CE 8087666(10)
2016-05

Veritor™ System

For Rapid Detection Flu A+B

Laboratory kit configured for testing liquid nasopharyngeal wash, aspirate and swab in transport media samples.

Kit de laboratoire conçu pour l'analyse d'échantillons liquides de lavage, d'aspiration et d'écouvillonnage rhino-pharyngés en milieu de transport.

Labor-Testkit zum Testen von flüssigen Nasopharyngeal-Spülungen, -Aspiraten und -Abstrichen in Proben in Transportmedien.

Kit per laboratorio configurato per l'analisi di lavaggi, tamponi e aspirati nasofaringei nei campioni di terreni di trasporto.

Kit de laboratorio configurado para analizar muestras de lavados, aspirados y torundas nasofaríngeos en medio de transporte.

Contact your local BD representative for instructions. / Свържете се с местния представител на BD за инструкзии. / Pokyny vám poskytne místní zástupce společnosti BD. / Kontakt den lokale BD repræsentant for at få instruktioner. / Επικοινωνήστε με τον τοπικό αντιπρόσωπο της BD για οδηγίες. / Kasutusjuhiste suhtes kontakteeruge oma kohaliku BD esindajaga. / Ota yhteys lähimpään BD:n edustajaan ohjeiden saamiseksi. / Kontaktiraj lokalnog predstavnika BD za upute. / A használati utasítást kérje a BD helyi képviseletétől. / Нұсқаулар үшін жергілікті BD өкілімен хабарласыңыз. / Lai saņemtu norādījumus, sazinieties ar vietējo BD pārstāvi. / Naudojimo instrukcijų teiraukitės vietos BD įgaliotojo atstovo. / Neem contact op met uw plaatselijke BD-vertegenwoordiger voor instructies. / Kontakt din lokale BD-representant for mer informasjon. / Aby uzyskać instrukcje użytkowania, skontaktuj się z lokalnym przedstawicielstwem BD. / Contacte o representante local da BD para instruções. / Pentru instrucţiuni, contactaţi reprezentantul local BD. / Для получения указаний обратитесь к местному представителю компании BD. / Inštrukcie získate u miestneho zástupcu spoločnosti BD. / Obratite se svom lokalnom predstavniku kompanije BD za uputstva. / Kontakta närmaste BD-representant för anvisningar. / Talimatlar için yerel BD temsilcinizle temasa geçin. / За інструкціями зверніться до місцевого представника компанії BD.

30

Determinations
Déterminations
Bestimmungen
Determinazioni
Determinaciones

BD Veritor™ System

For Rapid Detection of Flu A+B

Rx Only

For *in vitro* diagnostic use only.

INTENDED USE

The **BD Veritor**™ System for Rapid Detection of Flu A+B is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasopharyngeal wash, aspirate and swab in transport media samples from symptomatic patients. The **BD Veritor** System for Rapid Detection of Flu A+B is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. A negative test is presumptive and it is recommended that these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Outside the U.S. a negative test is presumptive and it is recommended that these results be confirmed by viral culture or a molecular assay cleared for diagnostic use in the country of use. FDA has not cleared this device outside the U.S. 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. The test is not intended to detect influenza C antigens.

Performance characteristics for influenza A and B nasopharyngeal (NP) washes/aspirates were established during January through March of 2011 when influenza viruses A/2009 H1N1, A/H3N2, B/Victoria lineage, and B/Yamagata lineage were the predominant influenza viruses in circulation according to the *Morbidity and Mortality Weekly Report* from the CDC entitled "Update: Influenza Activity—United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine." Performance characteristics may vary against other emerging influenza viruses.

Performance characteristics for influenza A and B NP swabs in transport media were established during January through April of 2012 when influenza viruses A/2009 H1N1, A/H3N2, B/Victoria lineage, and B/Yamagata lineage were the predominant influenza viruses in circulation according to the *Morbidity and Mortality Weekly Report* from the CDC entitled "Update: Influenza Activity—United States, 2011-2012 Season, and Composition of the 2012-2013 Influenza Vaccine." Performance characteristics may vary against other emerging influenza viruses.

If infection with a novel influenza 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. Virus culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

SUMMARY AND EXPLANATION

Influenza illness classically presents with sudden onset of fever, chills, headache, myalgias, and a non-productive cough. Epidemics of influenza typically occur during winter months with estimated 114,000 hospitalizations[1] and 36,000 deaths[2] per year in the U.S. Influenza viruses can also cause pandemics, during which rates of illness and death from influenza-related complications can increase dramatically.

Patients who present with suspected influenza may benefit from treatment with an antiviral agent especially if given within the first 48 hours of onset of illness. It is important to rapidly distinguish influenza A from influenza B in order to allow physicians a choice in selective antiviral intervention. Moreover, it is important to determine if influenza A or B is causing symptomatic disease in a particular institution (e.g., nursing home) or community, so that appropriate preventative intervention can be taken for susceptible individuals. It is therefore important to not only rapidly determine whether influenza is present, but also which type of influenza virus is present as severity and treatment can be different.[3]

Diagnostic tests available for influenza include rapid immunoassay, immunofluorescence assay, polymerase chain reaction (PCR), serology, and viral culture.[4-11] Immunofluorescence assays entail staining of specimens immobilized on microscope slides using fluorescent-labeled antibodies for observation by fluorescence microscopy.[6,12,13] Culture methods employ initial viral isolation in cell culture, followed by hemadsorption inhibition, immunofluorescence, or neutralization assays to confirm the presence of the influenza virus.[13-15]

The **BD Veritor** System for Rapid Detection of Flu A+B (also referred to as the **BD Veritor** System and **BD Veritor** System Flu A+B) is a digital immunoassay (DIA) to qualitatively detect influenza A or B nucleoprotein antigens from respiratory specimens of symptomatic patients with a time to result of 10 minutes. The speed and simplified workflow of the **BD Veritor** System for Rapid Detection of Flu A+B makes it applicable as a "STAT" influenza A and B antigen detection test providing relevant information to assist with the diagnosis of influenza. All **BD Veritor** System Flu A+B test devices are interpreted by a **BD Veritor** System Instrument, either a **BD Veritor** Reader or **BD Veritor** Plus Analyzer (the "Analyzer"). When using an Analyzer, procedures to evaluate test devices depend on the workflow configuration chosen. In **Analyze Now mode**, the instrument evaluates assay devices after manual timing of their development. In **Walk Away mode**, devices are inserted immediately after application of the specimen, and timing of assay development and analysis is automated. Additionally, connection of an Analyzer to a printer or IT system is possible if desired. Additional result documentation capabilities are possible with the integration of a **BD Veritor** InfoScan ("InfoScan") or **BD Veritor** InfoSync ("InfoSync") module. Please refer to the Analyzer *Instructions for Use* for details on how to implement these features. InfoSync is not available in all regions.

PRINCIPLES OF THE PROCEDURE

The **BD Veritor** System for Rapid Detection of Flu A+B is a qualitative digital immunoassay for the detection of influenza A and B viral antigens in samples processed from respiratory specimens. When specimens are processed and added to the test device, influenza A or B viral antigens bind to anti-influenza antibodies conjugated to detector particles in the A+B test strip. The antigen-conjugate complex migrates across the test strip to the reaction area and is captured by the line of antibody on the membrane. A positive result for influenza A is determined by the **BD Veritor** System Instrument when antigen-conjugate is deposited at the Test "A" position and the Control "C" position on the **BD Veritor** System Flu A+B assay device. A positive result for influenza B is determined by the **BD Veritor** System Instrument when antigen-conjugate is deposited at the Test "B" position and the Control "C" position in the **BD Veritor** System Flu A+B assay device. The instrument analyzes and corrects for non-specific binding and detects positives not recognized by the unaided eye to provide an objective digital result.

REAGENTS

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	Foil pouched device containing one reactive strip. Each strip has two test lines of monoclonal antibody specific to either Flu A or Flu B influenza viral antigen and murine monoclonal control line antibodies.
RV Reagent C	30 tubes with 100 µL reagent	Detergent with < 0.1% sodium azide
300 µL Pipette	30 each	Transfer pipette
Control A+/B- Swab	1 each	Flu A Positive and Flu B Negative Control Swab, influenza A antigen (inactive recombinant nucleoprotein) with < 0.1% sodium azide
Control B+/A- Swab	1 each	Flu A Negative and Flu B Positive Control Swab, influenza B antigen (inactive recombinant nucleoprotein) with < 0.1% sodium azide

Materials Required But Not Provided: BD Veritor™ System Reader (Cat. No. 256055) or **BD Veritor™** Plus Analyzer (Cat. No. 256066), Timer, Tube Rack for specimen testing.

Optional Equipment: BD Veritor™ InfoScan Module (Cat. No. 256068), **BD Veritor™** InfoSync Module (Cat. No. 256067), USB Printer Cable for **BD Veritor™** Analyzer (Cat. No. 443907), Epson Printer model TM-T20 II.

Warnings and Precautions:

Warning

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.

1. For *in vitro* Diagnostic Use.
2. Test results are not meant to be visually determined. **All test results must be determined using the BD Veritor System Instrument.**
3. 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.
4. 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.
5. Dispose of used **BD Veritor** System test devices as biohazardous waste in accordance with federal, state and local requirements.
6. 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.
7. Do not use kit components beyond the expiration date.
8. Do not reuse the **BD Veritor** System test device.
9. Do not use the kit if the Control A+/B- swab and Control B+/A- swab do not yield appropriate results.
10. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
11. To avoid erroneous results, specimens must be processed as indicated in the assay procedure section.

12. 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.
13. Specific training or guidance is recommended if operators are not experienced with specimen collection and handling procedures.

Storage and Handling: Kits may be stored at 2–30 °C. DO NOT FREEZE. **Reagents and devices must be at room temperature (15–30 °C) when used for testing.**

SPECIMEN COLLECTION AND HANDLING

Specimen Collection and Preparation: Acceptable specimens for testing with the **BD Veritor** System for Rapid Detection of Flu A+B include nasopharyngeal (NP) washes, aspirates and swab specimens in transport media. It is essential that correct specimen collection and preparation methods be followed. Specimens obtained early in the course of the illness will contain the highest viral titers.

Inadequate specimen collection, improper specimen handling and/or transport may yield a false negative result; therefore, training in specimen collection is highly recommended due to the importance of specimen quality to accurate test results.

Specimen Transport Media: The following transport media have been tested and found to be compatible using moderate positive samples with the **BD Veritor** System for Rapid Detection of Flu A+B:

- Modified Amies Medium (liquid), ESwab, Liquid Stuart Medium, Amies, Bartel ViraTrans™, **BD** Universal Transport, Hank's Balanced Salt solution, M4, M4-RT, M5, M6, Normal Saline, Phosphate Buffered Saline.

Samples in these transport media can be stored at 2–8 °C for up to 72 hours. Allow specimens that have been stored at 2–8 °C to warm to room temperature prior to use. Failure to do so may result in inconsistent flow.

Other transport media may be utilized if an appropriate validation exercise is performed.

Specimen Transport and Storage:

Freshly collected specimens should be processed within 1 hour. If necessary, specimens may be stored at 2–8 °C for up to 72 hours and then tested at room temperature. It is essential that correct specimen collection and preparation methods be followed. Do not centrifuge specimens prior to use, as the removal of cellular material may adversely affect test sensitivity.

Procedure for Nasopharyngeal Washes/Aspirates:

- For NP washes/aspirates, sample volumes of 1 to 3 mL are recommended. If transport medium is used, minimal dilution of specimens is recommended.
- Excessive wash volumes should be avoided as they may result in decreased test sensitivity.
- Process specimen as described in "Test Procedure."

Procedure for Nasopharyngeal Swabs in Transport Media:

- For NP swabs in transport media, a minimal volume of transport media (1 mL) is recommended to minimize dilution.
- Process specimen as described in "Test Procedure."

TEST PROCEDURE

NOTES: Allow specimens that have been stored at 2–8 °C to warm to room temperature prior to use. Thoroughly mix all specimens prior to removal of an aliquot for processing. Do not centrifuge specimens.

Prepare for testing

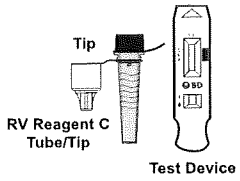
The following steps assume that users of a **BD Veritor** Plus Analyzer have chosen and set all configuration options, and that the Analyzer is ready to use. To choose or change these settings, see the **BD Veritor** Plus Analyzer *Instructions for Use*, section 4.7. A printer is not necessary to display results. However, if your facility has chosen to connect the **BD Veritor** Plus Analyzer to a printer, check that the printer is plugged into a power source, paper supply is adequate and any necessary network connections are enabled before testing.

For each patient specimen or control swab:

Step 1: Remove one **RV Reagent C** tube/tip and one **BD Veritor** System Flu A+B device from its foil pouch immediately before testing.

Step 2: Label one **BD Veritor** System device and one **RV Reagent C** tube for each specimen and control to be tested.

Step 3: Place the labeled **RV Reagent C** tube(s) in the designated area of the tube rack.

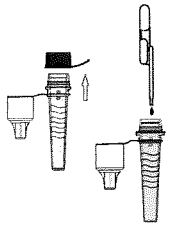


All reagents and specimens must be at room temperature prior to processing

Step 4: Process the Sample or Control:

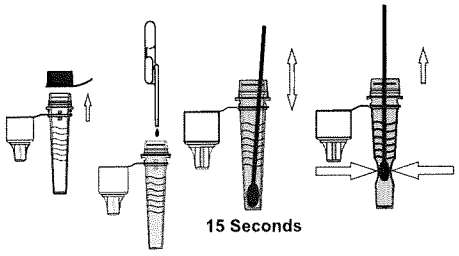
a. **For NP washes, aspirates and swab specimens in transport media:**

1. Vortex or thoroughly mix specimen. Do not centrifuge.
2. Remove and discard the cap from the **RV Reagent C** tube corresponding to the sample to be tested.
3. Using the transfer pipette, transfer 300 µL of the specimen into the **RV Reagent C** tube. Discard pipette after use.



b. **For kit swab controls:**

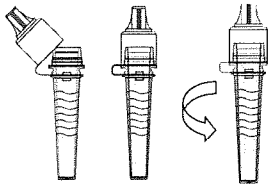
1. Remove and discard the cap from the **RV Reagent C** tube corresponding to the sample to be tested.
2. Using the transfer pipette add 300 µL of distilled or deionized water to the **RV Reagent C** tube.
3. Insert the control swab into the tube and vigorously plunge the swab up and down in the fluid for a minimum of 15 seconds.
4. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.



Step 5:

a. Press the attached tip firmly onto the **RV Reagent C** tube containing the processed specimen or control (threading/twisting not required).

b. Vortex or mix thoroughly by swirling or flicking the bottom of the tube.



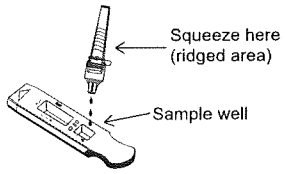
NOTE: Do not use tips from any other product, including other products from BD or other manufacturers.

After step 5, choose from the model and workflow option below before continuing to step 6:				
	BD Veritor Reader or Analyzer in **Analyze Now** mode	**BD Veritor** Plus Analyzer in **Walk Away** mode	**BD Veritor** Plus Analyzer with either InfoScan or InfoSync modules In **Analyze now** mode---or---**Walk Away** mode	
Instructions in section:	**A**	**B**	**C**	**D**

A Using a BD Veritor Reader or Analyzer in "*Analyze Now*" mode:

Step 6A: Adding the specimen

- Invert the **RV Reagent C** tube and hold the tube vertically (approximately one inch above the labeled **BD Veritor** System Flu A+B device sample well).
- Gently squeeze the ridged body of the tube, dispensing three (3) drops of the processed specimen into the sample well of a labeled **BD Veritor** System Flu A+B device.



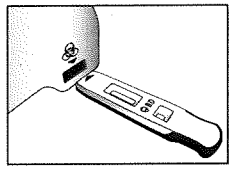
NOTE: Squeezing the tube too close to the tip may cause leakage

Step 7A: Timing development

- After adding the sample, allow the test to run for **10** minutes before inserting into the **BD Veritor** Instrument.
- **NOTE:** If running test under laminar flow hood or in an area with heavy ventilation, cover test device to avoid inconsistent flow.

Step 8A: Using the BD Veritor Instrument:

- During incubation time, turn the **BD Veritor** Instrument on by pressing the power button once.
- Insert the assay device when the 10 minute assay development time is complete. Follow the on screen prompts to complete the procedure.
- The status of the assay analysis process appears in the display window.



Do not touch the Instrument or remove the test device

Step 9A: Record the Result

- When analysis is complete, the test result appears in the display window.

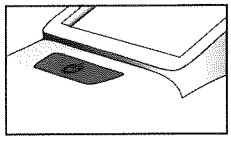
ATTENTION: TEST Results are NOT maintained in the display window when the device is removed or if the Analyzer is left unattended for more than 15 minutes (60 minutes if AC power adapter is connected).

B Using an Analyzer in *"Walk Away" mode:* with no optional module installed

To use Walk Away mode – connect the AC power adapter to the Analyzer and a power source

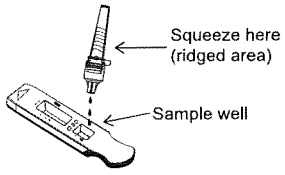
Step 6B: Starting Walk Away mode:

- Turn the Analyzer on by pressing the blue power button once.
- When the display window reads: "INSERT TEST DEVICE OR DOUBLE-CLICK FOR WALK AWAY MODE"
  - **Double-click** the blue power button.



Step 7B: Adding the specimen

- When the display window reads "ADD SPECIMEN TO TEST DEVICE AND INSERT IMMEDIATELY":
  - Invert the tube, holding it vertically (approximately one inch above the **BD Veritor** System Flu A+B device sample well).
  - Gently squeeze the ridged portion of the tube, allowing three (3) drops of the processed specimen to dispense into the sample well of a labeled **BD Veritor** System Flu A+B device.



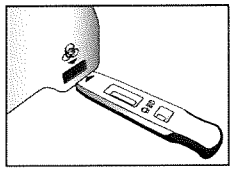
NOTE: Squeezing the tube close to the tip may cause leakage

Step 8B: Start the development and reading sequence

- Immediately insert the test device into the slot on the right side of the Analyzer.

The test device must remain horizontal to prevent spilling the specimen out of the sample well.

- "DO NOT DISTURB TEST IN PROGRESS" appears in the display window. Automatic timing of the assay development, image processing and result analysis begins.
- A countdown timer in the display window shows the remaining analysis time.



Do not touch the Analyzer or remove the test device during this time. Doing so will abort the assay analysis.

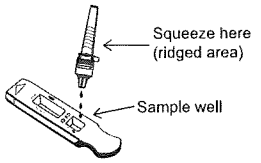
Step 9B: Record the result

- When analysis is complete, the test result appears in the display window.

ATTENTION: TEST Results are NOT maintained in the display window when the device is removed or if the Analyzer is left unattended for more than 60 minutes (if the AC power adapter is connected).

C Using an Analyzer in *"Analyze Now" mode:* with InfoScan or InfoSync module installed

Step 6C: Adding the specimen

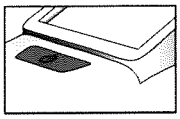


- Invert the tube, holding it vertically (approximately one inch above the **BD Veritor** System Flu A+B device sample well).
- Gently squeeze the ridged body of the tube, dispensing three (3) drops of the processed specimen into the sample well of a labeled **BD Veritor** System Flu A+B device. **NOTE: Squeezing the tube close to the tip may cause leakage.**

Step 7C: Timing development

- Allow the test to develop for **10** minutes.
- If running the test in a laminar flow hood or in an area with heavy ventilation, cover test device to avoid inconsistent flow.

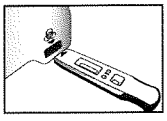
Step 8C: Using the Analyzer



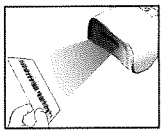
During incubation time, turn the BD Veritor Plus Analyzer on by pressing the blue button once.

The display window briefly shows "SCAN CONFIG BARCODE." This is an opportunity to change the configuration of the Analyzer. Please refer to the Analyzer *Instructions for Use* for configuration instructions. Ignore this message and postpone this process when an assay is awaiting analysis.

- When assay development time is complete and the Analyzer display window reads: "INSERT TEST DEVICE OR DOUBLE-CLICK FOR WALK AWAY MODE":
  - Insert the **BD Veritor** System Flu A+B device into the **BD Veritor** Plus Analyzer.



Step 9C: Using the Bar Code scanner



- Follow the prompts on the display window to complete any required barcode scans of:
  - OPERATOR ID
  - SPECIMEN ID and/or
  - KIT LOT NUMBER

  in accordance with site requirements and Analyzer settings.

- **Prompts for each scanning step appear in the display window for only 10 seconds. Failure to complete scans during that time will cause the Analyzer to default to the beginning of step 8C. To restart this step, remove and reinsert the test device to initiate a new sequence.**
- **Move the barcode slowly toward the window until a confirmation tone sounds. The scanned barcode value appears in the next display window.**
- **The Analyzer can record the kit Lot Number in the test record but does not restrict the use of expired or inappropriate reagents. Management of expired materials is the responsibility of the user. BD recommends against the use of expired materials.**

- After required scans are completed, the Analyzer displays a countdown timer and test analysis begins.
- **Do not touch the Analyzer or remove the test device during this process. Doing so will abort the assay analysis.**
- When analysis is complete a result appears in the display window. If configured to display, the specimen ID barcode value also appears. If a printer is connected, specimen ID and result are automatically printed.

If a printer is not connected, record the result before removing the assay device.

ATTENTION: TEST Results are NOT maintained in the display window when the device is removed or if the Analyzer is left unattended for more than 15 minutes (60 minutes if AC power adapter is connected).

Step 10C: Remove the test device

- Pull the device out. The display will show "INSERT TEST DEVICE OR DOUBLE-CLICK BUTTON FOR WALK AWAY MODE" to indicate the Analyzer is ready to perform another test.

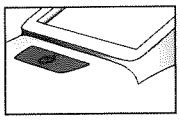
If an InfoSync module is installed the ENVELOPE symbol will appear to indicate that results are transmitting.

- In the event that the **BD Veritor** Plus Analyzer does not detect adequate cellular network strength while the ENVELOPE symbol is still displayed, it will queue all results to be transmitted and continuously attempt to transmit them. If it is powered off during this time, it will attempt to transmit as soon as power is restored.

D Using an Analyzer In "*Walk Away*" mode: with InfoScan or InfoSync module installed

To use Walk Away mode - connect the AC power adapter to the Analyzer and a power source

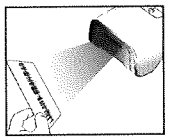
Step 6D: Starting Walk Away mode



- Turn the Analyzer on by pressing the blue power button once.

  The display window will briefly show "SCAN CONFIG BARCODE." This is an opportunity to change the configuration of the Analyzer. Please refer to the Analyzer *Instructions for Use* for configuration instructions. Ignore this message and postpone this process when an assay is awaiting analysis.
- When the display window reads: "INSERT TEST DEVICE OR DOUBLE-CLICK FOR WALK AWAY MODE"
  - **Double-click** the blue power button.

Step 7D: Using the Bar Code scanner

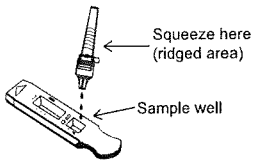


- Follow the prompts on the display window to complete any required barcode scans of:
  - OPERATOR ID
  - SPECIMEN ID and/or
  - KIT LOT NUMBER

According to site requirements and Analyzer settings.

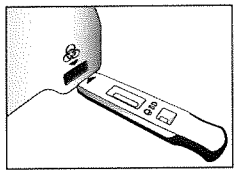
- **Prompts for each scanning step appear in the display window for only 10 seconds. Failure to complete scans during that time will cause the Analyzer to default to the beginning of step 6D. To restart this step, double-click the power button.**
- **Move the barcode slowly toward the window until a confirmation tone sounds. The scanned barcode value appears in the next display window.**
- **The Analyzer can record the kit Lot Number in the test record but does not restrict the use of expired or inappropriate reagents. Management of expired materials is the responsibility of the user. BD recommends against the use of expired materials.**

Step 8D: Add the specimen to the test device



- When the display window reads: "ADD SPECIMEN TO TEST DEVICE AND INSERT IMMEDIATELY":
  - Invert the tube, holding it vertically (approximately one inch above the **BD Veritor** System Flu A+B device sample well).
  - Gently squeeze the ridged portion of the tube, allowing three **(3) drops** of the processed specimen to dispense into the sample well of a labeled **BD Veritor** System Flu A+B device. **NOTE: Squeezing the tube close to the tip may cause leakage.**

Step 9D: Start the development and reading sequence



- Immediately insert the test device into the slot on the right side of the Analyzer.

The test device must remain horizontal to prevent spilling the specimen out of the sample well.

- "DO NOT DISTURB TEST IN PROGRESS" appears in the display window. Automatic timing of the assay development, image processing and result analysis begins.
- A countdown timer in the display window shows the remaining analysis time.

Do not touch the Analyzer or remove the test device during this process. Doing so will abort the assay analysis.

- When analysis is complete, a result appears in the display window. If configured to display, the specimen ID barcode value also appears. If a printer is connected, specimen ID and result are automatically printed. **If a printer is not connected, record the result before removing the assay device.**

ATTENTION: TEST Results are NOT maintained in the display window when the device is removed or if the Analyzer is left unattended for more than 60 minutes (when AC power adapter is connected).

Step 10D: Remove the test device

- Pull the device out. The display will show INSERT TEST DEVICE OR DOUBLE-CLICK BUTTON FOR WALK AWAY MODE to indicate the Analyzer is ready to perform another test. Note that the Analyzer returns to Analyze Now mode at the conclusion of each read sequence.

If an InfoSync module is installed the ENVELOPE symbol will appear to indicate that results are transmitting.

- In the event that the **BD Veritor** Plus Analyzer does not detect adequate cellular network strength while the ENVELOPE symbol is still displayed, it will queue all results to be transmitted and continuously attempt to transmit them. If it is powered off during this time, it will attempt to transmit as soon as power is restored.

OPTIONAL TEST PROCEDURE: Use this procedure to test for both INFLUENZA A+B and RSV using a single NP wash, aspirate or swab specimen in transport medium.

Note: The BD Veritor™ System for Rapid Detection of RSV (Cat. # 256042) is required for this procedure in addition to the BD Veritor™ System for Rapid Detection of Flu A+B (Cat. # 256041).

IMPORTANT NOTE: This optional procedure allows for use of the remaining processed sample from Step 5 above to test additionally for RSV. The sample to be tested with the RSV kit must be from a patient less than 20 years of age as indicated in the **BD Veritor** RSV laboratory kit package insert. **THE PROCESSED SAMPLE SHOULD BE TESTED WITHIN 15 MINUTES.**

Allow specimens that have been stored at 2–8 °C to warm to room temperature prior to use. Thoroughly mix all specimens prior to removal of an aliquot for processing. Do not centrifuge specimens.

1. Collect specimen from the patient and follow Steps 1-5 of the test procedure above to prepare the sample for testing.
2. Using the sample from Step 5, continue the test procedure using the test device for RSV and the same workflow configuration used to obtain the Flu A+B result.
3. Refer to the product insert for **BD Veritor**™ System for Rapid Detection of RSV (Cat. # 256042) for the test procedure and full description of the **BD Veritor** RSV test. Follow the Instructions in the insert and the Instrument on screen prompts to complete the test procedure and obtain results. Refer to the product insert for the **BD Veritor** System RSV Kit for result interpretation.

INTERPRETATION OF RESULTS

The **BD Veritor** System Instrument (purchased separately) must be used for interpretation of all test results. Operators should not attempt to interpret assay results directly from the test strip contained within the **BD Veritor** System Flu A+B assay device. With some specimens, up to four lines may be visible on the test device. The Instrument will appropriately interpret the result.

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
POSITIVE CONTROL INVALID	Test Invalid. Repeat the test.
NEGATIVE CONTROL INVALID	Test Invalid. Repeat the test.

Invalid Test – If the test is invalid, the **BD Veritor** System Instrument will display "RESULT INVALID" or "CONTROL INVALID" and the test or control must then be repeated. Because true dual positives are exceptionally rare, the **BD Veritor** System Instrument reports dual positive influenza A and influenza B results as "Result Invalid." 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.

REPORTING OF RESULTS

Positive Test Positive for the presence of influenza A or influenza B antigen. A positive result may occur in the absence of viable virus.

Negative Test Negative for the presence of influenza A and influenza B antigen. Infection due to influenza cannot be ruled-out because the antigen present in the sample may be below the detection limit of the test. A negative test is presumptive and it is recommended that these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay.

Invalid Test Test result is inconclusive. Do not report results. Repeat the test.

QUALITY CONTROL:

ATTENTION: To utilize the Analyzer's QC documentation capability, specimen barcode scanning must be enabled on an Analyzer equipped with either an InfoScan or InfoSync module. Please refer to the Analyzer *Instructions for Use*, section 4, to choose or change this configuration and for specific QC procedure steps.

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

1. The internal positive control validates the immunological integrity of the device, proper reagent function, and assures correct test procedure.
2. The membrane area surrounding test lines functions as a background check on the assay device.

   The BD Veritor System Instrument evaluates the positive and negative internal/procedural controls after insertion of each BD Veritor System test device. The BD Veritor System Instrument prompts the operator if a quality issue occurs during assay analysis. Failure of the internal/procedural controls will generate an invalid test result. NOTE: The internal controls do not assess proper sample collection technique.

External Positive and Negative Controls:

Flu A positive/B negative and Flu B positive/A negative control swabs are supplied with each kit. These controls provide additional quality control material to assess that the test reagents and the **BD Veritor** System Instrument perform as expected. Prepare kit control swabs and test using the same procedure (either **Analyze Now** or **Walk Away** mode) as used for patient specimen swabs. When using the barcode scanning feature to document QC procedures, scan the barcode on the control swab packaging when prompted for a Specimen ID.

Your laboratory's standard Quality Control procedures and applicable local, state and/or federal regulations or accreditation requirements dictate the performance of external quality control procedures.

BD recommends external controls be run once for:

- each new kit lot,
- each new operator,
- each new shipment of test kits,
- as required by internal quality control procedures and in accordance with local, state and federal regulations or accreditation requirements.

LIMITATIONS OF THE PROCEDURE

- 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.
- 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.

EXPECTED VALUES

The rate of positivity observed in respiratory testing will vary depending on the method of specimen collection, handling/ transport system employed, detection method utilized, the time of year, age of the patient, geographic location and most importantly, local disease prevalence.

The overall prevalence observed with an FDA-cleared influenza A and B molecular assay in the U.S. during the 2010–2011 clinical study was 23.9% for influenza A and 7.5% for influenza B. At the clinical site located in Hong Kong, the prevalence observed with the same FDA-cleared influenza A and B molecular assay was 7.2% for influenza A and 3.4% for influenza B.

The overall prevalence observed with an FDA-cleared influenza A and B molecular assay in the U.S. during the 2011–2012 clinical study was 31.7% for influenza A and 4.5% for influenza B. At the clinical sites located in Japan, the prevalence observed with the same FDA-cleared influenza A and B molecular assay was 0% for influenza A and 89% for influenza B.

PERFORMANCE CHARACTERISTICS

Explanation of Terms:

PPA: Positive Percent Agreement = a / (a+c) × 100%

NPA: Negative Percent Agreement = d / (b+d) × 100%

P: Positive

N: Negative

C.I.: Confidence Interval

	Comparator Method	
New Test Method	P	N
P	a	b
N	c	d
Total	(a+c)	(b+d)

Clinical Performance NP Washes/Aspirates 2010-2011:

Performance characteristics for the **BD Veritor** System for Rapid Detection of Flu A+B test were established using NP wash/aspirate specimens in multi-center clinical studies conducted at two U.S. trial sites and one Hong Kong trial site during the 2010-2011 respiratory season. A total of 1502 prospective specimens (1002 in the U.S and 500 in Hong Kong) were evaluated using the **BD Veritor** System for Rapid Detection of Flu A+B test and PCR. Five specimens were not evaluable because of data reconciliation issues, an additional 13 were excluded because of insufficient sample volume for reference method testing and 13 samples were excluded as "Result Invalid" (for an invalid rate of 0.9% [13/1484]).

The prospective specimens consisted of NP washes and aspirates from symptomatic patients. 49% of the samples were from females and 51% from males. 56.6% were from patients less than or equal to 5 years of age. 21.9% of the patients tested were in the 6-21 year age group, 5.7% were from 22-59 years of age and 15.8% were obtained from people greater than or equal to age 60 (the patient age was not provided for 0.1% of samples).

The performance of the **BD Veritor** System for Rapid Detection of Flu A+B test was compared to an FDA-cleared Influenza A and B molecular assay (PCR).

The performance is presented in Table 1 below.

Table 1: 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 – All Sites

	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%)			

An additional 263 frozen retrospective specimens were evaluated with the **BD Veritor** System for Rapid Detection of Flu A+B test. Twelve samples were excluded because there was insufficient sample volume for reference method testing, one sample was excluded as a PCR "Unresolved" and one sample was excluded as "Result Invalid" (for an invalid rate of 0.4% [1/250]). The retrospective specimens consisted of NP washes and aspirates from symptomatic patients. 44.9% of the samples were from females and 55.1% from males. 87.5% were from patients less than or equal to 5 years of age.

The performance is presented in Table 2 below.

Table 2: Summary of the Performance of the BD Veritor System for Rapid Detection of Flu A+B Test Compared to PCR for Retrospective NP Wash/Aspirate Specimens

	Reference PCR		
Clinical kit: **BD** Flu A	P	N	Total
P	58	2	60
N	5	184	189
Total	63	186	249
Reference Method: PCR PPA: 92.1% (95% C.I. 82.7%–96.6%) NPA: 98.9% (95% C.I. 96.2%–9.7%)			

	Reference PCR		
Clinical kit: **BD** Flu B	P	N	Total
P	29	2	31
N	10	208	218
Total	39	210	249
Reference Method: PCR PPA: 74.0% (95% C.I. 58.9%–85.4%) NPA: 99.0% (95% C.I. 96.6%–99.7%)			

Clinical Performance NP Swabs in Transport Media 2011-2012; U.S. and Japan Combined

Performance characteristics for the **BD Veritor** System for Rapid Detection of Flu A+B test were established using NP swabs in transport media in multi-center studies conducted at six clinical trial sites located in geographically diverse areas within the United States and five clinical sites in Japan using a total of 292 samples.

The combined results are presented in Table 3 below.

Table 3: Summary of the Performance of the BD Veritor System for Rapid Detection of Flu A+B Test Compared to PCR for NP Swabs in Transport Media - U.S. and Japan Combined

	Reference PCR		
Clinical kit: **BD** Flu A	P	N	Total
P	52	6	58
N	12	222	234
Total	64	228	292
Reference Method: PCR PPA: 81.3% (95% C.I. 70.0%–88.9%) NPA: 97.4% (95% C.I. 94.4%–98.8%)			

	Reference PCR		
Clinical kit: **BD** Flu B	P	N	Total
P	77	2	79
N	13	200	213
Total	90	202	292
Reference Method: PCR PPA: 85.6% (95% C.I. 76.8%–91.4%) NPA: 99.0% (95% C.I. 96.5%–99.7%)			

Clinical Performance NP Swabs in Transport Media 2011-2012; U.S

Performance characteristics for the **BD Veritor** System for Rapid Detection of Flu A+B test were established using NP swabs in transport media in multi-center studies conducted at six clinical trial sites located in geographically diverse areas within the United States. A total of 217 prospective specimens were evaluated using the **BD Veritor** System for Rapid Detection of Flu A+B test and PCR. Two specimens could not be evaluated because of data reconciliation issues, one was eliminated because of an invalid control reading and 13 were excluded because the PCR results were unresolved.

The specimens consisted of NP swabs in transport media from symptomatic patients. 55.8% of the samples were from females and 44.2% from males. 16.1% were from patients less than or equal to 5 years of age, 25.3% were from patients 6-21 years of age, 47.5% were from patients 22-59 years of age and 11.1% were obtained from patients greater than or equal to 60 years of age.

The performance of the **BD Veritor** System for Rapid Detection of Flu A+B test was compared to an FDA-cleared Influenza A and B molecular assay (PCR).

The results are presented in Table 4 below.

Table 4: Summary of the Performance of the BD Veritor System for Rapid Detection of Flu A+B Test Compared to PCR for NP Swabs in Transport Media - U.S.

	Reference PCR		
Clinical kit: **BD** Flu A	P	N	Total
P	52	6	58
N	12	131	143
Total	64	137	201
Reference Method: PCR PPA: 81.3% (95% C.I. 70.0%–88.9%) NPA: 95.6% (95% C.I. 90.8%–98.0%)			

	Reference PCR		
Clinical kit: **BD** Flu B	P	N	Total
P	7	0	7
N	2	192	194
Total	9	192	201
Reference Method: PCR PPA: 77.8% (95% C.I. 45.3%–93.7%) NPA: 100% (95% C.I. 98.0%–100%)			

Clinical Performance NP Swabs in Transport Media 2011-2012; Japan

Performance characteristics for the **BD Veritor** System for Rapid Detection of Flu A+B test were established using NP swabs in transport media in multi-center studies conducted at five clinical trial sites in Japan. A total of 93 prospective specimens were evaluated using the **BD Veritor** System for Rapid Detection of Flu A+B test and PCR. Two specimens were excluded as the results were undetermined with the comparator assay.

The specimens consisted of NP swabs in transport media from symptomatic patients. 49.5% of the samples were from females and 50.5% from males. 31.2% were from patients less than or equal to 5 years of age, 63.4% were from patients 6-21 years of age and 5.4% were from patients 22-59 years of age (there were no specimens from patients greater than or equal to 60 years of age).

The results are presented in Table 5 below.

Table 5: Summary of the Performance of the BD Veritor System for Rapid Detection of Flu A+B Test Compared to PCR for NP Swabs in Transport Media - Japan

	Reference PCR		
Clinical kit: **BD** Flu A	P	N	Total
P	0	0	0
N	0	91	91
Total	0	91	91
Reference Method: PCR No Data for PPA Calculation NPA: 100% (95% C.I. 95.9%–100%)			

	Reference PCR		
Clinical kit: **BD** Flu B	P	N	Total
P	70	2	72
N	11	8	19
Total	81	10	91
Reference Method: PCR PPA: 86.4% (95% C.I. 77.3%–92.2%) NPA: 80.0% (95% C.I. 49.0%–94.3%)			

Reproducibility

The reproducibility of the **BD Veritor** System for Rapid Detection of Flu A+B test was evaluated at three clinical laboratory sites in 2010–2011. The reproducibility panel was composed of 30 simulated influenza A or B samples. These included moderate positive samples, low positive samples (near the assay limit of detection), high negative samples (i.e., containing very low concentrations of virus such that positive results occur ~5% of the time) and negative samples. The panel was tested by two operators at each site for five consecutive days. The results are summarized below.

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%)
Moderate positive B	96.7% (29/30) (95% C.I. 83.3%–99.4%)	100.0% (30/30) (95% C.I. 88.6%–100.0%)	100.0% (30/30) (95% C.I. 88.6%–100.0%)	98.9% (89/90) (95% C.I. 94.0%–99.8%)
Negatives	0.0% (0/210) (95% C.I. 0%–1.8%)	0.0% (0/210) (95% C.I. 0.0%–1.8%)	0.0% (0/210) (95% C.I. 0.0%–1.8%)	0.0% (0/630) (95% C.I. 0.0%–0.6%)

Analytical Studies

Analytical Sensitivity (Limit of Detection)

The limit of detection (LOD) for the **BD Veritor** System for Rapid Detection of Flu A+B test was established for a total of 8 influenza strains: 5 influenza A and 3 influenza B. The LOD for each strain represents the lowest concentration producing a positivity rate of ≥95% based on testing 20 to 60 replicates.

Type	Influenza Viral Strain	Calculated LOD ($TCID_{50}$/mL)	Calculated LOD (EID_{50}/mL)	No. Positive / Total	% Positive
A	A/Brisbane/10/2007 H3N2	7.27×10^2	N/A	57/60	95%
A	A/Brisbane/59/2007 H1N1	3.30×10^2	N/A	57/60	95%
A	A/California/7/2009 H1N1	5.00×10^3	N/A	57/60	95%
A	A/Victoria/3/75 H3N2	3.11×10^3	N/A	59/60	98.3%
A	A/Anhui/1/2013 H7N9	N/A	5.42×10^6	59/60	98.3%
B	B/Brisbane/60/2008	7.42×10^3	N/A	58/60	96.7%
B	B/Florida/4/2006	1.30×10^3	N/A	58/60	96.7%
B	B/Lee/40	4.44×10^4	N/A	20/20	100%

$TCID_{50}$/mL = 50% Tissue Culture Infectious Dose

EID_{50}/mL= 50% Egg Infectious Dose

Strain Reactivity with Influenza A and B Viruses

The **BD Veritor** System for Rapid Detection of Flu A+B test was evaluated using a panel of influenza strains. Each strain was diluted and tested in triplicate until a point where not all of the replicates were positive. The dilution prior to that is provided in the table below as a minimal detected concentration. All influenza A strains showed positive Flu A test results and negative Flu B test results. Conversely, all of the influenza B strains showed positive Flu B test results and negative Flu A test results.

Although this test has been shown to detect novel avian influenza A (H7N9) and H3N2v cultured viruses the performance characteristics of this device with clinical specimens that are positive for novel avian influenza A (H7N9) and H3N2v influenza viruses have not been established. The **BD Veritor** System Flu A+B assay can distinguish between influenza A and B viruses, but it cannot differentiate influenza A subtypes.

Strain	Subtype	Minimal Detected Concentration
A/Brisbane/59/2007	H1N1	3.3×10^2 $TCID_{50}$/mL*
A/California/7/2009	H1N1	5.0×10^3 $TCID_{50}$/mL*
A/Denver/1/57	H1N1	4.45×10^4 $CEID_{50}$/mL
A/FM/1/47	H1N1	7.91×10^4 $CEID_{50}$/mL
A/Fujian-Gulou/1896/2009	H1N1	4.5×10^5 $CEID_{50}$/mL
A/Mal/302/54	H1N1	2.22×10^5 $CEID_{50}$/mL
A/New Caledonia/20/1999	H1N1	2.5×10^3 $TCID_{50}$/mL
A/New Jersey/8/76	H1N1	1.58×10^3 $CEID_{50}$/mL
A/NWS/33	H1N1	1.58×10^4 $CEID_{50}$/mL
A/PR/8/34	H1N1	6.31×10^2 $TCID_{50}$/mL
A/Solomon Island/03/2006	H1N1	2.5×10^3 $TCID_{50}$/mL
A/Washington/24/2012	H1N1	3.16×10^4 EID_{50}/mL
A/Weiss/43	H1N1	7.03×10^6 $CEID_{50}$/mL
A/WS/33	H1N1	7.91×10^2 $CEID_{50}$/mL
A/Aichi/2/68	H3N2	7.91×10^3 $CEID_{50}$/mL
A/Brisbane/10/2007	H3N2	7.27×10^2 $TCID_{50}$/mL*
A/California/02/2014	H3N2	1.45×10^2 $TCID_{50}$/mL
A/Hong Kong/8/68	H3N2	8.89×10^4 $CEID_{50}$/mL
A/Moscow/10/99	H3N2	5.8×10^6 $TCID_{50}$/mL
A/Perth/16/2009	H3N2	1.0×10^6 $TCID_{50}$/mL
A/Port Chalmers/1/73	H3N2	3.95×10^4 $CEID_{50}$/mL
A/Switzerland/9715293/2013	H3N2	3.25×10^2 $TCID_{50}$/mL
A/Texas/50/2012	H3N2	1.75×10^3 $TCID_{50}$/mL
A/Wisconsin/67/2005	H3N2	2.5×10^5 $TCID_{50}$/mL
A/Victoria/3/75	H3N2	3.11×10^3 $TCID_{50}$/mL*
A/Indiana/08/2011	H3N2v	1×10^4 $TCID_{50}$/mL
A/Indiana/10/2011	H3N2v	7.9×10^6 $CEID_{50}$/mL
A/Kansas/13/2009	H3N2v	1.0×10^3 $TCID_{50}$/mL
A/Minnesota/11/2010	H3N2v	7.9×10^5 $CEID_{50}$/mL
A/Pennsylvania/14/2010	H3N2v	1.26×10^6 $CEID_{50}$/mL
A/West Virginia/06/2011	H3N2v	7.9×10^3 $TCID_{50}$/mL
A/Anhui/01/2005	H5N1	0.512 HA
A/Vietnam/1203/2004	H5N1	0.512 HA
A/Northern Pintail/Washington/40964/2014	H5N2	6.28×10^5 EID_{50}/mL
A/Pheasant/NewJersey/1355/1998	H5N2	0.256 HA
A/Gyrfalcon/Washington/41088-6/2014	H5N8	1.98×10^6 EID_{50}/mL
A/Mallard/Netherlands/12/2000	H7N7	0.256 HA
A/Anhui/1/2013	H7N9	5.42×10^6 $CEID_{50}$/mL*
A/Chicken/HongKong/G9/1997	H9N2	1.024 HA

*Values taken from preceding Analytical Limit of Detection Table

a. EID_{50} = 50% Egg Infectious Dose

b. $TCID_{50}$ = 50% Tissue Culture Infectious Dose

c. $CEID_{50}$ = 50% Chicken Embryo Infectious dose

d. HA = Hemagglutination Assay

Strain	Minimal Detected Concentration
B/Brazil/178/96	2.32 x 10^4 $TCID_{50}$/mL
B/Brisbane/33/2008 (Victoria Lineage)	2.45 x 10^5 $CEID_{50}$/mL
B/Brisbane/60/2008	7.42 x 10^3 $TCID_{50}$/mL*
B/Brisbane/72/97	1.00 x 10^4 $TCID_{50}$/mL
B/Canada/548/99	>0.64 HA
B/Egypt/393/99	>1.28 HA
B/Florida/2/2006	1.08 x 10^5 $TCID_{50}$/mL
B/Florida/4/2006	1.30 x 10^3 $TCID_{50}$/mL*
B/Fujian/93/97	3.95 x 10^5 $TCID_{50}$/mL
B/Fukushima/220/99	9.33 x 10^2 $TCID_{50}$/mL
B/Guangdong-Liwan/1133/2014 (Yamagata Lineage)	9.0 x 10^5 $CEID_{50}$/mL
B/GuangXi/547/98	2.32 x 10^5 $TCID_{50}$/mL
B/Hawaii/01/97	>6.4 HA
B/Hong Kong/5/72	1.11 x 10^4 $CEID_{50}$/mL
B/Hong Kong/219/98	>1 HA
B/Hong Kong/259/2010 (Victoria Lineage)	1.35 x 10^6 $CEID_{50}$/mL
B/Jiangsu/10/2003	1.16 x 10^4 $TCID_{50}$/mL
B/Johannesburg/5/99	3.95 x 10^4 $TCID_{50}$/mL
B/Lee/40	4.44 x 10^4 $CEID_{50}$/mL*
B/Lisbon/03/96	>0.08 HA
B/Malaysia/2506/2004	5.0 x 10^4 $TCID_{50}$/mL

Strain	Minimal Detected Concentration
B/Maryland/1/59	3.51 x 10^2 $CEID_{50}$/mL
B/Massachusetts/2/2012 (Yamagata Lineage)	1.25 x 10^6 $CEID_{50}$/mL
B/Mass/3/66	1.58 x 10^5 $CEID_{50}$/mL
B/Montana/5/2012	3.14 x 10^5 EID_{50}/mL
B/Ohio/11/96	>0.16 HA
B/Ohio/1/05	1.34 x 10^5 $TCID_{50}$/mL
B/Phuket/3073/2013	6.08 x 10^3 $TCID_{50}$/mL
B/Puerto Mont/10427/98	0.02 HA
B/Russia/69	3.9 x 10^2 $TCID_{50}$/mL
B/Shandong/7/97	1.58 x 10^6 $TCID_{50}$/mL
B/Shanghai/04/97	1.58 x 10^5 $TCID_{50}$/mL
B/Shenzhen/135/97	3.16 x 10^4 $TCID_{50}$/mL
B/Sichuan/116/96	0.016 HA
B/Taiwan/2/62	2.81 x 10^2 $CEID_{50}$/mL
B/Texas/06/2011 (Yamagata Lineage)	6.2 x 10^5 $CEID_{50}$/mL
B/Texas/02/2013 (Victoria Lineage)	2.75 x 10^4 $CEID_{50}$/mL
B/Utah/09/2014 (Yamagata Lineage)	6.3 x 10^3 $CEID_{50}$/mL
B/Victoria/504/00	4.64 x 10^4 $TCID_{50}$/mL
B/Wisconsin/01/2010 (Yamagata Lineage)	7.0 x 10^2 $CEID_{50}$/mL
B/Yamagata/16/88	9.75 x 10^3 $TCID_{50}$/mL
B/Yamanashi/166/98	4.88 x 10^4 $TCID_{50}$/mL

*Values taken from preceding Analytical Limit of Detection Table

a. EID_{50} = 50% Egg Infectious Dose

b. $TCID_{50}$ = 50% Tissue Culture Infectious Dose

c. $CEID_{50}$ = 50% Chicken Embryo Infectious dose

d. HA = Hemagglutination Assay

Analytical Specificity (Cross Reactivity)

The **BD Veritor** System for Rapid Detection of Flu A+B test was evaluated with a total of 51 microorganisms. The 37 bacteria and yeast were tested at a target concentration of approximately 10^7 CFU/mL (CFU – Colony Forming Units) with the exception of *Staphylococcus aureus,* which was tested at a final concentration of 10^6 CFU/mL. The 14 viruses were evaluated at concentrations of 10^3 to 10^{10} $TCID_{50}$/mL. Of the 51 microorganisms tested, none showed cross-reactivity in either the Flu A or Flu B tests.

Bacteriodes fragilis
Bordetella pertussis
Candida albicans
Chlamydia pneumoniae
Corynebacterium diphtherium
Escherichia coli
Fusobacterium nucleatum
Haemophilus influenzae
Haemophilus parainfluenzae
Kingella kingae
Klebsiella pneumoniae
Lactobacillus sp.
Legionella sp.
Moraxella catarrhalis
Mycobacterium tuberculosis
Mycoplasma pneumoniae
Neisseria gonorrhoeae

Neisseria meningitides
Neisseria mucosa
Neisseria sp. *(Neisseria perflaus)*
Neisseria subflava
Peptostreptococcus anaerobius
Porphyromonas asaccharolyticus
Prevotella oralis
Propionibacterium acnes
Proteus mirabilis
Pseudomonas aeruginosa
Serratia marcescens
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus mutans
Streptococcus pneumoniae
Streptococcus pyogenes
Streptococcus sp. Group C

Streptococcus sp. Group G
Streptococcus salivarius
Veillonella parvula
Adenovirus, type 1
Adenovirus, type 7
Cytomegalovirus
Enterovirus
Epstein Barr Virus
HSV Type 1
Human Coronavirus OC43
Human Coronavirus 2229E
Human metapneumovirus (HMPV-27 A2)
Human Parainfluenza
Measles virus
Mumps virus
Respiratory syncytial virus
Rhinovirus

Interfering Substances

Various substances were evaluated with the **BD Veritor** System for Rapid Detection of Flu A+B test. These substances included whole blood (2%) and various medications. No interference was noted with this assay for any of the substances tested.

Substance	Concentration
4-Acetamidophenol	10 mg/mL
Acetylsalicylic acid	20 mg/mL
Albuterol	0.083 mg/mL
Amantadine Hydrochloride	500 ng/mL
Ayr Saline Nasal Gel	10 mg/mL
Beclomethasone	500 ng/mL
Budesonide	500 ng/mL
Chlorpheniramine maleate	5 mg/mL
Dexamethasone	10 mg/mL
Dextromethorphan	10 mg/mL
Diphenhydramine HCl	5 mg/mL
Fexofenadine	500 ng/mL
FluMist	1%
Flunisolide	500 ng/mL
Fluticasone	500 ng/mL
Four OTC nasal sprays	10 %
Four OTC throat drops	25 %
Guaiacol Glyceryl Ether	20 mg/mL

Substance	Concentration
Homeopathic Allergy Medicine	10 mg/mL
Ibuprofen	10 mg/mL
Loratidine	100 ng/mL
Menthol Throat Lozenges	10 mg/mL
Mometasone	500 ng/mL
Mupirocin	500 ng/mL
Oseltamivir	500 ng/mL
Oxymetazoline	0.05 mg/mL
Phenylephrine	1 mg/mL
Pseudoephedrine HCl	20 mg/mL
Purified Mucin Protein	1 mg/mL
Ribavirin	500 ng/mL
Rimantadine	500 ng/mL
Three OTC mouthwashes	5 %
Tobramycin	500 ng/mL
Triamcinolone	500 ng/mL
Whole Blood	2%
Zanamivir	1 mg/mL

Of the 44 substances tested in this study, none exhibited interfering reactions when tested with influenza A and influenza B positive samples. Based on the data, the substances tested at the indicated concentration levels did not interfere with the **BD Veritor** System for Rapid Detection of Flu A+B test.

AVAILABILITY

Cat. No.	Description
256041	**BD Veritor**™ System for Rapid Detection of Flu A+B, 30 tests
256042	**BD Veritor**™ System for Rapid Detection of RSV, 30 tests
256051	**BD Veritor**™ System Flu A+B Control Swab Set, 10 pairs of swabs
256055	**BD Veritor**™ System Reader
256066	**BD Veritor**™ Plus Analyzer
256067	**BD Veritor**™ InfoSync Module
256068	**BD Veritor**™ InfoScan Module
443907	USB Printer Cable for **BD Veritor**™ Analyzer

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Technical Information: In the United States, contact BD Technical Service and Support at 1.800.638.8663 or www.bd.com.

BD Veritor System

Français

For Rapid Detection of Flu A+B

Pour le diagnostic *in vitro* uniquement.

APPLICATION

Le test **BD Veritor** System for Rapid Detection of Flu A+B (système pour la détection rapide de Flu A+B) est un dosage immunologique chromatographique rapide conçu pour la détection qualitative et directe des antigènes de nucléoprotéine viraux d'influenza A et B à partir d'échantillons rhino-pharyngés prélevés par lavage, aspiration et écouvillonnage chez des patients présentant des symptômes. Le test **BD Veritor** System for Rapid Detection of Flu A+B est un test de différenciation, tel que les antigènes viraux d'influenza A peuvent être distingués de ceux d'influenza B à partir d'un même échantillon analysé sur un même dispositif. Le test devrait servir comme aide au diagnostic des infections par les virus influenza A ou B. Un test négatif est présomptif et il est recommandé de confirmer ces résultats par culture sur cellules virales ou un essai moléculaire pour l'influenza A et B agréé par la FDA. En dehors des États-Unis, un test négatif est présomptif et il est recommandé de confirmer ces résultats par culture sur cellules virales ou un essai moléculaire à des fins diagnostiques dans le pays d'utilisation. La FDA n'a pas donné son agrément pour l'utilisation de ce dispositif en dehors des États-Unis. Les résultats négatifs à l'influenza n'écartent pas la possibilité d'une infection virale et ne doivent pas servir de seule base à un traitement ou à d'autres décisions thérapeutiques. Le test n'est pas conçu pour la détection des antigènes de l'influenza de type C.

Les caractéristiques de performances des échantillons rhino-pharyngés prélevés par lavage/aspiration (LA) pour l'influenza A et B ont été établies de janvier à mars 2011 lorsque les virus d'influenza A/2009 H1N1, A/H3N2, lignée B/Victoria et lignée B/Yamagata étaient les principaux virus d'influenza en circulation d'après le rapport *Morbidity and Mortality Weekly Report* du CDC intitulé « Update: Influenza Activity—United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine ». Les caractéristiques de performances peuvent varier par rapport à d'autres nouveaux virus d'influenza.

Les caractéristiques de performances des échantillons LA placés dans un milieu de transport pour l'influenza A et B ont été établies de janvier à avril 2012 lorsque les virus d'influenza A/2009 H1N1, A/H3N2, lignée B/Victoria et lignée B/Yamagata étaient les principaux virus d'influenza en circulation d'après le rapport *Morbidity and Mortality Weekly Report* du CDC intitulé « Update: Influenza Activity—United States, 2011-2012 Season, and Composition of the 2012-2013 Influenza Vaccine ». Les caractéristiques de performances peuvent varier par rapport à d'autres nouveaux virus d'influenza.

Si, sur la base des critères cliniques et de dépistage épidémiologique actuellement recommandés par les autorités de santé publique, on soupçonne une infection avec un nouveau virus influenza, il convient de prélever des échantillons en prenant les précautions de contrôle de l'infection appropriées pour des nouveaux virus influenza virulents et de les envoyer aux laboratoires de dépistage nationaux ou locaux pour des tests de confirmation. Dans de tels cas, une culture virale ne doit pas être tentée à moins de disposer d'une unité BSL 3+ pour recevoir et mettre en culture les échantillons.