample immediately.
- Use only swabs provided with the kit.
- Refer to: Interim Guidelines for Collecting, Handling and Testing Clinical Specimens from persons for COVID-19 at <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

TEST PROCEDURE

Reagents, specimens and devices must be at room temperature (15–30 °C) for testing.

This BD Veritor System assay kit is only intended for nasal swab specimens that are collected and tested directly (i.e., swabs that have NOT been placed in transport media). The kit includes a pre-diluted processing reagent in a ready to use “unitized” tube. This kit IS NOT INTENDED for testing liquid samples such as wash or aspirate samples or swabs in transport media as results can be compromised by over dilution.

Getting ready to test

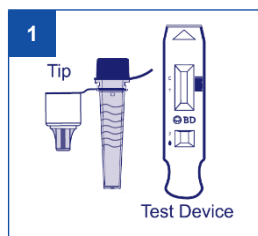
The following steps assume that the BD Veritor Plus Analyzer is ready to use. To choose or change any BD Veritor Plus Analyzer settings, see the BD Veritor Plus Analyzer Instructions for Use, section 4.7. A printer is not necessary to display results. However, if your facility has chosen to connect the BD Veritor Plus Analyzer to a printer, check that the BD Veritor Plus Analyzer is plugged into a power source, paper supply is adequate and any necessary network connections are enabled before testing.

Freshly collected specimens should be processed within 1 hour.

Procedure for Nasal Swabs or control swabs:

Step 1:

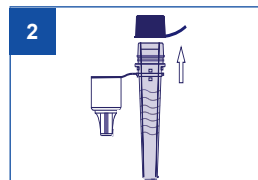
- Remove one extraction reagent tube/tip and one BD Veritor System test device from its foil pouch immediately before testing.
- Label one test device and one extraction reagent tube for each specimen or control to be tested.
- Place the labeled extraction reagent tube(s) in a rack in the designated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



Process the Specimen or Control Swab

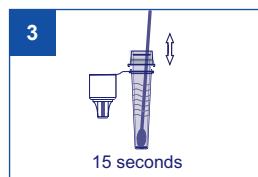
Step 2:

- Remove and discard the cap from the extraction reagent tube.



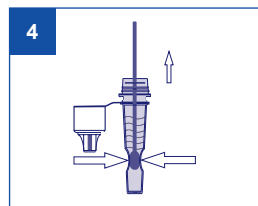
Step 3:

- 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.



Step 4:

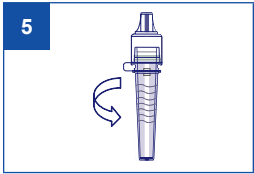
- Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.



Step 5:

- Press the attached tip firmly onto the extraction reagent tube containing the processed sample (threading or twisting is not required). Mix thoroughly by swirling or flicking the bottom of the tube.

NOTE: Do not use tubes or tips from any other product, including other products from BD or other manufacturers.



After processing the swab in the extraction reagent, the sample should be analyzed within 30 minutes.

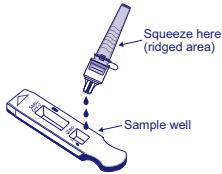
After step 5, choose from the BD Veritor Plus Analyzer workflow option below before continuing to step 6:				
	BD Veritor Plus Analyzer in Analyze Now mode	BD Veritor Plus Analyzer in Walk Away mode	BD Veritor Plus Analyzer with the BD Veritor InfoScan module	
			in Analyze Now mode	in Walk Away mode
Instructions in section:	A	B	C	D

A

Using a BD Veritor Plus Analyzer in “Analyze Now” mode:

Step 6A: Adding the specimen to the test device

- Invert the extraction reagent tube and hold it vertically (approximately one inch above the sample well).
- Gently squeeze the ridged body of the tube, dispensing three (3) drops of the processed specimen into the sample well.
- Excess volume remains for retesting if necessary.



NOTE: Squeezing the tube too close to the tip may cause leakage.

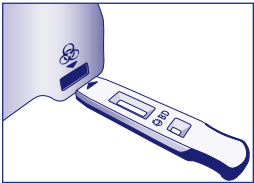
Step 7A: Timing test development

- After adding the sample, allow the test to run for **15 minutes** before inserting the test device into the BD Veritor Plus Analyzer.
- During incubation time, turn the BD Veritor Plus Analyzer on by pressing the blue power button once.
- **NOTE:** If running test under laminar flow hood, cover test device to avoid inconsistent flow.



Step 8A: Using the BD Veritor Plus Analyzer

- The BD Veritor Plus Analyzer will complete a self-test before it is ready for use. After the self-test the display window shows INSERT TEST DEVICE OR DOUBLE-CLICK BUTTON FOR WALK AWAY MODE.
- INSERT THE TEST DEVICE when the 15-minute assay development time is complete.
- 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.
- When analysis is complete, the test result appears in the display window.



Step 9A: Record the Result before removing the test device

ATTENTION: TEST Results are NOT maintained in the display window when the device is removed or if the BD Veritor Plus Analyzer is left unattended for more than 15 minutes (60 minutes if AC power adapter is connected).

To use Walk Away mode - connect the AC power adapter to the Analyzer and a power source

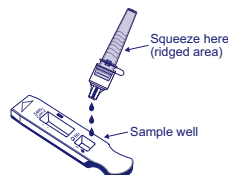
Step 6B: Starting Walk Away Mode

- Turn the BD Veritor Plus Analyzer on by pressing the blue power button once
- When the display window reads: "INSERT TEST DEVICE OR DOUBLE-CLICK FOR WALK AWAY MODE, Double-click the blue power button.
- The display window reads "ADD SPECIMEN TO TEST DEVICE AND INSERT IMMEDIATELY"



Step 7B: Adding the specimen to the test device

- Invert the tube, holding it vertically (approximately one inch above the BD Veritor System test device sample well).
- Gently squeeze the ridged body of the tube, dispensing three (3) drops of the processed specimen into the sample well.
- Excess volume remains for retesting if necessary.



NOTE: Squeezing the tube too close to the tip may cause leakage.

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.

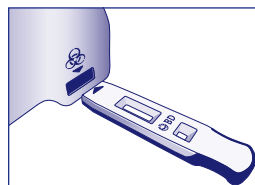
Step 8B: Starting the development and reading sequence

- Insert the test device into the slot on the right side of the BD Veritor Plus Analyzer.

The test device must remain horizontal to prevent spilling the specimen out of the sample well

- "DO NOT DISTURB TEST IN PROGRESS" appears in the display window. Automatic timing of the assay development, image processing and result analysis begins.
- The display window shows the remaining analysis time.

Do not touch the BD Veritor Plus Analyzer or remove the test device during this process. Doing so will abort the assay analysis.



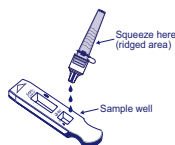
Step 9B: Record the Result

- When analysis is complete, the test result appears in the display window. Record the result and discard the test device appropriately.

ATTENTION: TEST Results are NOT maintained in the display window when the device is removed or if the BD Veritor Plus Analyzer is left unattended for more than 15 minutes (60 minutes if AC power adapter is connected).

Step 6C: Adding the specimen to the test device

- Invert the extraction reagent tube and hold it vertically (approximately one inch above the sample well).
- Gently squeeze the ridged body of the tube, dispensing three (3) drops of the processed specimen into the sample well.
- Excess volume remains for retesting if necessary.



NOTE: Squeezing the tube too close to the tip may cause leakage.

Step 7C: Timing development

- Allow the test to develop for **15 minutes**.

CAUTION: incorrect results may occur if development time is less than 15 minutes. Some lines may appear on the device sooner. Do not read device visually.

- If running the test in a laminar flow hood or in an area with heavy ventilation, cover test device to avoid inconsistent flow.

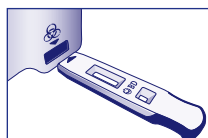


Step 8C: Using the BD Veritor Plus Analyzer

During the incubation time, turn on the BD Veritor Plus Analyzer by pressing the blue button once.

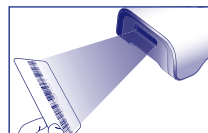
The display window briefly shows “SCAN CONFIG BARCODE.” This is an opportunity to change the configuration of the BD Veritor Plus Analyzer. Ignore this message and postpone this process when an assay is awaiting analysis. Please refer to the BD Veritor Plus Analyzer Instructions for Use for configuration steps.

- When assay development time is complete and the BD Veritor Plus Analyzer display window reads “INSERT TEST DEVICE OR DOUBLE-CLICK FOR WALK AWAY MODE”, insert the BD Veritor System SARS-CoV-2 device into the slot on the right side of the BD Veritor Plus Analyzer.



Step 9C: Using the barcode scanner

- Follow the prompts on the display screen to complete any required barcode scans of:
 - OPERATOR ID
 - SPECIMEN ID and/or
 - KIT LOT NUMBER



- Prompts for each scanning step appear in the display window for only 30 seconds. Failure to complete scans during that time will cause the BD Veritor Plus Analyzer to default to the beginning of step 8C. To restart this step, remove and reinsert the test device to initiate a new reading sequence.
- Move barcodes slowly toward the window until a confirmation tone sounds. The scanned barcode value appears in the next display window.
- The BD Veritor Plus Analyzer can record the Kit Lot Number and expiration date in the test record but does not restrict the use of expired or inappropriate reagents. Management of expired materials is the responsibility of the user.

After required scans are completed, the BD Veritor Plus Analyzer displays a countdown timer and test analysis begins.

- Do not touch the BD Veritor Plus Analyzer or remove the test device during this process. Doing so will abort the assay analysis.
- When analysis is complete a result appears in the display window. If configured to display, the specimen ID barcode value also appears. If a printer is connected, specimen ID and result are automatically printed.

If a printer is not connected, record the result before removing the assay device.

ATTENTION: TEST Results are NOT maintained in the display window when the device is removed or if the BD Veritor Plus Analyzer is left unattended for more than 15 minutes (60 minutes if AC power adapter is connected).

Step 10C: Remove the test device

- Remove and then discard the test device appropriately. The display will show “INSERT TEST DEVICE OR DOUBLE-CLICK BUTTON FOR WALK AWAY MODE” to indicate the BD Veritor Plus Analyzer is ready to perform another test.

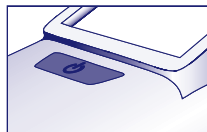


If the BD Veritor Plus Analyzer is connected to an LIS, a steady ENVELOPE symbol will appear to indicate that results are awaiting transmission. If a network connection is not detected while the ENVELOPE symbol is still displayed, the BD Veritor Plus Analyzer will queue all untransmitted results and attempt to transmit them when reconnected. If it is powered off during this time, it will attempt to transmit as soon as power is restored, and connection is re-established. A flashing envelope indicates that data are in the process of being transmitted.

To use Walk Away mode - connect the AC power adapter to the BD Veritor Plus Analyzer and a power source

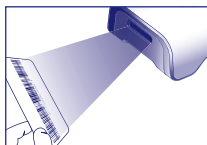
Step 6D: Starting Walk Away mode

- Turn on the BD Veritor Plus Analyzer by pressing the blue power button once. The display window will briefly show “SCAN CONFIG BARCODE”. This is an opportunity to change the configuration of the BD Veritor Plus Analyzer. Please refer to the BD Veritor Plus Analyzer Instructions for Use for configuration steps. Ignore this message and postpone this process when an assay is awaiting analysis.
- When the display window reads: INSERT TEST DEVICE OR DOUBLE-CLICK FOR WALK AWAY MODE, double-click the blue power button.



Step 7D: Using the barcode scanner

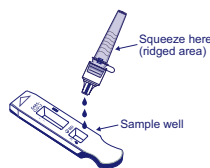
- Follow the prompts on the display screen to complete any required barcode scans of:
 - OPERATOR ID
 - SPECIMEN ID and/or
 - KIT LOT NUMBER



- Prompts for each scanning step appear in the display window for only 30 seconds. Failure to complete scans during that time will cause the BD Veritor Plus Analyzer to default to the beginning of step 8C. To restart this step, remove and reinsert the test device to initiate a new reading sequence.
- Move barcodes slowly toward the window until a confirmation tone sounds. The scanned barcode value appears in the next display window.
- The BD Veritor Plus Analyzer can record the Kit Lot Number and expiration date in the test record but does not restrict the use of expired or inappropriate reagents. Management of expired materials is the responsibility of the user.

Step 8D: Adding the specimen to the test device

- When the display window reads: ADD SPECIMEN TO TEST DEVICE AND INSERT IMMEDIATELY:
 - Invert the tube, holding it vertically (approximately one inch above the BD Veritor System SARS-CoV-2 device sample well).
 - Gently squeeze the ridged portion of the tube, dispensing three (3) drops of the processed specimen into the sample well.
 - Excess volume remains for retesting if necessary.

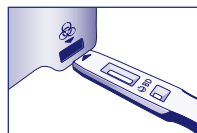


NOTE: Squeezing the tube close to the tip may cause leakage.

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.

Step 9D: Starting the development and reading sequence

- Insert the test device into the slot on the right side of the BD Veritor Plus Analyzer. The test device must remain horizontal to prevent spilling the specimen out of the sample well.
- “DO NOT DISTURB TEST IN PROGRESS” appears in the display window. Automatic timing of the assay development, image processing and result analysis begins.
- The display window shows the remaining analysis time.



Do not touch the BD Veritor Plus Analyzer or remove the test device during this process. Doing so will abort the assay analysis.

- When analysis is complete, a result appears in the display window. If configured to display, the Specimen ID barcode value also appears. If a printer is connected, specimen ID and result are automatically printed.

If a printer is not connected, record the result before removing the assay device.

ATTENTION: TEST Results are NOT maintained in the display window when the device is removed or if the BD Veritor Plus Analyzer is left unattended for more than 15 minutes (60 minutes if AC power adapter is connected).

Step 10D: Removing the test device

- Remove and then discard the test device appropriately. The display will show INSERT TEST DEVICE OR DOUBLE-CLICK BUTTON FOR WALK AWAY MODE to indicate the BD Veritor Plus Analyzer is ready to perform another test. Note that the BD Veritor Plus Analyzer returns to Analyze Now mode at the conclusion of each read sequence.



If the BD Veritor Plus Analyzer is connected to an LIS, a steady ENVELOPE symbol will appear to indicate that results are awaiting transmission. If a network connection is not detected while the ENVELOPE symbol is still displayed, the BD Veritor Plus Analyzer will queue all untransmitted results and attempt to transmit them when reconnected. If it is powered off during this time, it will attempt to transmit as soon as power is restored, and connection is re-established. A flashing envelope indicates that data are in the process of being transmitted.

INTERPRETATION OF RESULTS

The BD Veritor Plus Analyzer (provided separately) must be used for interpretation of all test results. Operators should not attempt to interpret assay results directly from the test strip contained within the BD Veritor assay device.

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.

*Invalid Test – If the test is invalid, the BD Veritor System Instrument will display “CONTROL INVALID” and the test or control must then be repeated. If the “CONTROL INVALID” reading recurs, contact BD.

REPORTING OF RESULTS

Positive Test – Positive for the presence of SARS-CoV-2 antigen. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative Test – 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.

Control Invalid – Do not report results. Repeat the test.

QUALITY CONTROL

Each BD Veritor System SARS-CoV-2 test device contains both positive and negative internal/procedural controls:

- The internal positive control line validates the immunological integrity of the device, proper reagent function, and assures correct test procedure.
- The membrane area surrounding test lines functions as a background check on the assay device.

The BD Veritor System Instrument evaluates the positive and negative internal/procedural controls after insertion of each test device. The BD Veritor Plus Analyzer prompts the operator if a quality issue occurs during assay analysis. Failure of the internal/procedural controls will generate an invalid test result. NOTE: The internal controls do not assess proper sample collection technique.

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.

If the kit controls do not perform as expected, do not report patient results. Contact BD Technical Services at 1.800.638.8663.

LIMITATIONS OF THE PROCEDURE

- Clinical performance was evaluated with frozen samples, and test performance may be different with fresh samples.
- Users should test specimens as quickly as possible after specimen collection.
- Positive test results do not rule out co-infections with other pathogens.
- Results from the BD Veritor System for Rapid Detection of SARS-CoV-2 test should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
- A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly; therefore, a negative test result does not eliminate the possibility of SARS-CoV-2 infection.
- The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5 of illness are more likely to be negative compared to a RT-PCR assay.
- Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.

- The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigens from nasal swab specimens only.
- The BD Veritor System for Rapid Detection of SARS-CoV-2 can detect both viable and non-viable SARS-CoV-2 material. The BD Veritor System for Rapid Detection of SARS-CoV-2 performance depends on antigen load and may not correlate with other diagnostic methods performed on the same specimen.
- Negative test results are not intended to rule in other non-SARS-CoV-2 viral or bacterial infections.
- Positive and negative predictive values are highly dependent on prevalence rates. Positive test results are more likely to represent false positive results during periods of little/no SARS-CoV-2 activity when disease prevalence is low. False negative test results are more likely when prevalence of disease caused by SARS-CoV-2 is high.
- This device has been evaluated for use with human specimen material only.
- Monoclonal antibodies may fail to detect, or detect with less sensitivity, SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.
- The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection and performance may differ in asymptomatic individuals.
- Sensitivity of the test after the first five days of the onset of symptoms has been demonstrated to decrease as compared to a RT-PCR SARS-CoV-2 assay.
- Negative results should be treated as presumptive and confirmed with an FDA authorized molecular assay, if necessary, for clinical management, including infection control.
- This BD Veritor System kit was validated with the Copan™ Standard and Copan Minitip swabs. Use of alternative swabs may result in false negative results.
- Specimen stability recommendations are based upon stability data from influenza testing and performance may be different with SARS-CoV-2. Users should test specimens as quickly as possible after specimen collection, and within one hour after specimen collection.
- The validity of the BD Veritor System for Rapid Detection of SARS-CoV-2 test has not been proven for identification/confirmation of tissue culture isolates and should not be used in this capacity.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY

The BD Veritor System for Rapid Detection of SARS-CoV-2 Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: <https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices>.

However, to assist clinical laboratories using the BD Veritor System for Rapid Detection of SARS-CoV-2 ("your product" in the conditions below), the relevant Conditions of Authorization are listed below.

- Authorized laboratories* using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using your product will use your product as outlined in the "BD Veritor System for Rapid Detection of SARS-CoV-2" Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/ OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and to BD by contacting BD Customer Support Services at 800.638.8663 (in the U.S.) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- Becton, Dickinson and Co., authorized distributors, and authorized laboratories and patient care settings using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

*The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests. This test is authorized for use 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." as "authorized laboratories".

CLINICAL PERFORMANCE

The performance of the BD Veritor System for Rapid Detection of SARS-CoV-2 was established with 226 direct nasal swabs prospectively collected and enrolled from individual symptomatic patients (within 5 days of onset) who were suspected of COVID-19. As with all antigen tests, performance may decrease as days since symptom onset increases. Samples were collected by qualified personnel in 21 geographically diverse areas across the United States.

Nasal swabs were collected following the dual nares method and handled as described in the package insert of the collection device. Specimens were frozen within 30 minutes of collection and stored until tested. All specimens within a pre-specified date range were selected and then sequentially tested in a blinded fashion. The performance of the BD Veritor System Assay was compared to results of a nasopharyngeal or oropharyngeal swab stored in 3 mL viral transport media tested with an Emergency Use Authorized molecular (RT-PCR) test for detection of SARS-CoV-2.

BD Veritor Results	Reference PCR Results		
	POS	NEG	Total
POS	26	0	26
NEG	5	195	200
Total	31	195	226

PPA: 84% (C.I. 67%–93%)
NPA: 100% (C.I. 98%–100%)
OPA: 98% (C.I. 95%–99%)

EXPLANATION OF TERMS:

PPA: Positive Percent Agreement = True Positives / True Positives + False Negatives
NPA: Negative Percent Agreement = True Negatives / True Negatives + False Positives.
OPA: Overall Percent Agreement = True Positives + True Negatives / Total Samples
C.I.: Confidence Interval

ANALYTICAL PERFORMANCE

LIMIT OF DETECTION (ANALYTICAL SENSITIVITY)

The LOD for the BD Veritor System for Rapid Detection of SARS-CoV-2 was established using limiting dilutions of a viral sample inactivated by gamma irradiation. The material was supplied at a concentration of 2.8×10^5 TCID₅₀/mL. In this study, designed to estimate the LOD of the assay when using a direct nasal swab, the starting material was spiked into a volume of pooled human nasal matrix obtained from healthy donors and confirmed negative for SARS-CoV-2. An initial range finding study was performed testing devices in triplicate using a 10-fold dilution series. At each dilution, 50 µL samples were added to swabs and then tested in the BD Veritor assay using the procedure appropriate for patient nasal swab specimens. A concentration was chosen between the last dilution to give 3 positive results and the first to give 3 negative results. Using this concentration, the LOD was further refined with a 2-fold dilution series. The last dilution demonstrating 100% positivity was then tested in an additional 20 replicates tested in the same way.

Starting Material Concentration	Estimated LOD	No. Positive/Total	% Positive
2.8×10^5 TCID ₅₀ /mL	1.4×10^2 TCID ₅₀ /mL	19/20	95%

CROSS REACTIVITY (ANALYTICAL SPECIFICITY)

Cross-reactivity of the BD Veritor System for Rapid Detection of SARS-CoV-2 was evaluated by testing a panel of high prevalence respiratory pathogens that could potentially cross-react with the BD Veritor System for Rapid Detection of SARS-CoV-2. Each organism and virus was tested in triplicate. The final concentration of each organism is documented in the following table.

Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
Human coronavirus 229E (heat inactivated)	1.0×10^5 U/mL	No
Human coronavirus OC43	1.0×10^5 TCID ₅₀ /mL	No
Human coronavirus NL63	1.0×10^5 TCID ₅₀ /mL	No
Adenovirus	1.0×10^5 TCID ₅₀ /mL	No
Human Metapneumovirus	1.0×10^5 TCID ₅₀ /mL	No
Parainfluenza virus 1	1.0×10^5 TCID ₅₀ /mL	No
Parainfluenza virus 2	1.0×10^5 TCID ₅₀ /mL	No
Parainfluenza virus 3	5.2×10^5 TCID ₅₀ /mL	No
Parainfluenza virus 4	1.6×10^4 TCID ₅₀ /mL	No

Potential Cross-Reacting Organism	Concentration Tested	Results
Influenza A	2.5 x 10 ⁵ TCID ₅₀ /mL	No
Influenza B	2.9 x 10 ⁵ TCID ₅₀ /mL	No
Enterovirus	4.0 x 10 ⁵ TCID ₅₀ /mL	No
Respiratory syncytial virus	4.0 x 10 ⁵ TCID ₅₀ /mL	No
Rhinovirus	1.1 x 10 ⁵ PFU/mL	No
SARS-coronavirus	4.5 x 10 ⁵ PFU/mL	No
MERS-coronavirus	1.5 x 10 ⁵ TCID ₅₀ /mL	No
<i>Haemophilus influenza</i>	1.4 x 10 ⁶ CFU/mL	No
<i>Streptococcus pneumoniae</i>	1.0 x 10 ⁶ CFU/mL	No
<i>Streptococcus pyogenes</i>	1.6 x 10 ⁶ CFU/mL	No
<i>Candida albicans</i>	1.8 x 10 ⁶ CFU/mL	No
Pooled human nasal wash	100%	No
<i>Bordetella pertussis</i>	1.4 x 10 ⁶ CFU/mL	No
<i>Mycoplasma pneumoniae</i>	1.0 x 10 ⁶ CFU/mL	No
<i>Chlamydia pneumoniae</i>	1.0 x 10 ⁶ IFU/mL	No
<i>Legionella pneumophila</i>	1.0 x 10 ⁶ CFU/mL	No

To estimate the likelihood of cross-reactivity with SARS-CoV-2 of organisms that were not available for wet testing, *In silico* analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology.

- For *P. jirovecii* one area of sequence similarity shows 45.4% homology across 9% of the sequence, making cross-reactivity in the BD Veritor sandwich immunoassay highly unlikely.
- No protein sequence homology was found between SARS-CoV-2 and *M. tuberculosis*, and thus homology-based cross-reactivity can be ruled out.
- The comparison between SARS-CoV-2 nucleocapsid protein and human coronavirus HKU1 revealed that the only potential for homology is with the HKU1 nucleocapsid phosphoprotein. Homology is relatively low, at 36.7% across 82% of sequences, but cross-reactivity cannot be ruled out.

HIGH DOSE HOOK EFFECT

No high dose hook effect was observed up to 2.8 x 10⁵ TCID₅₀/mL of gamma-inactivated SARS-CoV-2 with the BD Veritor System for Rapid Detection of SARS-CoV-2 test.

TECHNICAL SUPPORT

For questions, or to report a problem, please call Technical Support at 1.800.638.8663. Test system problems may also be reported to the FDA using the MedWatch reporting system:

(phone: 1.800.FDA.1088; fax: 1.800.FDA.1078; or <http://www.fda.gov/medwatch>).

REFERENCES

1. Centers for Disease Control and Prevention. <https://www.cdc.gov/coronavirus/2019-ncov/index.html> Accessed March 30, 2020.
2. bioRxiv. (<https://www.biorxiv.org/content/10.1101/2020.02.07.937862v1>). Accessed March 30, 2020.
3. Lauer, Stephen A et al. "The Incubation Period of Coronavirus Disease 2019 (COVID-19) From Publicly Reported Confirmed Cases: Estimation and Application." *Annals of internal medicine* vol. 172,9 (2020): 577-582. doi:10.7326/M20-0504

Technical Information: In the United States contact BD Technical Service and Support at 1.800.638.8663 or bd.com.

Change History

Revision	Date	Change Summary
01	2020-07	Initial release.

Some symbols listed below may not apply to this product.

US Customers only: For symbol glossary, refer to bd.com/symbols-glossary.



Manufacturer / Производител / Yröbce / Fabrikant / Hersteller / Κατασκευαστής / Fabricante / Tootja / Fabricant / Proizvođač / Gyártó / Fabricante / Аткарушы / 제조업체 / Gamintojas / Ražotājs / Tilvirker / Producent / Producător / Производител / Yröbca / Proizvođač / Tiltverkare / Üretici / Виробник / 生产厂商



Use by / Исполняйте до / Spottføjbygt do / Brug før / Verwendbar bis / Χρήση έως / Usar antes de / Kasutada enne / Date de péremption / 사용 기한 / Upotrijebiti do / Felhasználhatóság dátuma / Usare entro / Дейін пайдалануға / Naudokite iki / Izlietot līdz / Houdbaar tot / Brukes for / Stosować do / Prazo de validade / A se utiliza până la / Исползовать до / Použite do / Upotrebiti do / Använd före / Son kulanma tarihi / Використати до / 使用截止日期
 YYYY-MM-DD / YYYY-MM (MM = end of month)
 ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = края на месеца)
 RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
 AAAA-MM-DD / AAAA-MM (MM = slutning af måned)
 JJJJ-MM-TT / JJJJ-MM (MM = Monatsende)
 EEEE-MM-HH / EEEE-MM (MM = τέλος του μήνα)
 AAAA-MM-DD / AAAA-MM (MM = fin del mes)
 AAAA-KK-PP / AAAA-KK (KK = kuu lõpp)
 AAAA-MM-JJ / AAAA-MM (MM = fin du mois)
 GGGG-MM-DD / GGGG-MM (MM = kraj mjeseca)
 ÉÉÉÉ-HH-NN / ÉÉÉÉ-HH (HH = hónap utolsó napja)
 AAAA-MM-GG / AAAA-MM (MM = fine mese)
 ЖЖЖЖ-АА-КК / ЖЖЖЖ-АА / (АА = айдың соңы)
 YYYY-MM-DD/YYYY-MM (MM = 월말)
 MMMM-MM-DD / MMMM-MM (MM = mēnesio pabaiga)
 GGGG-MM-DD/GGGG-MM (MM = mēneša beigas)
 JJJJ-MM-DD / JJJJ-MM (MM = einde maand)
 AAAA-MM-DD / AAAA-MM (MM = sluttet av måneden)
 RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
 AAAA-MM-DD / AAAA-MM (MM = fim do mês)
 AAAA-LL-ZZ / AAAA-LL (LL = sfârșitul lunii)
 ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = конец месяца)
 RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
 GGGG-MM-DD / GGGG-MM (MM = kraj meseca)
 AAAA-MM-DD / AAAA-MM (MM = slutet av månaden)
 YYYY-AA-GG / YYYY-AA (AA = ayın sonu)
 PPPP-MM-DD / PPPP-MM (MM = кінець місяця)
 YYYY-MM-DD / YYYY-MM (MM = 月末)



Catalog number / Каталоген номер / Katalogové číslo / Katalognummer / Αριθμός καταλόγου / Número de catálogo / Katalooginumber / Numéro catalogue / Kataloški broj / Katalogszám / Numero di catalogo / Каталог номер / 카탈로그 번호 / Katalog / numeris / Kataloga numurs / Catalogus number / Numer katalogowy / Număr de catalog / Номер по каталогу / Katalogové číslo / Kataloški broj / Katalog numarası / Номер за каталогом / 目录号



Authorized Representative in the European Community / Оторизирани представител в Европейската общност / Autorizovaný zástupce pro Evropskou společnost / Autoriseret repræsentant i De Europæiske Fællesskaber / Autorisierter Vertreter in der Europäischen Gemeinschaft / Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα / Representante autorizado en la Comunidad Europea / Volitatus esindaja Euroopa Nõukogus / Representant autorisé pour la Communauté européenne / Autorizirani predstavnik u Europskoj uniji / Meghatalmazott képviselő az Európai Közösségekben / Reprezentante autorizzato nella Comunità Europea / Европа қауымдастығындағы уәкілетті өкіл / 유럽 공동체의 위임 대표 / Įgaliotasis atstovas Europos Bendrijoje / Pilsnarotais pārstāvis Eiropas Kopienā / Bevoegde vertegenwoordiger in de Europese Gemeenschap / Autoriseret repræsentant i EU / Autoryzowane przedstawicielstwo we Wspólnocie Europejskiej / Reprezentante autorizado na Comunidade Europeia / Reprezentantul autorizat pentru Comunitatea Europeană / Уполномоченный представитель в Европейском сообществе / Autorizovaný zástupce v Európskom spoločenstve / Autorizovano predstavništvo u Evropskoj uniji / Autoriserad representant i Europeiska gemenskapen / Avrupa Topluluğu Yetkili Temsilcisi / Уповноважений представник у країнах ЄС / 歐洲共同體授权代表



In Vitro Diagnostic Medical Device / Медицински уред за диагностика ин витро / Lékařské zařízení určené pro diagnostiku in vitro / In vitro diagnostisk medicinsk anordning / Medizinisches In-vitro-Diagnostikum / In vitro διαγνωστική ιατρική συσκευή / Dispositivo médico para diagnóstico in vitro / In vitro diagnostika meditsiiniaparatuur / Dispositif médical de diagnostic in vitro / Medicinska pomagala za In Vitro Dijagnostiku / In vitro diagnostikai orvosi eszköz / Dispositivo medicale per diagnostica in vitro / Жасанды жағдайда жүргізілетін медициналық диагностика аспабы / In Vitro Diagnostic 의료 기기 / In vitro diagnostikos prietais / Medicinas ierīces, ko lieto in vitro diagnostikā / Medisch hulpmiddel voor in-vitro diagnostiek / In vitro diagnostisk medicinsk utstyr / Urządzenie medyczne do diagnostyki in vitro / Dispositivo médico para diagnóstico in vitro / Dispositiv medicel pentru diagnostic in vitro / Медицинский прибор для диагностики in vitro / Medicinska pomôcka na diagnostiku in vitro / Medicinski uređaj za in vitro dijagnostiku / Medicinteknisk produkt för in vitro-diagnostik / In Vitro Diyagnostik Tibbi Cihaz / Медицинский прибор для диагностики in vitro / 体外诊断医疗设备



Temperature limitation / Температурни ограничения / Teplotní omezení / Temperaturbegrænsning / Temperaturbegrenzung / Περιορισμοί θερμοκρασίας / Limitación de temperatura / Temperaturi piirang / Limites de température / Dozvoljena temperatura / Hörmersékelti határ / Limiti di temperatura / Температураны шекер / 온도 제한 / Lakymo temperatūra / Temperatūras ierobežojumi / Temperaturilimiet / Temperaturbegrænsning / Ograniczenie temperatury / Limites de temperatura / Limite de temperatură / Ограничение температуры / Ohraničenie teploty / Ograničenje temperature / Temperaturgräns / Sanktikali sinirlaması / Обмеження температури / 温度限制



Batch Code (Lot) / Код на партидата / Kód (číslo) šarže / Batch-kode (lot) / Batch-Code (Charge) / Κωδικός παρτίδας (παρτίδα) / Código de lote (lote) / Partii kod / Numéro de lot / Lot (kodu) / Tétel száma (lot) / Codice batch (lotti) / Топтама коды / 배치 코드(로트) / Partijos numeris (LOT) / Partijas kods (laidiens) / Lot number / Batch-code (parti) / Kod partii (serie) / Código do lote / Cod de serie (Lot) / Код партии (лот) / Kód série (šarža) / Kod serie / Partinummer (lot) / Parti Kodu (lot) / Kod partii / 批号 (亚批)



Contains sufficient for <n> tests / Съдържащието е достатъчно за <n> теста / Dostatečné množství pro <n> testů / Indeholder tilstrækkeligt til <n> tests / Ausreichend für <n> Tests / Περιέχει επαρκή ποσότητα για <n> εξετάσεις / Contenido suficiente para <n> pruebas / Kõllaldane <n> teste jaoks / Contenu suffisant pour <n> tests / Sadržaj za <n> testova / <n> testhez elegendő / Contenido suficiente per <n> test / <n> testetri yüsin jetkinliği / <n> 테스트가 충분한 포함량 / Pakankamas kiekis atlikti <n> testų / Satur pietiekami <n> pārbaudam / Inhoud voldoende voor <n> testen / Innholder tilstrekkelig til <n> tester / Zawiera ilość wystarczającą do <n> testów / Conteúdo suficiente para <n> testes / Conținut suficient pentru <n> teste / Достаточное для <n> тестов(a) / Obsah vyštíň na <n> testov / Sadržaj dovoljan za <n> testova / Innehåller tillräckligt för <n> analyser / <n> test için yeterli miktarda içerir / Вистачить для аналісів. <n> / 足够进行 <n> 次检测



Consult Instructions for Use / Направете справка в инструкции за употреба / Prostudujte pokyny k použití / Se brugsanvisningen / Gebrauchsanweisung beachten / Συμβουλευτείτε τις οδηγίες χρήσης / Consultar las instrucciones de uso / Lugeda kasutusjuhendit / Consulter la notice d'emploi / Koristi upute za upotrebu / Olvassa el a használati utasítást / Consultare le istruzioni per l'uso / Пайдалану нускалыгынмен танысын алыңыз / 사용 지침 참조 / Skaitlykite naudojimo instrukcijas / Skatīt lietošanas pamācību / Raadpleeg de gebruiksaanwijzing / Se i brugsanvisningen / Zobacz instrukcja użytkowania / Consultar as instruções de utilização / Consultati instructiunile de utilizare / Nao rukovodstvo po eksploataci / Pozri Pokyny na používání / Pogledajte uputstvo za upotrebu / Se bruksanvisningen / Kullanna Tallimat / na başvurun / Див. інструкції за використання / 请参阅使用说明



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Serial number / Серийн номер / Sériové číslo / Seriennummer / Seriennummer / Σειριακός αριθμός / N° de serie / Seriennummer / Número de série / Serijski broj / Sorozatszám / Numero di serie / Toplamalıq nımırları / 일련 번호 / Serijos numeris / Sérijas numeris / Serien number / Nummer seryjny / Número de série / Număr de serie / Серийный номер / Seri numarası / Номер серії / 序列号



For IVD Performance evaluation only / Само за оценка качеството на работа на IVD / Pouze pro vyhodnocení výkonu IVD / Kun til evaluering af IVD ydeelse / Nur für IVD-Leistungsbewertungszwecke / Móvo yia efólouloghí apóthoxh IVD / Sólo para la evaluación del rendimiento en diagnóstico in vitro / Ainult IVD seadme hindamiseks / Réserve à l'évaluation des performances IVD / Samo u znanstvene svrhe za in Vitro Diagnostiku / Kizárólag in vitro diagnosztikához / Solo per valutazione delle prestazioni IVD / Жасанды жағдайда «пробирка ішінде» диагностикада тек жұмысты бағалау үшін / IVD 성능 평가에 대해서만 사용 / Tik IVD prietaisui veikimo charakteristikoms tikrinti / Vienligi IVD darbības novērtēšanai / Uitsluitend voor doeltreffendheidsonderzoek / Kun for evaluering av IVD-ydeelse / Tilgode to oseny vydaynosti IVD / Uso exclusivo para avaliação de IVD / Numai pentru evaluarea performanței IVD / Tolyko für oцenки качества диагностики in vitro / Urceně iba na diagnostiku in vitro / Samo za procenu účinka u in vitro dijagnostici / Endast för utvärdering av diagnostisk användning in vitro / Yalnızca IVD Performans değerlendirmesi için / Tolyki для оцінювання якості діагностики in vitro / 仅限 IVD 性能评估

For US: "For Investigational Use Only"



Lower limit of temperature / Dolni limit na temperaturata / Dolní hranice teploty / Nedre temperaturgrænse / Temperaturuntergrenze / Kaittéro öro verrykroqloq / Limite inferior de temperatură / Alumine temperatuuripiiri / Limite inférieure de température / Najnižja dozvoljena temperatura / Alsó hőmérsékleti határ / Limite inferiore di temperatura / Температурный төменгі рұқсат шегі / 하한 온도 / Žemiausia laikymo temperatūra / Temperatūras zemākā robeža / Laagste temperatuurlimiet / Nedre temperaturgrænse / Dolna granica temperatury / Limite minimo de temperatura / Limită minimă de temperatură / Нижний предел температуры / Spodná hranica teploty / Donja granica temperature / Nedre temperaturgräns / Sicaklık alt sınırı / Мінімальна температура / 温度下限



Control / Контролно / Kontrola / Kontrol / Kontrolle / Μάρτυρας / Kontroll / Contrôle / Controllo / Бақылау / 컨트롤 / Kontrolle / Kontrolle / Controle / Controllo / Контроль / kontroll / Kontrolle / 对照



Positive control / Положительный контроль / Pozitívna kontrola / Positiv kontrol / Positive Kontrolle / Θετικός μάρτυρας / Control positivo / Positivne kontrol / Contrôle positif / Pozitívna kontrola / Pozitiv kontroll / Controllo positivo / Оң бақылау / 양성 컨트롤 / Teigiama kontrolė / Pozitívna kontrola / Positive controle / Kontrola dodatnia / Controllo positivo / Control pozitiv / Положительный контроль / Pozitif kontrol / Позитивный контроль / 阳性对照试剂



Negative control / Отрицательный контроль / Negativni kontrola / Negativ kontrol / Negative Kontrolle / Αρνητικός μάρτυρας / Control negativo / Negativne kontrol / Negativne kontrol / Negativna kontrola / Negativ kontroll / Controllo negativo / Негативный бақылау / 음성 컨트롤 / Neigiama kontrolė / Negativná kontrola / Negative controle / Kontrola ujemna / Controllo negativo / Control negativ / Отрицательный контроль / Negatif kontrol / Негативный контроль / 阴性对照试剂



Method of sterilization: ethylene oxide / Метод на стерилизация: этиленов оксид / Způsob sterilizace: etylenoxid / Steriliseringsmetode: etylenoxid / Sterilisationsmethode: Ethylenoxid / Μέθοδος αποστείρωσης: αιθυλενοξείδιο / Método de esterilización: óxido de etileno / Sterilisierungsmethode: etylenoxid / Méthode de stérilisation : oxyde d'éthylène / Metoda sterilizacije: etilen oksid / Sterilizálás módszere: etilén-oxid / Metoda di sterilizacije: ossido di etilene / Sterilizacija adici – etilen totyгы / 소독 방법: 에틸렌옥사이드 / Sterilizavimo būdas: etileno oksidas / Sterilizēšanas metode: etilēnoksīds / Gesteriliseerd met behulp van ethyleenoxid / Steriliseringsmetode: etylenoksid / Metoda sterilizacji: tlenek etylu / Método de esterilização: óxido de etileno / Metódă de sterilizare: oxid de etilenă / Metoda sterilizacije: etilenoksid / Metoda sterilizacije: etylenoxid / Metoda sterilizacije: etilen oksid / Steriliseringsmetode: etenoxid / Sterilizasyon yöntemi: etilen oksit / Metoda sterilizacji: etilenoksidum / 灭菌方法: 环氧乙烷



Method of sterilization: irradiation / Метод на стерилизация: ирадиация / Způsob sterilizace: záření / Steriliseringsmetode: bestrålning / Sterilisationsmethode: Bestrahlung / Μέθοδος αποστείρωσης: ακτινοβολία / Método de esterilización: irradiación / Sterilisierungsmethode: kiurgung / Méthode de stérilisation : irradiation / Metoda sterilizacije: zračenje / Sterilizálás módszere: besugárzás / Metoda di sterilizacije: irradiazione / Sterilizacija adici – saune tipu / 소독 방법: 방사 / Sterilizavimo būdas: radiacija / Sterilizēšanas metode: apstarošana / Gesteriliseerd met behulp van bestraling / Steriliseringsmetode: bestråling / Metoda sterilizacji: napromienianie / Método de esterilização: irradiação / Metódă de sterilizare: iradiere / Metoda sterilizacije: obučenje / Metoda sterilizacije: ožarenie / Metoda sterilizacije: ozračavanje / Steriliseringsmetod: strålning / Sterilizasyon yöntemi: irdayasyon / Metoda sterilizacji: oprómnieniam / 灭菌方法: 辐射



Biological Risks / Биологични рискове / Biologická rizika / Biologisk fare / Biogefährdung / Βιολογικοί κίνδυνοι / Riesgos biológicos / Biologilised riskid / Risques biologiques / Biološki rizik / Biológiallag veszélyes / Rischio biologico / Биологиялык төүөкдөр / 생물학적 위험 / Biologinis pavojus / Biologiskie riski / Biološki risico / Biologisk risiko / Zagrożenia biologiczne / Perigo biológico / Riscuri biologice / Биологическая опасность / Biologické riziko / Biološki rizici / Biologisk risk / Biyolojik Riskler / Биологична безбедка / 生物学风险



Caution, consult accompanying documents / Внимание, направете справка в придружаващите документи / Pozor! Prostudujte si příložený dokumentaci / Forsigtig, se ledsagende dokumenter / Achtung, Begleitdokumente beachten / Προσοχή, συμβουλευτείτε τα συνοδευτικά έγγραφα / Precaución, consultar la documentación adjunta / Ettevõtjalt! Lugeda kaasnevat dokumentatsiooni / Attention, consulter les documents joints / Uropejzenie, koristi pratecu dokumentaciju / Figyelem! Olvassa el a mellékelt tájékoztató / Attenzione: consultare la documentazione allegata / Абайлаңыз, тілсіз құжаттармен танысыңыз / 주의, 동봉된 설명서 참조 / Dămesio, zădărește pridedamarea documentus / Piesardzība, skatīt pavaddokumentus / Voorzichtig, raadpleeg bijgevoegde documenten / Forsiktig, se vedlagt dokumentasjon / Należy zapoznać się z dołączonymi dokumentami / Cuidado, consulte a documentação fornecida / Atenție, consultați documentele însoțitoare / Внимание: см. прилагаемую документацию / Výstraha, pozri sprievodné dokumenty / Pažnjal! Pogledajte priložena dokumenta / Obs! Se medföljande dokumentation / Dikkat, birlikte verilen belgelere başvurun / Увага: див. супутню документацію / 小心, 请参阅附带文档。



Upper limit of temperature / Горен лимит на температурата / Horní hranice teploty / Øvre temperaturgrænse / Temperaturobergrenze / Avúteró öro verrykroqloq / Limite superior de temperatură / Ülemine temperatuuripiiri / Limite supérieure de température / Gornja dozvoljena temperatura / Felső hőmérsékleti határ / Limite superiore di temperatura / Температурный рұқсат етілен жоғары шегі / 상한 온도 / Augššiausia laikymo temperatūra / Augšējā temperatūras robeža / Hoogste temperatuurlimiet / Øvre temperaturgrænse / Górná granica temperatury / Limite máximo de temperatura / Limită maximă de temperatură / Верхний предел температуры / Horná hranica teploty / Gornja granica temperature / Øvre temperaturgräns / Sicaklık üst sınırı / Максимальна температура / 温度上限



Keep dry / Пазете сухо / Skladujte v suchém prostředí / Opbevaras tørt / Trocklegen / Φυλάξτε το στεγνό / Mantener seco / Houde kuiv / Conserver au sec / Držati na suhom / Százraz helyen tartandó / Tenere all'asciutto / Курақ күйінде ұста / 건조 상태 유지 / Laikykite sausai / Uzglabāt sausu / Droog houden / Houdes tørt / Przechowywać w stanie suchym / Manter seco / A se feri de umezeală / Не допускать попадания влаги / Uchovávať v suchu / Držite na suvom mestu / Förvaras tørt / Kuru bir şekilde muhafaza edin / Беретти від вологоти / 请保持干燥



Collection time / Време на събиране / Čas odběru / Opsamlingstidspunkt / Entnahmeuhrzeit / Ώρα συλλογής / Hora de recogida / Kogumisaeg / Heure de prélèvement / Sati prikupljanja / Mintavétel időpontja / Ora di raccolta / Жинау уақыты / 수집 시간 / Paëmimo laikas / Savākšanas laiks / Verzameltijd / Tid prøvetagning / Godzina pobrania / Hora de coleta / Ora colectării / Время сбора / Doba odboru / Vreme prikupljanja / Uppsamlingstid / Toplama zamanı / Час забору / 采集时间



Peel / Обелете / Otevete zde / Abn / Abziehen / Αποκολλήστε / Desprender / Koorida / Décoller / Otvoriti skini / Húzza le / Vreccare / Ξτιρίκι καθαίρων αλμπ ταστα / 벗기거나 / Aftmet / Schillen / Trekk av / Oderwac / Destacar / Se dezlipeste / Отклеивать / Odrhните / Oluštiti / Dura isår / Айырма / Відклеїти / 撕下



Perforation / Перфорация / Perforace / Perforering / Διάτρηση / Perforación / Perforatsioon / Perforacija / Perforálás / Perforazione / Тесик тесы / 찔림선 / Perforacija / Perforăcija / Perforatie / Perforacja / Perforação / Perforare / Перфорация / Perforácia / Perforasyon / Перфорация / 穿孔



Do not use if package damaged / Не използвайте, ако опаковката е повредена / Nepoužívejte, je-li obal poškozený / Må ikke anvendes hvis emballagen er beskadiget / Inhal beschädigter Packungsnicht verwenden / Μη χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιά / No usar si el paquete está dañado / Mitte kasutada, kui pakend on kahjustatud / Ne pas l'utiliser si l'emballage est endommagé / Ne koristite ali el paketi on mädanenud / Ne használja, ha a csomagolás sérült / Non usare se la confezione è danneggiata / Επερ paket õhusõrnat lõpetatud, pakikandab / 폐기되거나 손상된 경우 사용 금지 / Jei paketo pažeista, nenaudoti / Nelietot, ja iepakojums bojāts / Niet gebruiken indien de verpakking beschadigd is / Må ikke brukes hvis pakke er skadet / Nie używać, jeśli opakowanie jest uszkodzone / Não usar se a embalagem estiver danificada / A nu se folosi dacă pachetul este deteriorat / Не използвайте при повредени опаковки / Nepoužívejte, ak je obal poškozený / Ne koristite ako je pakovanje oštećeno / Använd ej om förpackningen är skadad / Ambalaj hasar görmüştse kullanmayın / Не використовуйте при пошкодженій упаковці / 如果包裝破損, 請勿使用



Keep away from heat / Пазете от топлина / Nevstavujte přilišnému teplu / Må ikke udsættes for varme / Vor Wärme schützen / Κρατήστε το μακριά από τη θερμότητα / Mantener alejado de fuentes de calor / Hoida eemal valgusest / Protéger de la chaleur / Držati dalje od izvora topline / Øvja a melegtli / Tenere lontano dal calore / Саққын жерде сақта / 열을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargāt no karstuma / Beschermen tegen warmte / Må ikke utsettes for varme / Przechowywać z dala od źródeł ciepła / Manter ao abrigo do calor / A se feri de căldură / Не награвате / Uchovávejte mimo zdroja tepla / Držite dalje od toplote / Får ej utsättas för värme / Isidan uzak tutun / Беретти від віді тєплн / 请远离热源



Cut / Срежете / Odstřihněte / Klip / Schneiden / Κόψτε / Cortar / Lõigata / Découper / Reži / Vágja ki / Tagliare / Keciñiz / 잘라내기 / Kirpti / Nogriezet / Knippen / Kutt / Odciać / Cortar / Decupati / Отрезать / Odstrhните / Iseći / Klipp / Kesme / Ποσιπάτι / 剪下



Collection date / Дата на събиране / Datum odběru / Opsamlingsdato / Entnahmdatum / Ημερομηνία συλλογής / Fecha de recogida / Kogumikuupäev / Date de prélèvement / Dani prikupljanja / Mintavétel dátuma / Data di raccolta / Жинау тәуелік күні / 수집 날짜 / Paëmimo data / Savākšanas datums / Verzameldatum / Dato preveetaking / Data pobrania / Data de coleta / Data colectării / Дата сбора / Datum odboru / Datum prikupljanja / Uppsamlingsdatum / Toplama tarihi / Дата забору / 采集日期



µL/test / mL/тест / µL/Test / mL/εξέταση / µL/prueba / mL/тест / mL/테스트 / mL/тест / mL/tyrimas / µL/pārbaude / mL/teste / mL/анализ / mL/检测



Keep away from light / Пазете от светлина / Nevstavujte světlu / Må ikke udsættes for lys / Vor Licht schützen / Κρατήστε το μακριά από το φως / Mantener alejado de la luz / Hoida eemal valgusest / Conserver à l'abri de la lumière / Držati dalje od svetla / Fény nem érheti / Tenere al riparo dalla luce / Қараңғыланған жерде ұста / 빛을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargāt no gaismas / Niet blootstellen aan zonlicht / Må ikke utsettes for lys / Przechowywać z dala od źródeł światła / Manter ao abrigo da luz / Feriti de lumină / Хранити в темноті / Uchovávejte mimo dosahu svetla / Držite dalje od svetlosti / Får ej utsättas för ljus / Işıktan uzak tutun / Беретти від віді світла / 请远离光源



Hydrogen gas generated / Образован в водород газ / Možnost úniku plyného vodíku / Frembringer hydrogensgas / Wasserstoffgases erzeugt / Δημιουργία αερίου υδρογόνου / Producción de gas de hidrógeno / Vesinikigaasi tekitatud / Produit de l'hydrogène gazeux / Sadržaji hydrogen vodik / Hydrogen gázt fejezt / Produzione di gas idrogeno / Газтөрес сүрети найда болды / 수소 가스 생성됨 / Ißskria vandenilio dujas / Rodas udegnarai / Waterstofgas gegenereerd / Hydrogenngas generert / Powoduje powstawanie wodoru / Produção de gás de hidrogénio / Generare gaz de hidrogen / Выделение водорода / Vyrobené použitím vodíku / Oslobada se vodonik / Genererad vätsgas / Açığa çıkan hidrojen gazı / Реакция з виділенням водню / 会产生氢气



Patient ID number / ID номер на пациента / ID pacienta / Patientens ID-nummer / Patienten-ID / Αριθμός αναγνώρισης ασθενούς / Número de ID del paciente / Patsiendi ID / No d'identification du patient / Identifikacijski broj pacijenta / Beteg azonosító száma / Numero ID paziente / Пациенттінк идентификациялык нөмүрү / 환자 ID 번호 / Paciento identifikavimo numeris / Pacienta ID numurs / Identificatienummer van de patiënt / Patientens ID-nummer / Numer ID pacienta / Número da ID do doente / Număr ID pacient / Идентификационный номер пациента / Identifikacné číslo pacienta / ID broj pacijenta / Patientnummer / Hasta kimlik numarasi / Идентификатор пациента / 患者标识号



Fragile, Handle with Care / Чупливо, Роботете с необходимото внимание. / Кřekk. Pfi manipulaci postupujte opatrně. / Forsigtig, kan gå i stykker. / Zerbrechlich, vorsichtig handhaben. / Ευθρόστο. Χειρτείτε το με προοχη. / Frágil. Manipular con cuidado. / Õrn, käsitsese ettevaatlikult. / Fragile. Manipuler avec précaution. / Lomljivo, rukujte pažljivo. / Törékeny! Óvatosan kezelendő. / Fragile, maneggiare con cura. / Сыньш, абайлан пайдаланыңыз. / 조심 깨지거나 쉬운 처리 / Trapp, elkites atsargial. / Trausis, rikotes uzmanigi / Breekbaar, voorzichtig behandelen. / Ömtålig, händter försiktig. / Kruha zawartość, przenosić ostrożnie. / Frágil, Manuseie com Cuidado. / Fragil, manipulați cu atenție. / Хрупкое! Обращаться с осторожностью. / Křekk, vyžaduje sa opatrná manipulácia. / Lomljivo - rukujte pažljivo. / Bräckligt. Hantera försiktigt. / Kolay Kırılır, Dikkatli Taşın. / Тендіткі, звертатися з обережністю / 易碎, 小心轻放

Rx Only

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