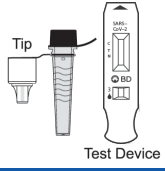
Quick Reference Instructions
BD Kit for Rapid Detection of SARS-CoV-2

REF 256091

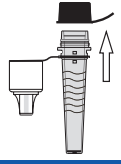
Read the complete test procedure, including recommended QC procedures before performing the test. Refer to the package insert for complete information about the test. Ensure ALL components are at room temperature (15–30 °C) when running the test.

Sample preparation

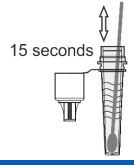
1 Gather test materials and label test device with specimen ID.



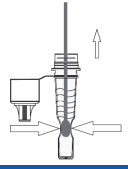
2 Remove cap from extraction reagent tube. Use only reagent tubes provided with this kit.



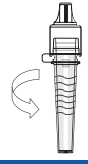
3 Insert patient sample swab and vigorously plunge the swab up and down for 15 seconds taking care not to splash contents out of tube.



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



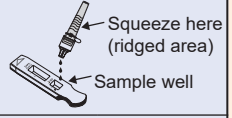
5 Press dispensing tip on the tube firmly. Mix the sample by flicking or swirling the bottom of the tube. Add sample to test device within 30 minutes.



Using the BD assay device

RUNNING THE ASSAY

6 Add **3 drops** of the processed sample to the test device sample well.



7 Allow 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. If running test under laminar flow hood, cover test device to avoid inconsistent flow.

8 When the test is ready, elevate the test device, if necessary, to a position where the test device reading window is optimally positioned for user visualization. Slowly tilt the test device back and forth to remove unnecessary glare.
Examine the device reading window for the visual presence of lines in the Control (C), Test (T) and Non-specific (N) regions.

9 Record result. Properly dispose of test device. Do not read test devices after 20 minutes.

RESULTS INTERPRETATION

Positive Test

A **positive** specimen result will give two visible lines, one in the Control (C) line region and one in the Test (T) line region. This indicates SARS-CoV-2 antigen is detected. Specimens with a low level of antigen may give a faint Test (T) line. The presence of **any visible Test (T) line,** even if faint, is considered positive.

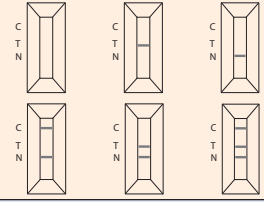
Negative Test

A **negative** specimen result will give a single visible line in the Control (C) line region.

Invalid Test

Invalid test results: Invalid tests should be repeated.
There are six possible invalid test results:

- No visible lines apparent
- Test (T) line only
- Non-specific (N) line only
- Control (C) and Non-specific (N) lines
- Test (T) and Non-specific (N) lines
- Control (C), Test (T), and Non-specific (N) Lines



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CE IVD 2 °C 30 °C

INTERPRETATION OF RESULTS

Test results must be read visually.

Positive Test Results – SARS-CoV-2 antigen detected; 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 due to the presence of a Non-specific (N) line and/or absence of a Control (C) line, the test must 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.

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. Read the test device results visually.
3. Handle all specimens and related materials as if capable of transmitting infectious agents.
4. This assay is compatible with some components of the BD Veritor™ Plus System kits. However, test device will not work with the BD Veritor™ Plus System Analyzer.
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. Keep test devices level and undisturbed for duration of the 15 minute incubation.
8. Please refer to the package insert for detailed assay instructions, cautions, limitations and warnings.

Technical Service and Support: contact your local BD representative or bd.com.

Made in China

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bd.com/e-labeling

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