

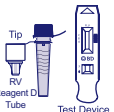

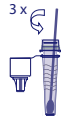

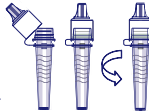


Use of BD Veritor™ System for Rapid Detection of Flu A+B with the BD Veritor™ Plus Analyzer

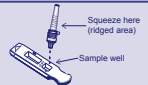



Nasal and Nasopharyngeal Swab Test Procedure R_x Only

Read the complete test procedure, including recommended QC procedures before performing the test. Refer to the package insert for complete information about the test. 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. Failure to follow the manufacturer's instructions or modifications to the test system instructions will result in the test no longer meeting the requirements for waived category and will be subject to all applicable CLIA requirements. 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 **RV Reagent D** tube.
 
- 3** Insert patient sample swab completely. Swirl against inside wall of tube 3 times.
 
- 4** Remove swab while squeezing tube to extract liquid. Properly dispose of swab.
 
- 5** Press the dispensing tip on the tube firmly and mix the sample thoroughly by swirling the bottom of the tube.
 

Using the BD Veritor Plus Analyzer to read the assay device

ANALYZE NOW MODE		OR	WALK AWAY MODE (instrument must be plugged in)	
6	Add 3 drops of the processed sample to the test device sample well.		6	Press blue start button once to power on. When prompt appears, double click to enter Walk-Away mode. Three minute countdown timer displays time remaining for test device insertion.
7	Allow test to develop for 10 minutes. CAUTION: Incorrect results may occur if development time is less than 10 minutes. Cover test device if working in a drafty environment.	10 min 	7	Optional: If using the barcode scanning accessory, follow screen prompts to scan any required barcodes.
8	When test is ready, power on instrument by pressing blue start button once. When prompted, insert device to read.		8	Add 3 drops of the processed sample to the test device sample well.
9	Result will appear on screen. Record result and remove test device. Properly dispose of test device.		9	Confirm timer is visible and Walk Away mode is activated before inserting device. Insert device to start assay timing and analysis. Do not touch instrument during analysis. Keep level.
				Result will appear on the screen after analysis is complete (10 minutes). Record result, remove test device and discard properly. Instrument returns to Analyze Now mode when test device is removed.

See reverse for interpretation of results and quality control procedures. For Questions and Technical Support call 1.800.638.8663.

Use of BD Veritor™ System for Rapid Detection of Flu A+B with the BD Veritor™ Plus Analyzer

Nasal and Nasopharyngeal Swab Test Procedure R_x Only

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 Plus System Analyzer 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.

WARNINGS AND PRECAUTIONS

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

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 one 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 procedures on the reverse side of this card beginning at step 4. BD recommends running controls for each new kit lot, each new operator, and each new shipment of test kits or at periodic intervals required by your facility. If the kit controls do not perform as expected, do not report patient results and contact BD Technical Support at 1.800.638.8663.



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INTERPRETATION OF RESULTS

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

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

Positive Test Results - Influenza B antigen present; does not rule out coinfection with other pathogens.

Negative test results - Negative results are presumptive. 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 Plus System Analyzer will display a "RESULT INVALID" or "CONTROL INVALID" result and the test or control must then be repeated.