Quick Reference Guide for BD Veritor™ RSV CLIA waived kit cat no. 256038

BD Veritor™ System for Rapid Detection of RSV

Nasopharyngeal Swab Test Procedure R_x Only

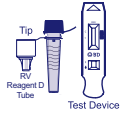
Read the complete test procedure, including recommended QC procedures before performing the test. Refer to the package insert for complete information about the test.

For Questions and Technical Support call 1-800-638-8663.

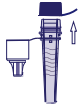
A Certificate of Waiver is required to perform this test in a CLIA waived setting. Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived category.

I. Sample preparation steps 1-5 are shared by all instrument configurations:

1 Gather materials and label with specimen ID

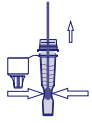


2 Remove cap from **Reagent D** tube

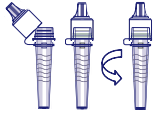


3 Insert sample swab completely, swirl against inside wall of tube 3 times

4 Remove swab while squeezing tube to extract liquid



5 Press the dispensing tip on the tube firmly and vortex the sample



II. Before continuing to step 6, choose from the instrument and work flow configurations below:

A — Reader or Analyzer in Analyze Now mode

6 Add 3 drops of the processed sample to the device.

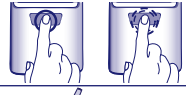
7 Time test development for 10 minutes.

8 Power on instrument with a **single click** and insert device to read when prompted.

9 Record result and remove device.

B — Analyzer in Walk Away mode

6 Click once to power on, wait for prompt then **double-click** to start WalkAway mode.



7 Add 3 drops of the processed sample to the device.

8 Insert device to start timing and analysis. **Do not touch/keep level.**

9 Record result and remove device - Analyzer returns to Analyze Now mode.

INTERPRETATION OF RESULTS

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

Positive Test Results – RSV antigen present; does not rule out co-infection with other pathogens.

Negative Test Results – Negative results are presumptive and it is recommended that these results be confirmed by viral culture or an FDA-cleared RSV molecular test. Negative test results do not preclude RSV viral infection and should not be used as the sole basis for treatment or other patient management decisions.

Invalid Test – If the test is invalid, the **BD Veritor** System Instrument will display a "CONTROL INVALID" result and the test or control must then be repeated.

Display	Interpretation
RSV: +	Positive Test for RSV (RSV antigen present)
RSV: -	Negative Test for RSV (no antigen detected)
CONTROL INVALID	Test Invalid. Repeat the test.

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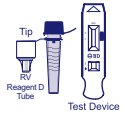
Nasopharyngeal Swab Test Procedure R_x Only

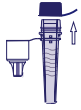
With the Addition of an Optional InfoScan or InfoSync module

I. Sample preparation steps 1-5 are shared by all instrument configurations:

1 Gather materials and label with specimen ID

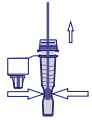


2 Remove cap from **Reagent D** tube

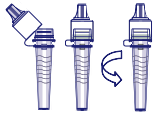


3 Insert sample swab completely, swirl against inside wall of tube 3 times.

4 Remove swab while squeezing tube to extract liquid



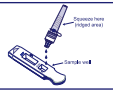
5 Press the dispensing tip on the tube firmly and vortex the sample



II. Before continuing to step 6, choose from the work flow configurations below:

C Analyzer in **Analyze Now** mode + **InfoScan/Sync**

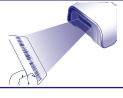
6 Add 3 drops of the processed sample to the device.



7 Time test development for 10 minutes.

8 Power on instrument with a **single click** and insert device to read when prompted.

9 Scan required bar codes to start analysis.

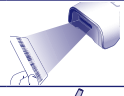


10 Record result and remove device.

D Analyzer in **Walk Away** mode + **InfoScan/Sync**

6 Click once to power on, wait for prompt then **double-click** to start WalkAway mode.

7 Scan required bar codes.



8 Add 3 drops of the processed sample to the device.

9 Insert device to start timing and analysis. **Do not touch/keep level.**

10 Record result and remove device - Analyzer returns to Analyze Now mode.

1. For *in vitro* Diagnostic use.
2. Proper specimen collection and handling is required to ensure accurate results (see specimen collection guide). Freshly collected specimens should be processed within 1 hour. Additional training or guidance is recommended if operators are not experienced with specimen collection and handling.
3. Handle all specimens and materials as if capable of transmitting infectious agents.
4. Dispose of used materials as biohazardous waste according to federal, state and local requirements.
5. Ensure ALL components are at room temperature (15–30 °C) when running the test.

Display	Interpretation
RSV: +	Positive Test for RSV (RSV antigen present)
RSV: -	Negative Test for RSV (no antigen detected)
CONTROL INVALID	Test Invalid. Repeat the test.

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