

Rapid Detection of Influenza A+B using BD Veritor™ System

Purpose	The Veritor™ System for Rapid Detection of Flu A+B, a moderately complex test under CLIA, is a rapid chromatographic immunoassay used for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasopharyngeal (NP) swabs of symptomatic patients.
Scope	Clinical Laboratory Scientists and Medical Laboratory Technicians. CLIA – Moderately complex
Policy	<ul style="list-style-type: none">• This rapid detection of Influenza A and B is intended for <i>in vitro</i> diagnostic use only.• Reporting of positive Veritor™ Flu A+B to the Southern California County agencies per Title 17, section 2050 requirements is not required.
Specimen Sources	<ul style="list-style-type: none">• Nasopharyngeal (NP) swabs in Universal Transport Medium or Universal Viral Transport Medium (UTM/UVT) are acceptable specimens for this test.
Specimen Collection	<ul style="list-style-type: none">• Collect sample as soon as possible after onset of symptoms.• Acceptable specimens for testing with the BD Veritor™ System for Rapid Detection of Flu A+B include nasopharyngeal (NP) swab specimens in appropriate transport media.• Specimens obtained early in the course of illness will contain the highest viral titers.
Specimen Transport and Storage	<ul style="list-style-type: none">• Freshly collected specimens should be processed as soon as possible or within 1 hour.• If necessary, specimens may be stored at 2–8 °C for up to 72 hours and then tested at room temperature. After testing, samples should be saved for 3 days at 2-8°C in case the provider will request further testing.• Do not centrifuge specimens prior to use, as the removal of cellular material may adversely affect test sensitivity.

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Rapid Detection of Influenza A+B using BD Veritor™ System , Continued

Specimen Rejection

- Specimen collected using cotton tips, wood shafts and calcium alginate swabs
- Specimens received with discrepant patient information (i.e., name, medical record number, date of birth)
- Unlabeled specimens
- Specimens other than NP swab
- Improperly collected or transported specimens
- Samples not in appropriate transport media (UTM/UVT)

Kit Reagents

Description	Vendor	Storage
BD Veritor™ System Flu A+B - Laboratory kit (moderately complex) 30 test	Becton Dickinson Cat. Nos 256041	Room Temp.

Materials and Supplies Not Provided

- Timer and Tube Rack
- UTM- Universal transport medium / UVT- Universal viral transport medium
- BD Veritor™ System Flu A+B control Swab Set, 10 pairs swabs (Catalog No.256051)

Materials and Supplies Provided

The following components are included in the BD Veritor System for Rapid Detection of Flu A+B kit:

- BD Veritor System Flu A+B Devices: 30 devices with reactive strips
- RV Reagent C: 30 tubes with 100 µL reagent
- 300 µL Transfer pipette: 30 each
- Control **A+**/B- Swab, 1 each of Flu A Positive and Flu B Negative Control Swab influenza A antigen (inactive recombinant nucleoprotein).
- Control **B+**/A- Swab, 1 each of Flu A Negative and Flu B Positive Control Swab, influenza B antigen (inactive recombinant nucleoprotein).

Equipment

- BD Veritor™ Plus System Analyzer (Catalog No. 256066)
- BD Veritor™ InfoScan (optional- Catalog No. 256068)

New **Veritor™ Plus System** must be validated before use.

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Rapid Detection of Influenza A+B using BD Veritor™ System , Continued

Safety and Precautions

- H302 Harmful if swallowed. H402 Harmful to aquatic life. H412 Harmful to aquatic life with long lasting effects. P273 Avoid release to the environment. P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor /physician if you feel unwell. P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- 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.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.

Warning and Precautions

- For in vitro Diagnostic Use.
- Test results are not meant to be visually determined. All test results must be determined using the BD Veritor System Instrument.
- If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to the state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.
- Pathogenic microorganisms, including hepatitis viruses, Human Immunodeficiency Virus and novel influenza viruses, may be present in clinical specimens. “Standard Precautions”¹⁶⁻¹⁹ and institutional guidelines should be followed in handling, storing and disposing of all specimens and all items contaminated with blood and other body fluids.
- Dispose of used BD Veritor System test devices as biohazardous waste in accordance with federal, state and local requirements.
- Do not use kit components beyond the expiration date.
- Do not reuse the BD Veritor System test device.
- Do not use the kit if the Control A+/B- swab and Control B+/A- swab do not yield appropriate results.
- To avoid erroneous results, specimens must be processed as indicated in the assay procedure section.
- FluMist® is made from attenuated live flu virus and although the concentration tested (1%) was non-interfering, it is possible when tested with higher concentrations that an influenza A and/or influenza B false positive may occur.
- Specific training or guidance is recommended if operators are not experienced with specimen collection and handling procedures.

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Rapid Detection of Influenza A+B using BD Veritor™ System , Continued

Specimen Collection Procedure

Follow the steps below to properly collect the required nasopharyngeal swab specimens.

DOs and DON'Ts of Sample Collection:

- Do collect sample as soon as possible after onset of symptoms
- Do test sample immediately – within ONE hour of collection
- BD recommends flocked swabs.
- Do not use cotton tips and wood shafts
- Do not use calcium alginate swab

Specimen collection	
Step	Action
1	Use the flexible flocked nylon tip swab to collect the nasopharyngeal specimen. 
2	Nasopharyngeal: Insert the swab into one nostril of the patient, reaching the surface of the posterior nasopharynx. 
3	Nasopharyngeal: Rotate the swab over the surface of the posterior nasopharynx. 
4	Withdraw the swab from the nasal cavity and place it into a transport medium. The sample is now ready for processing/testing using the BD Veritor™ System Kit. 

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Rapid Detection of Influenza A+B using BD Veritor™ System , Continued

Before you begin

- Patient specimens, reagents and devices must be at room temperature (15-30° C) before beginning the assay.
 - Check expiration date on each component and outer box before using. Do NOT use any test kit components that are expired/past the expiration date
 - Make sure that the BD Veritor™ System Reader is powered-on and ready prior to use.
 - Perform a function test using the verification cartridge on the Analyzer
-

Quality Control

Each BD Veritor System Flu A+B device contains both positive and negative internal/procedural controls:

- The internal positive control 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.
- These positive and negative internal/procedural controls are evaluated by the BD Veritor™ System Reader after insertion of the BD Veritor™ System test device.
- The BD Veritor™ System Reader will prompt the operator, should a quality issue occur. Failure of the internal/procedural controls will generate an invalid test result.
- When the reader displays “RESULT INVALID” or “CONTROL INVALID” it means that the internal/procedural controls failed. The test or control must be repeated.
- If the result of repeat testing is still invalid (internal/procedural controls failed), do not release the patient results. Notify the Manager or contact Becton Dickinson technical support at (800) 638-8663.

External Positive and Negative Controls:

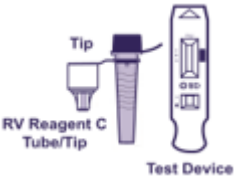
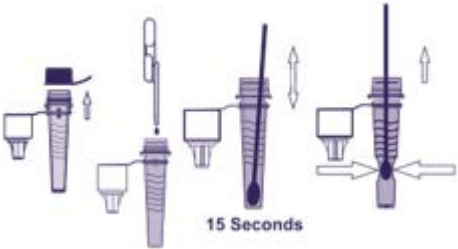
- Swab controls (Flu A positive /B negative and Flu B positive/A negative) are supplied with each kit. Controls must be run daily or follow IQCP.
- BD recommends that positive and negative controls be run once for:
 1. Each new kit lot#
 2. Each new operator
 3. Each new shipment of test kits
 4. As required by internal quality control policies and procedures and in accordance with local, state and federal regulations or accreditation agencies requirements.
- If the results of the kit controls are INVALID, DO NOT test patient specimens/release patient results. Notify the Manager or contact Becton Dickinson technical support at (800) 638-8663.

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Rapid Detection of Influenza A+B using BD Veritor™ System , Continued

Testing Control Swab Procedure

Follow the steps below to perform the Testing Control Swab procedure

Testing Control Swab	
Step	Action
1	<p>Prepare for Control Swab Testing:</p> <p>For each Control A+/B- Swab and Control B+/A- Swab:</p> <ul style="list-style-type: none"> Remove one RV Reagent C tube/tip and one BD Veritor System Flu A+B device from its foil pouch immediately before testing. Label each RV Reagent C tubes and BD Veritor System Flu A+B device with each control to be tested. Place the labeled RV Reagent C tube(s) in the designated area of the tube rack. <div style="text-align: center;">  <p>The diagram shows a small white pipette tip labeled 'Tip' next to a purple 'RV Reagent C Tube/Tip'. To the right is a white 'Test Device' with a purple cap and a window.</p> </div>
2	<p>Prepare the Control Swabs:</p> <ul style="list-style-type: none"> Remove and discard the cap from the RV Reagent C tube corresponding to the control to be tested. Using the transfer pipette, transfer 300uL of distilled or deionized water to the RV Reagent C tube Insert the Control Swab all the way into the appropriately labeled RV Reagent C tube and vigorously plunge the swab up and down in the fluid for a minimum of 15 seconds. Remove the Control swab while squeezing the sides of the tube to extract the liquid from the swab. Properly discard the swab in the biohazardous waste. <div style="text-align: center;">  <p>The diagram shows a sequence of four steps: 1. A pipette adding liquid to a tube. 2. The tube with liquid. 3. A swab being inserted into the tube. 4. The swab being plunged up and down in the liquid. A double-headed arrow indicates the motion, and the text '15 Seconds' is written below.</p> </div>
3	Proceed to Step 3 of the Testing Patient Specimens Procedure block.

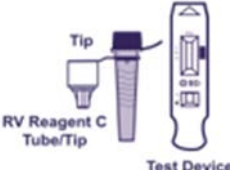
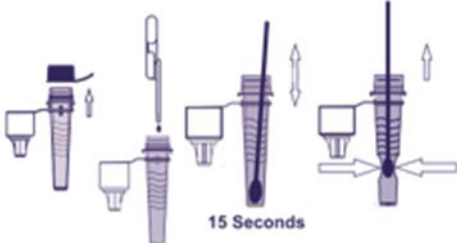
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Rapid Detection of Influenza A+B using BD Veritor™ System , Continued

Testing Patient Specimens Procedure

Follow the steps below for testing patient nasopharyngeal swab specimens.


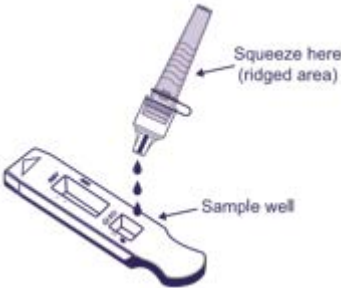

Perform a functional test using the verification cartridge on the Analyzer

Testing Patient Specimens	
Step	Action
1	<p>Prepare for patient testing:</p> <ul style="list-style-type: none"> For each patient specimen, remove one RV Reagent C tube/tip and one BD Veritor™ System Flu A+B device from its foil pouch immediately before testing. Label the RV Reagent C tube and device with each patient's name. Place the labeled RV Reagent C tube(s) in the designated area of the tube rack. <div style="text-align: center;">  <p>The diagram shows a 'RV Reagent C Tube/Tip' on the left, which is a small, clear plastic tube with a white cap. To its right is the 'Test Device', a larger, white, rectangular plastic device with a clear window and a small opening at the top.</p> </div>
2	<p>Prepare the patients' nasopharyngeal swab specimens:</p> <ul style="list-style-type: none"> Vortex or thoroughly mix NP swabs in transport media. Do not centrifuge. Remove and discard the cap from the RV Reagent C tube corresponding to the sample to be tested. Using the transfer pipette, transfer 300 µL of the specimen into the RV Reagent C tube. Discard pipette after use. <div style="text-align: center;">  <p>The diagram shows a sequence of four steps: 1. A transfer pipette is used to draw liquid from a vial. 2. The pipette is held over the open RV Reagent C tube. 3. The pipette tip is inserted into the tube, and liquid is dispensed. 4. The pipette is removed, and the tube is capped. A double-headed vertical arrow indicates a 15-second vortexing period. Below the diagram, the text '15 Seconds' is written.</p> </div>

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Rapid Detection of Influenza A+B using BD Veritor™ System , Continued


**Testing Patient
 Specimens
 Procedure,**
 continued

Step	Action
3	<ul style="list-style-type: none"> • Press the attached tip firmly onto the RV Reagent C tube containing the processed specimen or control (threading/twisting not required). • Vortex or mix thoroughly by swirling or flicking the bottom of the tube <div style="text-align: center;">  </div> <p>Run the Test:</p> <ul style="list-style-type: none"> • Invert the RV Reagent C tube and hold the tube vertically (approximately one inch above the BD Veritor System Flu A+B device sample well). • Holding the RV Reagent C tube at the ridged area, squeeze gently allowing three (3) drops of the processed sample to be dispensed into the sample well of the appropriately labeled BD Veritor System Flu A+B device. <p><i>Note: Squeezing the tube close to the tip may cause leakage.</i></p> <div style="text-align: center;">  </div>
4	<p>Incubate and Turn on the BD Veritor System Reader:</p> <ul style="list-style-type: none"> • After adding the sample, allow the test to run for 10 minutes. <div style="text-align: center;">  </div> <p style="text-align: center;">Note: If running the test under laminar flow hood or in area with heavy ventilation, cover the test device to avoid inconsistent flow.</p>

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Rapid Detection of Influenza A+B using BD Veritor™ System , Continued

Testing Patient Specimens Procedure, continued

Step	Action															
5	<p>Analyze the Results:</p> <ul style="list-style-type: none"> When the test is ready, insert the BD Veritor System Flu A+B device into the BD Veritor Plus Sytem Reader. Follow the Reader on-screen prompts to complete the procedure and obtain the test result. 															
6	<p>Interpretation of External Controls and Patient Specimen results:</p> <p><i>Notes:</i></p> <ul style="list-style-type: none"> <i>The BD Veritor™ Plus System Reader must be used for all interpretation of results.</i> <p><u>Testing personnel should not attempt to interpret assay results directly from the test strip contained within the BD Veritor™ Plus System Flu A+B assay device.</u></p> <table border="1" data-bbox="540 1178 1468 1774"> <thead> <tr> <th data-bbox="540 1178 764 1213">Reader Display</th> <th data-bbox="764 1178 1159 1213">Interpretation</th> <th data-bbox="1159 1178 1468 1213">Report in Cerner as:</th> </tr> </thead> <tbody> <tr> <td data-bbox="540 1213 764 1367">FLU A: + FLU B: -</td> <td data-bbox="764 1213 1159 1367">Positive Test for Flu A (influenza A antigen present) Negative Test for Flu B (no influenza B antigen detected)</td> <td data-bbox="1159 1213 1468 1367">Positive Negative</td> </tr> <tr> <td data-bbox="540 1367 764 1514">FLU A: - FLU B: +</td> <td data-bbox="764 1367 1159 1514">Negative Test for Flu A (no influenza A antigen detected) Positive Test for Flu B (influenza B antigen present)</td> <td data-bbox="1159 1367 1468 1514">Negative Positive</td> </tr> <tr> <td data-bbox="540 1514 764 1591">FLU A: - FLU B: -</td> <td data-bbox="764 1514 1159 1591">Negative Test for Flu A and Flu B (no antigen detected)</td> <td data-bbox="1159 1514 1468 1591">Negative Negative</td> </tr> <tr> <td data-bbox="540 1591 764 1774">Flu A and Flu B Positive RESULT INVALID</td> <td data-bbox="764 1591 1159 1774"> <ul style="list-style-type: none"> Result Invalid, both Flu A and Flu B Repeat the test If result is still Invalid, Report as INVALID </td> <td data-bbox="1159 1591 1468 1774">Invalid Invalid</td> </tr> </tbody> </table>	Reader Display	Interpretation	Report in Cerner as:	FLU A: + FLU B: -	Positive Test for Flu A (influenza A antigen present) Negative Test for Flu B (no influenza B antigen detected)	Positive Negative	FLU A: - FLU B: +	Negative Test for Flu A (no influenza A antigen detected) Positive Test for Flu B (influenza B antigen present)	Negative Positive	FLU A: - FLU B: -	Negative Test for Flu A and Flu B (no antigen detected)	Negative Negative	Flu A and Flu B Positive RESULT INVALID	<ul style="list-style-type: none"> Result Invalid, both Flu A and Flu B Repeat the test If result is still Invalid, Report as INVALID	Invalid Invalid
Reader Display	Interpretation	Report in Cerner as:														
FLU A: + FLU B: -	Positive Test for Flu A (influenza A antigen present) Negative Test for Flu B (no influenza B antigen detected)	Positive Negative														
FLU A: - FLU B: +	Negative Test for Flu A (no influenza A antigen detected) Positive Test for Flu B (influenza B antigen present)	Negative Positive														
FLU A: - FLU B: -	Negative Test for Flu A and Flu B (no antigen detected)	Negative Negative														
Flu A and Flu B Positive RESULT INVALID	<ul style="list-style-type: none"> Result Invalid, both Flu A and Flu B Repeat the test If result is still Invalid, Report as INVALID	Invalid Invalid														

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Rapid Detection of Influenza A+B using BD Veritor™ System , Continued

**Testing Patient
 Specimens
 Procedure,**
 continued

Step	Action		
6, con't	Reader Display	Interpretation	In Cerner:
	POSITIVE CONTROL INVALID OR NEGATIVE CONTROL INVALID	<ul style="list-style-type: none"> • Test invalid • Repeat the test. If Control result is still invalid, Do not report patient results. Notify the Manager or contact Becton Dickinson technical support at (800) 638-8663	Cancel test order using the Cerner cancel message: “Technical Error; Test Not Performed [Under Notes: add reason: Control Invalid]
<p>ALWAYS MESSAGE: Please see below for interpretive criteria:</p> <p>“Positive” Positive for the presence of Influenza A or Influenza B antigen.</p> <p>“Negative” Presumptive negative for Influenza A and Influenza B antigen. If clinically indicated, an alternate method of testing may be warranted.</p> <p>“Invalid” Results inconclusive. If clinically indicated, an alternate method of testing may be warranted.</p>			
7	Document the test results on the Manual Patient Logs and Cerner		

- FLU A [**Positive**, Negative, Invalid] (required)
- FLU B [**Positive**, Negative, Invalid] (required)
- dns Analyzer ID [Veritor #1, Veritor #2] (required)
- dns Lot number (optional)
- dns Expiration date (optional)

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Rapid Detection of Influenza A+B using BD Veritor™ System , Continued

**Method
 Performance
 Specifications
 in
 Manufacturers
 Product Insert**

Summary of the Performance of the BD Veritor System for Rapid Detection of Flu A+B Test Compared to PCR for All NP Wash/Aspirate Specimens:

Reference Method: PCR Flu A

Positive Percent Agreement: 83.0% (95% C.I. 78.0%–87.0%)

Negative Percent Agreement: 97.6% (95% C.I. 96.6%–98.3%)

Reference Method: PCR Flu B

Positive Percent Agreement: 81.0% (95% C.I. 72.1.0%–88.0%)

Negative Percent Agreement: 97.6% (95% C.I. 99.4%–99.9%)

Reproducibility Results – Percent of Flu A Positives				
Sample	Site 1	Site 2	Site 3	Total
High negative H1N1 A	3.3% (1/30) (95% C.I. 0.6%–16.7%)	0.0% (0/30) (95% C.I. 0.0%–11.3%)	0.0% (0/30) (95% C.I. 0.0%–11.3%)	1.1% (1/90) (95% C.I. 0.2%–6.0%)
Low positive H1N1 A	93.3% (28/30) (95% C.I. 78.7%–98.2%)	86.7% (26/30) (95% C.I. 70.3%–94.7%)	93.3% (28/30) (95% C.I. 78.7%–98.2%)	91.1% (82/90) (95% C.I. 83.4%–95.4%)
Moderate positive H1N1 A	100.0% (30/30) (95% C.I. 88.6%–100.0%)	96.7% (29/30) (95% C.I. 83.3%–99.4%)	100.0% (30/30) (95% C.I. 88.6%–100.0%)	98.9% (89/90) (95% C.I. 94.0%–99.8%)
High negative H3N2 A	16.7% (5/30) (95% C.I. 7.3%–33.6%)	3.3% (1/30) (95% C.I. 0.6%–16.7%)	0.0% (0/30) (95% C.I. 0.0%–11.3%)	6.7% (6/90) (95% C.I. 3.1%–13.8%)
Low positive H3N2 A	93.3% (28/30) (95% C.I. 78.7%–98.2%)	86.7% (26/30) (95% C.I. 70.3%–94.7%)	93.3% (28/30) (95% C.I. 78.7%–98.2%)	91.1% (82/90) (95% C.I. 83.4%–95.4%)
Moderate positive H3N2 A	100.0% (30/30) (95% C.I. 88.6%–100.0%)	100.0% (30/30) (95% C.I. 88.6%–100.0%)	96.7% (29/30) (95% C.I. 83.3%–99.4%)	98.9% (89/90) (95% C.I. 94.0%–99.8%)
Negatives	0.8% (1/120) (95% C.I. 0.1%–4.6%)	0.0% (0/120) (95% C.I. 0.0%–3.1%)	0.0% (0/119) (95% C.I. 0.0%–3.1%)	0.3% (1/359) (95% C.I. 0.0%–1.6%)
Reproducibility Results – Percent of Flu B Positives				
Sample	Site 1	Site 2	Site 3	Total
High negative B	3.3% (1/30) (95% C.I. 0.6%–16.7%)	0.0% (0/30) (95% C.I. 0.0%–11.3%)	0.0% (0/30) (95% C.I. 0.0%–11.3%)	1.1% (1/90) (95% C.I. 0.2%–6.0%)
Low positive B	90.0% (27/30) (95% C.I. 74.4%–96.5%)	63.3% (19/30) (95% C.I. 45.5%–78.1%)	82.8% (24/29) (95% C.I. 65.5%–92.4%)	78.7% (70/89) (95% C.I. 69.0%–85.9%)

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Rapid Detection of Influenza A+B using BD Veritor™ System , Continued

**Calculations in
 Manufacturers
 Product Insert**

	Reference PCR		
Clinical kit: BD Flu A	P	N	Total
P	224	29	253
N	46	1172	1218
Total	270	1201	1471
Reference Method: PCR PPA: 83.0% (95% C.I. 78.0%–87.0%) NPA: 97.6% (95% C.I. 96.6%–98.3%)			

	Reference PCR		
Clinical kit: BD Flu B	P	N	Total
P	74	3	77
N	17	1377	1394
Total	91	1380	1471
Reference Method: PCR PPA: 81.3% (95% C.I. 72.1%–88.0%) NPA: 99.8% (95% C.I. 99.4%–99.9%)			

PPA: Positive Percent Agreement = $a / (a+c) \times 100\%$

NPA: Negative Percent Agreement = $d / (b+d) \times 100\%$

**Reference
 Range**

**Negative for Flu A
 Negative for Flu B**

Rapid Detection of Influenza A+B using BD Veritor™ System , Continued

Limitations

- 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 influenza type A and B antigens from NP wash, aspirate and swab in transport media specimens.
- The BD Veritor System for Rapid Detection of Flu A+B is capable of detecting both viable and non-viable influenza particles. The BD Veritor System for Rapid Detection of Flu A+B performance depends on antigen load and may not correlate with other diagnostic methods performed on the same specimen.
- Results from the BD Veritor System for Rapid Detection of Flu A+B 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 influenza A or influenza B infection, and should be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay.
- Positive test results do not rule out co-infections with other pathogens.
- Positive test results do not identify specific influenza A virus subtypes.
- Negative test results are not intended to rule out other non-influenza viral or bacterial infections.
- Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children.
- 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 influenza activity when disease prevalence is low. False negative test results are more likely during peak influenza activity when prevalence of disease 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, influenza A viruses that have undergone minor amino acid changes in the target epitope region.

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Rapid Detection of Influenza A+B using BD Veritor™ System , Continued

Limitations,
continued

- The analytical reactivity of this device has not been established for avian or swine origin influenza strains other than those included in the “Strain Reactivity” tables.
 - The BD Veritor System Instrument 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.
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Controlled Documents

The following controlled documents support this procedure.

- Flu A+B Patient log (FLU A+B-020)
 - Flu A+B Quality Control Log (FLU A+B-021)
 - Flu A+B New Reagent Shipment Log (FLU A+B-022)
 - Flu A+B Reagent kit Parallel test log (FLU A+B-023)
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Non-Controlled Documents

The following non-controlled documents support this procedure.

- BD Veritor™ Plus System Reader Instruction Manual
 - BD Veritor™ System for Rapid Detection for Flu A+B package Insert (2016-05)
-

end

Rapid Detection of Influenza A+B using BD Veritor™ System, Continued

Reviewed and approved by (for Medical Center Area Approval Only):

SIGNATURE	DATE
Name: _____ Operations Director, Area Laboratory	
Name: _____ CLIA Laboratory Director	

Signature Manifest

Document Number: SCPMG-PPP-0169

Revision: 01

Title: Procedure Rapid Detection of Flu A+B

All dates and times are in Pacific Standard Time.

Procedure Rapid Detection of Flu A+

Change Request

Name/Signature	Title	Date	Meaning/Reason
Paulette Medina (K088673)	ASST DIR REGL LAB		
Onie Bueno (K109914)	DIR OPER REGL LAB		
Sienna Mendoza (Z344484)	Assistan Director		
Vahe Khanlian (O532803)	RRL DIR OF LAB SVCS, MIC	13 Oct 2017, 03:07:02 PM	Approved

Collaboration

Name/Signature	Title	Date	Meaning/Reason
Sienna Mendoza (Z344484)	Assistan Director		
Onie Bueno (K109914)	DIR OPER REGL LAB		
Vahe Khanlian (O532803)	RRL DIR OF LAB SVCS, MIC	13 Oct 2017, 03:07:41 PM	Complete
Ruby Hines (K118167)	RRL VIR Assistant Dir	16 Oct 2017, 11:44:21 AM	Complete

Initial Approval

Name/Signature	Title	Date	Meaning/Reason
Jonathan Gullett (A278318)	Physician Dir, Microbiology	17 Oct 2017, 11:41:13 AM	Approved

Final Approval

Name/Signature	Title	Date	Meaning/Reason
David Quam (P092597)	Rgnl Mg Admn-Pmg Executive	17 Oct 2017, 12:31:20 PM	Approved

Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Matthew Jones (F754627)	Systems Consultant		
Laura Perry (S533438)	Admin Spec II	17 Oct 2017, 12:33:44 PM	Approved

Notify Users

Name/Signature	Title	Date	Meaning/Reason
Suzy Ghazarossian (S789445)	DIR AREA LAB	17 Oct 2017, 12:33:44 PM	Email Sent
Mary Lou Beaumont (A335097)	Lab Operations Director	17 Oct 2017, 12:33:44 PM	Email Sent
Dennis Sevilla (E555721)	RRL Dir of Lab Svcs, AP	17 Oct 2017, 12:33:44 PM	Email Sent
Marina Bonus (F234915)	Area Lab Manager	17 Oct 2017, 12:33:44 PM	Email Sent
Matthew Jones (F754627)	Systems Consultant	17 Oct 2017, 12:33:44 PM	Email Sent
Justin Welch (L835238)	Dir Regl Lab Ancillary Svcs	17 Oct 2017, 12:33:44 PM	Email Sent
Princess Vergara (G862357)	RRL EHS Director	17 Oct 2017, 12:33:44 PM	Email Sent
Vasundara Ramarajan (I678169)	DIR OPER AREA LAB	17 Oct 2017, 12:33:44 PM	Email Sent

Timothy McSkane (W394565)	Exe Ldr, Lab Care Delivery	17 Oct 2017, 12:33:44 PM	Email Sent
Louie Farnacio (I575517)	RL OPERATIONS DIRECTOR	17 Oct 2017, 12:33:44 PM	Email Sent
Vincent Dizon (I713793)	Director of Lab Services, Chem	17 Oct 2017, 12:33:44 PM	Email Sent
Richard Robertson (K089911)	Lab Ops Director	17 Oct 2017, 12:33:44 PM	Email Sent
Fred Ung (K057175)	SCPMG LABORATORY QCD	17 Oct 2017, 12:33:44 PM	Email Sent
Keith Lawson (K059352)	LTS Director	17 Oct 2017, 12:33:44 PM	Email Sent
Stephanie Prien (K081422)	SCPMG Lab Informatics Director	17 Oct 2017, 12:33:44 PM	Email Sent
Deborah Chantry (K082598)	DIR AREA LAB	17 Oct 2017, 12:33:44 PM	Email Sent
Julie Toti (K084521)	DIR AREA LAB	17 Oct 2017, 12:33:44 PM	Email Sent
Paulette Medina (K088673)	ASST DIR REGL LAB	17 Oct 2017, 12:33:44 PM	Email Sent
Denise Topliff (K104172)	DIR AREA LAB	17 Oct 2017, 12:33:44 PM	Email Sent
Onie Bueno (K109914)	DIR OPER REGL LAB	17 Oct 2017, 12:33:44 PM	Email Sent
Janice Wolf (K119893)	Operations Director	17 Oct 2017, 12:33:44 PM	Email Sent
Diane Giles (K123520)	Director	17 Oct 2017, 12:33:44 PM	Email Sent
Roberto Rabot (K131446)	Director	17 Oct 2017, 12:33:44 PM	Email Sent
Chongbae Lee (K153165)	Director Core Lab	17 Oct 2017, 12:33:44 PM	Email Sent
Kenneth Campbell (K237295)	DIR AREA LAB	17 Oct 2017, 12:33:44 PM	Email Sent
Charles Park (K239415)	Director of Operations	17 Oct 2017, 12:33:44 PM	Email Sent
Vahe Khanlian (O532803)	RRL DIR OF LAB SVCS, MIC	17 Oct 2017, 12:33:44 PM	Email Sent
Laura Perry (S533438)	Admin Spec II	17 Oct 2017, 12:33:44 PM	Email Sent
Hany Boutros (T193254)	OPS Director	17 Oct 2017, 12:33:44 PM	Email Sent
Karen Schellhardt (G586652)	Lab Ops Director	17 Oct 2017, 12:33:44 PM	Email Sent
Charles Mabaquiao (W134322)	Lab Ops Director	17 Oct 2017, 12:33:44 PM	Email Sent
Mike Moradian (W555134)	DIR LAB SERVICES, Genetics	17 Oct 2017, 12:33:44 PM	Email Sent
Timothy Cotroneo (Y383647)	Operations Director	17 Oct 2017, 12:33:44 PM	Email Sent
Sienna Mendoza (Z344484)	Assistan Director	17 Oct 2017, 12:33:44 PM	Email Sent