Procedure*	BD Veritor™ System For Rapid Detection of Flu A+B
For use with nasal and nasopharyngeal swab specimens.	

Prepared by	Date Adopted	Supersedes Procedure #

Review Date	Revision Date	Signature

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BD Veritor™ System

CLSI For Rapid Detection of Flu A+B

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 nasal and nasopharyngeal swabs of symptomatic patients. 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 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 for use outside of 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 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.

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.[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 chromatographic immunoassay to 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.

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 Reader 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 Reader 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 Reader 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 influenza A or B viral antigen and murine monoclonal control line antibodies.
RV Reagent D	30 tubes with 400 µL reagent	Detergent with < 0.1% sodium azide
Flexible minitip flocked swab	30 each	Swab for nasopharyngeal or nasal collection
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)**,** Timer, Tube Rack for specimen testing

Warnings and Precautions:

Warning

H315 Causes skin irritation.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.

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 Reader.**
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. For optimal results, use the flocked swabs provided with the kit for specimen collection.
8. Other than the flocked swabs that are used for specimen collection, kit components should not make contact with the patient.
9. Do not use kit components beyond the expiration date.
10. Do not reuse the device.
11. Do not use the kit if the Control A+/B- swab and Control B+/A- swab do not yield appropriate results.
12. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
13. To avoid erroneous results, swab specimens must be processed as indicated in the assay procedure section.
14. Specific training or guidance is recommended if operators are not experienced with specimen collection and handling procedures.
15. 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.

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

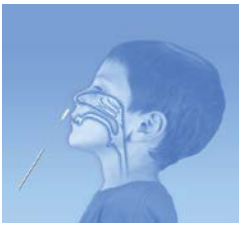
Acceptable specimens for testing with the **BD Veritor** System Flu A+B test include nasal swabs and nasopharyngeal (NP) swabs. Freshly collected specimens should be processed within 1 hour. It is essential that correct specimen collection and preparation methods be followed. Specimens obtained early 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, specimen collection requires specific training and guidance due to the importance of specimen quality to accurate test results.

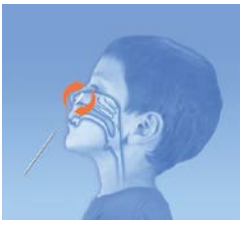
Proper Nasal Swab Sample Collection

1. The **BD Veritor** System Kit includes swabs with a flocked tip for nasal specimen collection.

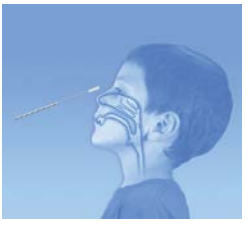
2. Insert the swab into one nostril of the patient.



3. Rotate the swab two complete 360-degree turns; pressing firmly against the nasal mucosa to help ensure the swab obtains both cells and mucus.



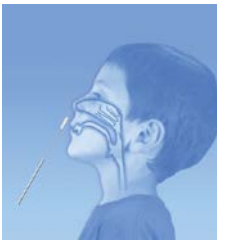
4. Withdraw the swab from the nasal cavity. The sample is now ready for processing using the **BD Veritor™** System Kit.



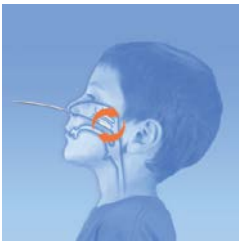
Proper Nasopharyngeal Swab Sample Collection

1. The **BD Veritor** System Kit includes swabs with a flocked tip for nasopharyngeal specimen collection.

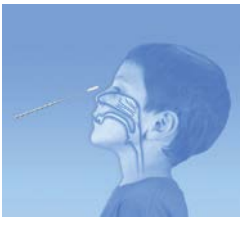
2. Insert the swab into one nostril of the patient, reaching the surface of the posterior nasopharynx.



3. Rotate the swab over the surface of the posterior nasopharynx.



4. Withdraw the swab from the nasal cavity. The sample is now ready for processing using the **BD Veritor** System Kit.



DOs and DON'Ts of Sample Collection

- Do collect sample as soon as possible after onset of symptoms
- Do test sample immediately
- BD recommends flocked swabs which are provided in the **BD Veritor** System Flu A+B Kit
- Do not use cotton tips and wood shafts
- Do not use calcium alginate swabs

TEST PROCEDURE

Nasal and Nasopharyngeal Swab Test Procedure

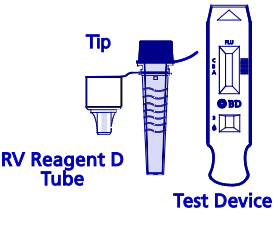
NOTES:
- Reagents, specimens and devices must be at room temperature (15 – 30 °C) prior to testing.
- The CLIA-waived **BD Veritor** System for Rapid Detection of Flu A+B kit is only intended for nasal and nasopharyngeal swab specimens that are collected and tested directly (i.e., dry swabs that have not been placed in transport media). The kit includes a pre-diluted process reagent in a ready to use "unitized" tube. This CLIA-waived kit IS NOT INTENDED for testing liquid samples such as wash or aspirate samples or swabs in transport media as results can be compromised by over dilution.

NOTES: Reagents, specimens and devices must be at room temperature (15 – 30 °C) for testing.

Prepare for Testing

Step 1

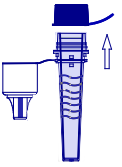
- For each patient specimen, remove one **RV Reagent D** tube/tip and one **BD Veritor** System Flu A+B device from its foil pouch immediately before testing. Label with patient's name. Place the labeled **RV Reagent D** tube(s) in the designated area of the tube rack.



Prepare the Sample

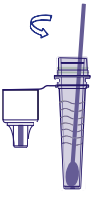
Step 2

- Remove and discard the cap from the **RV Reagent D** tube corresponding to the sample to be tested.



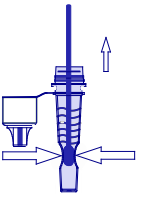
Step 3

- Insert the patient sample swab all the way into the **RV Reagent D** tube and swirl it against the inside wall three (3) times.



Step 4

- Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Properly discard the swab.



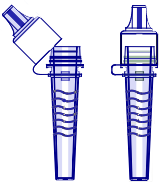
Run the Test

Step 5

- Press the attached tip firmly onto the **RV Reagent D** tube containing the processed sample (threading/twisting not required).

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

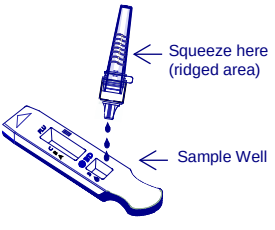
- Vortex or mix thoroughly by swirling or flicking the bottom of the tube.



Step 6

- Invert the **RV Reagent D** tube and hold the tube vertically (approximately one inch above the **BD Veritor** System Flu A+B device sample well). Holding the 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.

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



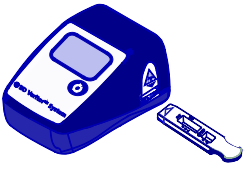
Step 7

- After adding the sample, allow the test to run for **10** minutes before inserting into Reader.

Analyze the Results

The **BD Veritor** System Reader should be powered-on prior to use and will indicate when it is ready for insertion of the **BD Veritor** System device.

Step 8



- When the test is ready, insert the **BD Veritor** System Flu A+B device into the **BD Veritor** System Reader. (The **BD Veritor** System Reader should be powered-on prior to use and will indicate when it is ready for insertion of the **BD Veritor** System device.)

  Follow the Reader on-screen prompts to complete the procedure and obtain the test result.

INTERPRETATION OF RESULTS
The **BD Veritor** System Reader (purchased separately) must be used for all interpretation of 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.

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

Invalid Test – If the test is invalid, the **BD Veritor** System Reader will display a “RESULT INVALID” or “CONTROL INVALID” result and the test or control must then be repeated. If the “CONTROL INVALID” reading recurs, contact BD Technical Support.

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 or 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. 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.

OPTIONAL TEST PROCEDURE: Testing for INFLUENZA A+B and RSV using a single NP swab

Note: The BD Veritor™ System for Rapid Detection of RSV (Cat. # 256038) is required for this procedure in addition to the BD Veritor System for Rapid Detection of Flu A+B (Cat. # 256045).

IMPORTANT NOTE: THE SAMPLE TO BE TESTED IN THE RSV KIT MUST BE FROM A PATIENT LESS THAN 6 YEARS OF AGE AS INDICATED IN THE BD VERITOR RSV POC KIT PACKAGE INSERT. THE PROCESSED SAMPLE SHOULD BE TESTED WITHIN 15 MINUTES.

This alternative procedure allows for use of the remaining processed sample from Step 5 above to test for RSV. When using this optional test procedure, the sample may be used up to 15 minutes after initial processing.

1. Collect NP swab from the patient and follow Steps 1-5 of the test procedure above as instructed for the **BD Veritor** System for Rapid Detection of Flu A+B.
2. Using the sample from Step 5, Preparing the Sample, continue the test procedure using the test device for RSV.
3. Refer to the product insert for **BD Veritor** System for Rapid Detection of RSV, (Cat. # 256038) for the test procedure and full description of the **BD Veritor** RSV test.

Follow the Reader on-screen prompts to complete the procedure and obtain test results. Refer to the product insert for the **BD Veritor** System RSV Kit (Cat. # 256038) for result interpretation.

QUALITY CONTROL
Quality control procedures must be performed in accordance with local, state and/or federal regulations or accreditation requirements and your laboratory’s standard Quality Control procedures.

External Positive and Negative Controls

Swab controls (Flu A positive/B negative and Flu B positive/A negative) are supplied with each kit. These controls provide additional quality control material to assess that the test reagents and the the **BD Veritor** System Reader perform as expected. BD recommends that positive and negative controls be run once for:

- each new kit lot
- each untrained 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.

Control Swab Test Procedure

1. Insert the swab all the way into the appropriately labeled **RV Reagent D** tube and vigorously plunge the swab up and down in the fluid for a minimum of 15 seconds.
2. Continue processing the swab according to the Test Procedure for Nasal and Nasopharyngeal swabs above beginning at Step 4 “Remove the swab.”

If the kit controls do not perform as expected, do not test patient specimens. Contact BD Technical Support at 1-800-638-8663.

Additionally, 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 that the correct test procedure was followed.
2. 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.

Note: The internal control does not assess that the sample was properly collected.

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 nasal swab and nasopharyngeal swab 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 in 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 performance characteristics of this test with specimens from humans infected with H5N1 or other avian influenza viruses are unknown.
- The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection.
- The **BD Veritor** System Reader 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.

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

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 has 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 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.

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/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/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/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/Wisconsin/67/2005	H3N2	2.5×10^5 $TCID_{50}$/mL
A/Victoria/3/75	H3N2	3.11×10^3 $CEID_{50}$/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/1/2013	H7N9	5.42×10^6 $CEID_{50}$/mL*

*Values taken from preceding Analytical Limit of Detection Table

Strain	Minimal Detected Concentration
B/Brazil/178/96	2.32×10^4 $TCID_{50}$/mL
B/Brisbane/60/2008	7.42×10^3 $TCID_{50}$/mL*
B/Brisbane/72/97	1.00×10^4 $TCID_{50}$/mL
B/Canada/548/99	>0.64 HA
B/Egypt/393/99	>1.28 HA
B/Florida/2/2006	1.08×10^5 $TCID_{50}$/mL
B/Florida/4/2006	1.30×10^3 $TCID_{50}$/mL*
B/Fujian/93/97	3.95×10^5 $TCID_{50}$/mL
B/Fukushima/220/99	9.33×10^2 $TCID_{50}$/mL
B/GuangXi/547/98	2.32×10^5 $TCID_{50}$/mL
B/Hawaii/01/97	>6.4 HA
B/Hong Kong/5/72	1.11×10^4 $CEID_{50}$/mL
B/Hong Kong/219/98	>1 HA
B/Jiangsu/10/2003	1.16×10^4 $TCID_{50}$/mL
B/Johannesburg/5/99	3.95×10^4 $TCID_{50}$/mL
B/Lee/40	4.44×10^4 $CEID_{50}$/mL*
B/Lisbon/03/96	>0.08 HA
B/Malaysia/2506/2004	$5.0 \times 10^4$$TCID_{50}$/mL
B/Maryland/1/59	3.51×10^2 $CEID_{50}$/mL
B/Mass/3/66	1.58×10^5 $CEID_{50}$/mL
B/Ohio/11/96	>0.16 HA
B/Ohio/1/05	1.34×10^5 $TCID_{50}$/mL
B/Puerto Mont/10427/98	0.02 HA
B/Russia/69	3.9×10^2 $TCID_{50}$/mL
B/Shangdong/7/97	1.58×10^6 $TCID_{50}$/mL
B/Shanghai/04/97	1.58×10^5 $TCID_{50}$/mL
B/Shenzhen/135/97	3.16×10^4 $TCID_{50}$/mL
B/Sichuan/116/96	0.016 HA
B/Taiwan/2/62	2.81×10^2 $CEID_{50}$/mL
B/Victoria/504/00	4.64×10^4 $TCID_{50}$/mL
B/Yamagata/16/88	9.75×10^3 $TCID_{50}$/mL
B/Yamanashi/166/98	4.88×10^4 $TCID_{50}$/mL

*Values taken from preceding Analytical Limit of Detection Table

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	*Neisseria* sp.*(Neisseria perflaus)*
Bordetella pertussis	*Neisseria subflava*
Candida albicans	*Peptostreptococcus anaerobius*
Chlamydia pneumoniae	*Porphyromonas asaccharolyticus*
Corynebacterium diphtherium	*Prevotella oralis*
Escherichia coli	*Propionibacterium acnes*
Fusobacterium nucleatum	*Proteus mirabilis*
Haemophilus influenzae	*Pseudomonas aeruginosa*
Haemophilus parainfluenzae	*Serratia marcescens*
Kingella kingae	*Staphylococcus aureus*
Klebsiella pneumoniae	*Staphylococcus epidermidis*
Lactobacillus sp.	*Streptococcus mutans*
Legionella sp.	*Streptococcus pneumoniae*
Moraxella catarrhalis	*Streptococcus pyogenes*
Mycobacterium tuberculosis	*Streptococcus* sp. Group C
Mycoplasma pneumoniae	*Streptococcus* sp. Group G
Neisseria gonorrhoeae	*Streptococcus salivarius*
Neisseria meningitidis	*Veillonella parvula*
Neisseria mucosa	

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	Substance	Concentration
4-Acetamidophenol	10 mg/mL	Homeopathic Allergy Medicine	10 mg/mL
Acetylsalicylic acid	20 mg/mL	Ibuprofen	10 mg/mL
Albuterol	0.083 mg/mL	Loratidine	100 ng/mL
Amantadine Hydrochloride	500 ng/mL	Menthol Throat Lozenges	10 mg/mL
Ayr Saline Nasal Gel	10 mg/mL	Mometasone	500 ng/mL
Beclomethasone	500 ng/mL	Mupirocin	500 ng/mL
Budesonide	500 ng/mL	Oseltamivir	500 ng/mL
Chlorpheniramine maleate	5 mg/mL	Oxymetazoline	0.05 mg/mL
Dexamethasone	10 mg/mL	Phenylephrine	1 mg/mL
Dextromethorphan	10 mg/mL	Pseudoephedrine HCl	20 mg/mL
Diphenhydramine HCl	5 mg/mL	Purified Mucin Protein	1 mg/mL
Fexofenadine	500 ng/mL	Ribavirin	500 ng/mL
FluMist	1%	Rimantadine	500 ng/mL
Flunisolide	500 ng/mL	Three OTC mouthwashes	5 %
Fluticasone	500 ng/mL	Tobramycin	500 ng/mL
Four OTC nasal sprays	10 %	Triamcinolone	500 ng/mL
Four OTC throat drops	25 %	Whole Blood	2%
Guaiacol Glyceryl Ether	20 mg/mL	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.

Technical Support

For questions, or to report a problem, please call Technical Support at 1-800-638-8663. Test system problems may also be reported to the FDA using the MedWatch reporting system (phone: 1-800 FDA-1088; fax: 1-800 FDA-1078: or http://www.fda.gov/medwatch).

AVAILABILITY

Cat. No.	Description
256045	**BD Veritor™** System for Rapid Detection of Flu A+B, 30 tests
256055	**BD Veritor™** System Reader
256051	**BD Veritor™** System Flu A+B Control Swab Set, 10 pairs of swabs
220252	COPAN Flexible Minitip Flocked Swab, 100 swabs

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Technical Information: In the United States, contact BD Technical Service and Support at 800-638-8663 or www.bd.com/ds/.