BD Veritor™ System For Rapid Detection of Flu A+B

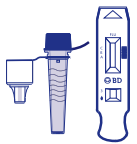
Nasal and Nasopharyngeal Swab Test Procedure Rx Only

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

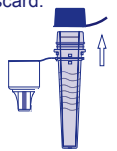
For Questions and Technical Support call 1.800.638.8663.

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.

1 Remove a reagent tube and test device from the foil pouch and label with patient's name.

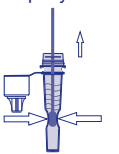


2 Remove the cap from the **RV Reagent D** tube and discard.

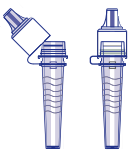


3 Insert the patient sample swab all the way into the tube and swirl it against the inside wall **3** times.

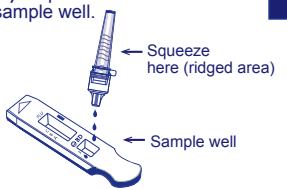
4 Remove the swab while squeezing the sides of the tube. Properly discard the swab.



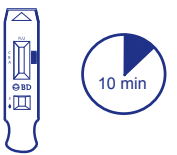
5 Press the attached tip firmly onto the tube.



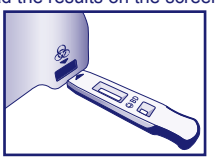
6 Invert the tube and add **(3)** drops to the test device sample well.



7 Let the test run for **(10)** minutes before inserting into reader. Cover device if testing in a laminar flow hood to avoid inconsistent flow.



8 When the test is ready, power-on the reader. When prompted, insert the test device into the reader and read the results on the screen.



INTERPRETATION OF RESULTS

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

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

Positive Test Results – Influenza B 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 influenza A and B molecular test. Negative test results do not preclude influenza 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 Reader will display a "RESULT INVALID" or "CONTROL INVALID" result and the test or control must then be repeated.

Reader Display	Interpretation
FLU A: + FLU B: -	Positive Test for Flu A (influenza A antigen present)
FLU A: - FLU B: +	Positive Test for Flu B (influenza B antigen present)
FLU A: - FLU B: -	Negative Test for Flu A and Flu B (no antigen detected)
RESULT INVALID	Result Invalid. Repeat the Test.
CONTROL INVALID	Test Invalid. Repeat the Test.

The **BD Veritor** System Reader reports dual positive influenza A and influenza B results as "Result Invalid." True dual positives are exceptionally rare. Specimens generating a "Result Invalid" should be retested. Upon retesting, if the specimen produces a "Result Invalid" the user may want to consider other methods to determine whether the sample is positive or negative for influenza virus.

BD Veritor™ System For Rapid Detection of Flu A+B

Rx Only

Nasal and Nasopharyngeal Swab Test Procedure

QUICK REFERENCE GUIDE

This test is CLIA-waived for direct testing of nasal and nasopharyngeal swab specimens. A Certificate of Waiver is required to perform this test in a CLIA waived setting. Follow manufacturer's instructions. Any modifications to the test procedure instructions will result in the test no longer meeting the requirements for waived category and will be subject to all applicable CLIA requirements.

WARNINGS AND PRECAUTIONS

1. For *in vitro* Diagnostic Use Only.
2. All test results must be obtained using the **BD Veritor** System Reader.
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.**

SPECIMEN COLLECTION AND HANDLING

Proper specimen collection and handling is required to ensure accurate results (see enclosed specimen collection guide). Specimens should be tested within 1 hour of collection. Additional training or guidance is recommended if operators are not experienced with specimen collection and handling procedures.

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 swab into the RV Reagent D tube and vigorously plunge the swab up and down for 15 seconds, then process according to the test procedure on the reverse side of this card beginning at Step 4. BD recommends controls are run for each new kit lot, each new operator, and each new shipment of test kits and at periodic intervals as 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.

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