8086100(01)
2012-09

BD

Veritor™ System

For Rapid Detection of Respiratory Syncytial Virus (RSV)

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

30
Determinations

BD Veritor™ System

For Rapid Detection of Respiratory Syncytial Virus (RSV)

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

For *in vitro* diagnostic use only.

INTENDED USE
The **BD Veritor**™ System for Rapid Detection of Respiratory Syncytial Virus (RSV) is a chromatographic immunoassay with an instrumented read for the direct and qualitative detection of RSV fusion protein from nasopharyngeal wash, aspirate and swab in transport media samples from patients suspected of having a viral respiratory infection. This test is intended for *in vitro* diagnostic use to aid in the diagnosis of RSV infections in infants and pediatric patients under the age of 20 years. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by viral cell culture or an alternative method, such as a FDA-cleared molecular assay. The test is intended for professional and laboratory use. It is to be used in conjunction with the **BD Veritor™** System Reader.

SUMMARY AND EXPLANATION
Viral respiratory tract infections are responsible for widespread disease. Respiratory syncytial virus (RSV) is a leading cause of lower respiratory tract infections (LRI) in young children in both the developed and developing worlds. Worldwide, it is estimated that RSV is responsible for greater than 30 million cases of LRI in children under 5 years of age each year.[1,2] RSV has also been implicated in severe respiratory infections in the elderly and immunocompromised.[3,4] RSV has been identified as causing 20% of "influenza-like" illness in people 15–44 years of age and is responsible for greater than 17,000 deaths per year in the United States, almost 80% of which occur in adults over age 65.[5,6]

Diagnostic methods for detection of respiratory viruses include viral cell culture, direct fluorescent antibody (DFA), rapid immunoassays, and nucleic acid amplification assays such as the polymerase chain reaction (PCR).[7,8] Each has been demonstrated to have clinical utility for the detection of respiratory viruses including RSV. Rapid immunoassays available for specific viruses such as influenza A/B and RSV allow a quick diagnosis so that patients may be appropriately isolated and treated to prevent the nosocomial spread of infections to fellow patients with compromised cardiac, respiratory or immune functions.[9] In addition, rapid tests assist with the selection of appropriate antiviral therapy. The most common specimen types collected for RSV testing include nasopharyngeal washes, nasopharyngeal aspirates, nasal swabs and nasopharyngeal swabs.

The **BD Veritor** System for Rapid Detection of RSV (also referred to as the **BD Veritor** System and **BD Veritor** System RSV) is a chromatographic immunoassay to detect RSV fusion protein extracted from various specimens of symptomatic patients.

PRINCIPLES OF THE PROCEDURE
The **BD Veritor** System for Rapid Detection of RSV is a chromatographic assay to qualitatively detect RSV fusion protein in samples processed from respiratory specimens. When specimens are processed and added to the test device, RSV antigen binds to anti-RSV antibodies conjugated to detector particles in the RSV test strip. The antigen-conjugate complex migrates across the test strip to the reaction area and is captured by the line of RSV antibody on the membrane. A positive result for RSV is determined by the **BD Veritor** System Reader (purchased separately) when antigen-conjugate is deposited at the Test "T" position and the Control "C" position on the **BD Veritor** System RSV assay device.

REAGENTS
The following components are included in the **BD Veritor** System for Rapid Detection of RSV kit:

BD Veritor System RSV Devices	30 devices	Foil pouched device containing one reactive strip. Each strip has one test line of monoclonal antibody specific to RSV viral antigen and murine monoclonal control line antibodies.
RV Reagent C	30 tubes with 100 µL reagent	Detergent with < 0.1% sodium azide (preservative).
300 µL Pipette	30 each	Transfer pipette
RSV Positive Control Swab	1 each	RSV Positive Control Swab, RSV antigen (noninfectious cell lysate) with < 0.1% sodium azide (preservative)
RSV Negative Control Swab	1 each	RSV Negative Control Swab, (detergent-treated non-infected cells) with < 0.1% sodium azide (preservative)

Materials Required But Not Provided: BD Veritor System Reader (Cat. No. 256055), timer, vortex mixer, transport media (see Specimen Collection and Handling), distilled or deionized water, tube rack for specimen testing.

Warnings and Precautions:
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. The RSV Positive Control Swab and the positive control line on the **BD Veritor** System for Rapid Detection of RSV device have been prepared from RSV-infected tissue culture cells which have been inactivated by detergent treatment and sonication then subsequently tested by bioassay procedures.

4. Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. "Standard Precautions"[10-13] 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 RSV Positive Swab and Control RSV Negative 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. The addition of excess sample may give invalid test results.
12. Proper specimen collection, storage and transport are critical to the performance of this test.
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 ºC. DO NOT FREEZE. Reagents and devices must be at room temperature (15–30 ºC) 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 RSV 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 for generating 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 RSV:

- Amies, Bartel ViraTrans™, BD Universal Transport, Earle's Minimal Essential, 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.

Other transport media may be utilized if an appropriate validation exercise is performed. **NOTE: Media containing lactalbumin (i.e., 0.5% or 1.0%) or any other transport media containing lactalbumin may not be compatible with the BD Veritor System for Rapid Detection of RSV.**

Specimen Transport and Storage:
Freshly collected specimens should be processed and tested immediately. If necessary, specimens may be stored at 2–8 °C for up to 72 hours. 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".

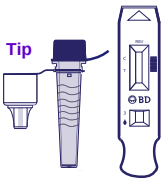
Procedure for Nasopharyngeal Swabs in Transport Media:

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

TEST PROCEDURE

NOTES: Reagents, specimens and devices must be at room temperature (15–30 °C) for testing. Thoroughly mix all specimens prior to removal of an aliquot for processing. Do not centrifuge specimens.

1. For each patient specimen and control swab, remove one **RV Reagent C** tube/tip and one **BD Veritor** System RSV device from its foil pouch immediately before testing.
2. Label one **BD Veritor** System device and one **RV Reagent C** tube for each specimen and control to be tested.
3. Place the labeled **RV Reagent C** tube(s) in the designated area of the tube rack.

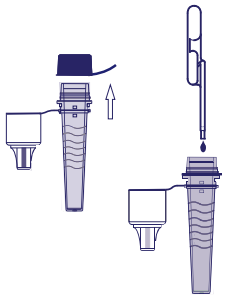


RV Reagent C Tube **Test Device**

4. Process the specimen or control as directed below:

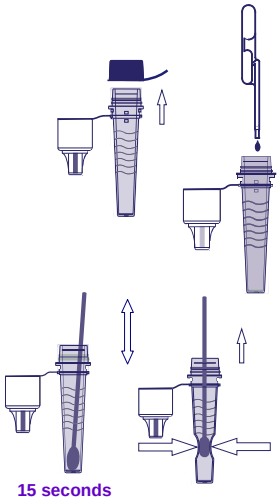
a. For NP washes, aspirates and swab specimens in transport media:

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 specimen into the **RV Reagent C** tube. Discard pipette after use.



b. For Kit Swab Controls:

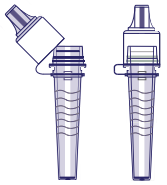
1. Remove and discard the cap from the **RV Reagent C** tube corresponding to the sample to be tested.
2. Using the transfer pipette add 300 µL of distilled or deionized water to the **RV Reagent C** tube.
3. Insert the control swab into the tube and vigorously plunge the swab up and down in the fluid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



15 seconds

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

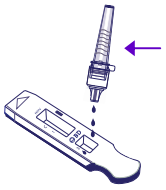
NOTE: Do not use tips from any other product, including other products from BD or other manufacturers.



6. Vortex or mix thoroughly.

7. Invert the **RV Reagent C** tube and hold the tube vertically (approximately one inch above the **BD Veritor** System RSV 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 RSV device.

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

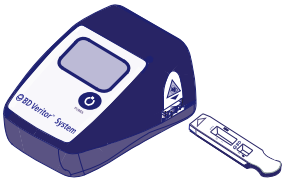


Squeeze here (ridged area)

8. After adding the sample, allow the test to run for 10 minutes before inserting into the reader.

9. When the test is ready, insert the **BD Veritor** System RSV 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.



Quality Control:
Quality control requirements must be performed in accordance with local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. Each **BD Veritor** System RSV 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.

External Positive and Negative Controls:
Swab controls (RSV positive and RSV negative) are supplied with each kit. These controls provide additional quality control material to demonstrate positive or negative assay results using the **BD Veritor** System Reader and **BD Veritor** System test device. BD recommends that positive and negative controls be run once for:

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

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

INTERPRETATION OF RESULTS
The **BD Veritor** System Reader instrument (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 RSV assay device.

Reader Display	Interpretation
RSV: +	Positive Test for RSV (RSV antigen present)
RSV: -	Negative Test for RSV (no antigen detected)
CONTROL INVALID	Control line error

Invalid Test – If the test is invalid, the **BD Veritor** System Reader will display a "CONTROL INVALID" result and the test or control must then be repeated.

REPORTING OF RESULTS

Positive Test	Positive for the presence of RSV antigen. A positive result may occur in the absence of viable virus.
Negative Test	Negative for the presence of RSV antigen. Infection due to RSV 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 cell culture or an FDA-cleared RSV molecular assay.
Control Invalid	Do not report results. Repeat the test.

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 RSV antigens from NP wash, aspirate and swab in transport media specimens.

- The **BD Veritor** System for Rapid Detection of RSV is capable of detecting both viable and non-viable RSV particles. The **BD Veritor** System for Rapid Detection of RSV 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 RSV 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 RSV infection, and should be confirmed by viral cell culture or an FDA-cleared RSV molecular assay.
- Positive test results do not rule out co-infections with other pathogens.
- Negative test results are not intended to rule in other non-RSV viral or bacterial infections.
- 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 RSV activity when disease prevalence is low. False negative test results are more likely during peak RSV 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, RSV viruses that have undergone minor amino acid changes in the target epitope region.
- The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection.
- The validity of the **BD Veritor** System for Rapid Detection of RSV test has not been proven for identification/confirmation of tissue culture isolates and should not be used in this capacity.
- Therapeutic anti-RSV monoclonal antibodies may interfere with the **BD Veritor™** System for Rapid Detection of RSV.
- Performance characteristics have not been established for use with patients older than 20 years of age and for immunocompromised patients

EXPECTED VALUES

The rate of positivity observed in RSV testing will vary depending on the method of specimen collection, handling/transport system employed, detection method utilized, time of year, age of the patient, geographic location and most importantly, local disease prevalence. In the 2011/2012 clinical trial, the overall prevalence of RSV as determined by viral cell culture for the nasopharyngeal swabs (NPS) in transport media was 24.5% (range of 5.6% to 31.8%). The overall prevalence of RSV as determined by viral cell culture for the nasopharyngeal washes and aspirates (NPWA) was 37.7% (range of 10.5% to 49.6%).

PERFORMANCE CHARACTERISTICS

Explanation of Terms

P: Positive
N: Negative
C.I.: Confidence Interval

Clinical Performance:

Performance characteristics for the **BD Veritor** System for Rapid Detection of RSV test were established in multi-center clinical studies conducted at five U.S. trial sites during the 2011-2012 respiratory season. A total of 1174 prospectively collected specimens received in the laboratory with an order for respiratory virus testing were enrolled in the study, of which, 26 were noncompliant with the study protocol and one was noncompliant on the viral cell culture reference testing level. Removal of these specimens yields a total of 1147 specimens. One additional specimen had a final undetermined viral cell culture reference result which could not be verified. Removal of this specimen results in a total of 1146 specimens. A total of 1146 were evaluated using the **BD Veritor** System for Rapid Detection of RSV test and viral cell culture. The prospective specimens consisted of 440 NPWA and 706 NPS in transport media from symptomatic patients. 44.3% of the samples were from females and 55.7% from males. 80% of patients were 2 years and under.

The performance of the **BD Veritor** System for Rapid Detection of RSV test was compared to an FDA cleared D^3 *Duet*™ DFA on R-Mix cell culture and is presented in the following tables.

Table 1. Summary of the performance of the BD Veritor System for Rapid Detection of RSV Test compared to viral cell culture by specimen type, all sites.

		Viral Cell Culture		
Specimen Type	**BD Veritor RSV**	**P**	**N**	
NPS	**P**	153	9*	162
	N	20	524	544
		173	533	706
Reference Method: Viral Cell Culture Sensitivity: 88.4% (95% CI: 82.8% – 92.4%) Specificity: 98.3% (95% CI: 96.8% – 99.1%)				
NPWA	**P**	152	15**	167
	N	14	259	273
		166	274	440
Reference Method: Viral Cell Culture Sensitivity: 91.6% (95% CI: 86.3% – 94.9%) Specificity: 94.5% (95% CI: 91.2% – 96.7%)				

*Of the 9 **BD Veritor** RSV Positive, Viral Cell Culture negative specimens, 6 were positive by FDA cleared Prodesse ProFlu+ molecular assay.
Of the 15 **BD Veritor RSV Positive, Viral Cell Culture negative specimens, 8 were positive by FDA cleared Prodesse ProFlu+ molecular assay.

Reproducibility

The reproducibility of the **BD Veritor** System for Rapid Detection of RSV test was evaluated at three clinical laboratory sites. The reproducibility panel was composed of 12 simulated RSV 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) 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 RSV Positives				
Sample	**Site 1**	**Site 2**	**Site 3**	**Total**
High negative RSV	0% (0/30) (95% CI: 0% – 11.3%)	3.3% (1/30) (95% CI: 0.6% – 16.7%)	3.3% (1/30) (95% CI: 0.6% – 16.7%)	2.2% (2/90) (95% CI: 0.6% – 7.7%)
Low positive RSV	93.3% (28/30) (95% CI: 78.7% – 98.2%)	76.7% (23/30) (95% CI: 59.1% – 88.2%)	93.3% (28/30) (95% CI: 78.7% – 98.2%)	87.8% (79/90) (95% CI: 79.4% – 93%)
Moderate positive RSV	100% (30/30) (95% CI: 88.6% – 100%)	100% (30/30) (95% CI: 88.6% – 100%)	100% (30/30) (95% CI: 88.6% – 100%)	100% (90/90) (95% CI: 95.9% – 100%)
Negative	0% (0/30) (95% CI: 0% – 11.3%)	0% (0/30) (95% CI: 0% – 11.3%)	0% (0/30) (95% CI: 0% – 11.3%)	0% (0/90) (95% CI: 0% – 4.1%)

Analytical Studies

Analytical Sensitivity (Limit of Detection)

The limit of detection (LOD) for the **BD Veritor** System for Rapid Detection of RSV test was established for the following RSV strains The LOD for each strain represents the lowest concentration producing a positivity rate of ≥95% based on testing 60 to 80 replicates.

Viral Strain	**Calculated LOD ($TCID_{50}$/mL)**	**No. Positive / Total**	**% Positive**
VR-26 (Long Subgroup A)	$1.43x10^5$	57/60	95.0
VR-955 (9320 subgroup B)	$3.98x10^4$	57/60	95.0
VR-1540 (A-2)	$1.94x10^3$	59/60	98.3
VR-1580 (Washington subgroup B)	$1.08x10^4$	58/60	96.7
VR-1400 (Wild Type subgroup B)	$2.96x10^3$	76/80	95.0

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

Analytical Specificity (Cross Reactivity)

The **BD Veritor** System for Rapid Detection of RSV test was evaluated with bacteria and yeast at a target concentration of approximately 10^6 CFU/mL (CFU – Colony Forming Units) with the exception of *Fusobacterium nucleatum* which was tested at 1.5 X 10^5.The viruses were evaluated at concentrations of 10^3 $TCID_{50}$/mL or greater. Of the microorganisms tested, none showed cross-reactivity in the RSV test.

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
HSV Type 1
Human Coronavirus OC43
Human metapneumovirus (HMPV-27 A2)
Human Parainfluenza
Measles virus
Mumps virus
Rhinovirus

Interfering Substances

Various substances were evaluated with the **BD Veritor** System for Rapid Detection of RSV test. These substances included whole blood (2%) and various medications. No interference was noted with this assay for any of the substances at the concentrations 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	12.5 %
Guaiacol Glyceryl Ether	20 mg/mL
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
Synagis	4 μg/mL
Tobramycin	500 ng/mL
Triamcinolone	500 ng/mL
Two OTC mouthwashes	5 %
Whole Blood	2%
Zanamivir	1 mg/mL

AVAILABILITY

Cat. No.	Description
256055	**BD Veritor™** System Reader
256042	**BD Veritor™** System for Rapid Detection of RSV, 30 tests

REFERENCES

1. Hall, C.B, Weinberg, G.A., Iwane, M.K., et al. 2009. The Burden of Respiratory Syncytial Virus Infection in Young Children. N Engl J Med 2009; *360*:588-598
2. Nair, H., Nokes, D.J., Gessner, B.D., et al., 2010. Global burden of acute lower respiratory infections due to respiratory syncytial virus in young children: a systematic review and meta-analysis. Lancet *375* (9725), 1545–1555.
3. Falsey, A.R. and E. E. Walsh. 2000. Respiratory syncytial virus infection in adults. Clin. Microbiol. Rev. *13*: 371-384.
4. Murata Y. and A. R. Falsey. 2006. RSV Infection in Elderly Adults, In: Patricia Cane, Editor(s), Perspectives in Medical Virology, Elsevier, Volume 14, Pages 163-182
5. Crowcroft, N.S., F. Cutts and M.C. Zambon. 1999. Respiratory syncytial virus: an underestimated cause of respiratory infection, with prospects for a vaccine. Commun Dis Public Health. *2*: 234-241.
6. Thompson WW, Shay DK, Weintraub E, et al. 2003. Mortality associated with influenza and respiratory syncytial virus in the United States. JAMA. 2003. *289*(2):179-186.
7. Henrickson KJ and C.B.Hall, Diagnostic assays for respiratory syncytial virus disease. 2007. Pediatr Infect Dis J. Nov; 26(11 Suppl):S36-40.
8. Therese Popow-Kraupp, T and J. H. Aberle. 2011. Diagnosis of Respiratory Syncytial Virus Infection. Open Microbiol J.; *5*:128–134. Published online 2011 December 30.
9. Barenfanger, J., C. Drake, N. Leon, T. Mueller and T. Troutt. 2000. Clinical and financial benefits of rapid detection of respiratory viruses: an outcomes study. J. Clin. Microbiol. *38*:2824-2828.

10. Clinical and Laboratory Standards Institute. 2005. Approved Guideline M29-A3. Protection of laboratory workers from occupationally acquired infections, 3rd ed., CLSI, Wayne, PA.
11. Garner, J. S. 1996. Hospital Infection Control Practices Advisory Committee, U. S. Department of Health and Human Services, Center for Disease Control and Prevention. Guideline for isolation precautions in hospitals. Infect. Control Hospital Epidemiol. *17*:53-80.
12. U.S. Department of Health and Human Services. 2007. Biosafety in microbiological and biomedical laboratories, HHS Publication (CDC), 5th ed. U.S. Government Printing Office, Washington, D.C.
13. Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC). Official Journal L262, 17/10/2000, p. 0021-0045.

Manufacturer / Výrobce / Producent / Fabrikant / Tootja / Valmistaja / Fabricant / Hersteller / Κατασκευαστής / Gyártó / Ditta produttrice / Gamintojas / Producent / Fabricante / Výrobca / Tillverkare / Производител / Producător / Üretici / Proizvođač / Производитель / Атқарушы

Use by / Spotřebujte do / Anvendes før / Houdbaar tot / Kasutada enne / Viimeinkäyttöpäivä / A utiliser avant / Verwendbar bis / Ημερομηνία λήξης / Felhasználhatóság dátuma / Usare entro / Naudokite iki / Brukes før / Stosować do / Utilizar em / Použite do / Usar antes de / Använd före / Използвайте до / A se utiliza până la / Son kullanma tarihi / Upotrebiti do / Использовать до / дейін пайдалануға / Upotrijebiti do /
YYYY-MM-DD / YYYY-MM (MM = end of month) /
RRRR-MM-DD / RRRR-MM (MM = konec měsíce)
ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutning af måned) /
JJJJ-MM-DD / JJJJ-MM (MM = einde maand)
AAAA-KK-PP / AAAA-KK (KK = kuu lõpp)
VVVV-KK-PP / VVVV-KK (kuukauden loppuun mennessä)
AAAA-MM-JJ / AAAA-MM (MM = fin du mois) /
JJJJ-MM-TT / JJJJ-M M (MM = Monatsende) /
EEEE-MM-HH / EEEE-MM (MM = τέλος του μήνα) /
ÉÉÉÉ-HH-NN / ÉÉÉÉ-HH (HH = hónap utolsó napja)
AAAA-MM-GG / AAAA-MM (MM = fine mese) /
MMMM-MM-DD / MMMM-MM (MM = mėnesio pabaiga)
ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutten av måneden)
RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
AAAA-MM-DD / AAAA-MM (MM = fim do mês) /
RRRR-MM-DD / RRRR-MM (MM = koniec mesiaca)
aaaa-mm-dd / aaaa-mm (mm = fin del mes) /
ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutet på månaden) /
ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = края на месеца) /
AAAA-LL-ZZ / AAAA-LL (LL = sfârşitul lunii) /
YYYY-AA-GG / YYYY-AA (AA = ayın sonu) /
GGGG-MM-DD / GGGG-MM (MM = kraj meseca) /
ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = конец месяца) /
ЖЖЖЖ-АА-КК / ЖЖЖЖ-АА (АА = айдың соңы) /
GGGG-MM-DD / GGGG-MM (MM = kraj mjeseca)

REF Catalog number / Katalogové číslo / Katalognummer / Catalogusnummer / Kataloogi number / Tuotenumero / Numéro catalogue / Bestellnummer / Αριθμός καταλόγου / Katalógusszám / Numero di catalogo / Katalogo numeris / Numer katalogowy / Número do catálogo / Katalógové číslo / Número de catálogo / Каталожен номер / Număr de catalog / Katalog numarası / Kataloški broj / Номер по каталогу / Каталог нөмірі

EC REP Authorized Representative in the European Community / Autorizovaný zástupce pro Evropskou unii / Autoriseret repræsentant i EU / Erkend vertegenwoordiger in de Europese Unie / Volitatud esindaja Euroopa Nõukogus / Valtuutettu edustaja Euroopan yhteisössä / Représentant agréé pour la C.E.E. / Autorisierte EG-Vertretung / Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα / Hivatalos képviselet az Európai Unióban / Rappresentante autorizzato nella Comunità europea / Įgaliotasis atstovas Europos Bendrijoje / Autorisert representant i EU / Autoryzowane przedstawicielstwo w Unii Europejskiej / Representante autorizado na União Europeia / Autorizovaný zástupca v Európskom spoločenstve / Representante autorizado en la Comunidad Europea / Auktoriserad representant i EU / Оторизиран представител в EU / Reprezentant autorizat în Uniunea Europeană / Avrupa Topluluğu Yetkili Temsilcisi / Ovlašćeni predstavnik u Evropskoj zajednici / Уполномоченный представитель в Европейском сообществе / Европа қауымдастығындағы уәкілетті өкіл / Autorizuirani predstavnik u EU

IVD In Vitro Diagnostic Medical Device / Lékařské zařízení určené pro diagnostiku in vitro / In vitro diagnostisk medicinsk anordning / Medisch hulpmiddel voor in vitro diagnose / In vitro diagnostika meditsiiniaparatuur / Lääkinnällinen in vitro -diagnostiikkalaite / Dispositif médical de diagnostic in vitro / Medizinisches In-vitro-Diagnostikum / In vitro διαγνωστική ιατρική συσκευή / In vitro diagnosztikai orvosi eszköz / Dispositivo medico diagnostico in vitro. / In vitro diagnostikos prietaisas / In vitro diagnostisk medisinsk utstyr / Urządzenie medyczne do diagnostyki in vitro / Dispositivo médico para diagnóstico in vitro / Medicínska pomôcka na diagnostiku in vitro / Dispositivo médico de diagnóstico in vitro / Medicinsk anordning för in vitro-diagnostik / Медицински уред за диагностика ин витро / Aparatură medicală de diagnosticare in vitro / In Vitro Diyagnostik Tıbbi Cihaz / Medicinski uređaj za in vitro dijagnostiku / Медицинский прибор для диагностики in vitro / Жасанды жағдайда жүргізетін медициналық диагностика аспабы / Medicinska pomagala za In Vitro Dijagnostiku

Temperature limitation / Teplotní omezení / Temperaturbegrænsning / Temperatuurlimiet / Temperatuuri piirang / Lämpötilarajoitus / Température limite / Zulässiger Temperaturenbereich / Όριο θερμοκρασίας / Hőmérsékleti határ / Temperatura limite / Laikymo temperatūra / Temperaturbegrensning / Ograniczenie temperatury / Limitação da temperatura / Ohraničenie teploty / Limitación de temperatura / Temperaturbegränsning / Температурни ограничения / Limitare de temperatură / Sıcaklık sınırlaması / Ograničenje temperature / Ограничение температуры / Температураны шектеу / Dozvoljena temperatura

LOT Batch Code (Lot) / Kód (číslo) šarže / Batch kode (Lot) / Chargenummer (lot) / Partii kood / Eräkoodi (LOT) / Code de lot (Lot) / Chargencode (Chargenbezeichnung) / Κωδικός παρτίδας (Παρτίδα) / Tétel száma (Lot) / Codice del lotto (partita) / Partijos numeris (Lot) / Batch-kode (Serie) / Kod partii (seria) / Código do lote (Lote) / Kód série (šarža) / Código de lote (Lote) / Satskod (parti) / Код (Партида) / Număr lot (Lotul) / Parti Kodu (Lot) / Kod serije / Код партии (лот) / Топтама коды / Lot (kod)

Σ Contains sufficient for <n> tests / Dostatečné množství pro <n> testů / Indeholder tilstrækkeligt til <n> test / Voldoende voor <n> tests / Küllaldane <n> testide jaoks / Sisältöon riittävä <n> testejä varten / Contenu suffisant pour <n> tests / Ausreichend für <n> Tests / Περιέχει επαρκή ποσότητα <n> εξετάσεις / <n> teszthez elegendő / Contenuto sufficiente per <n> test / Pakankamas kiekis atlikti <n> testų / Innholder tilstrekkelig for <n> tester / Zawiera ilość wystarczającą do <n> testów / Contémo suficiente para <n> testes / Obsah vystačí na <n> testov / Contenido suficiente para <n> pruebas / Räckertill <n> antal tester / Съдържанието е достатъчно за <n> теста / Conţine suficient pentru <n> teste / <n> testleri için yeterli miktarda içerir / Sadržaj dovoljan za <n> testova / Достаточно для <n> тестов(а) / <n> тесттері үшін жеткілікті / Sadržaj za (n) testova

Consult Instructions for Use / Prostudujte pokyny k použití / Læs brugsanvisningen / Raadpleeg gebruiksaanwijzing / Lugeda kasutusjuhendit / Tarkista käyttöohjeista / Consulter la notice d'emploi / Gebrauchsanweisung beachten / Συμβουλευτείτε τις οσηγίες χρήσης / Olvassa el a használati utasítást / Consultare le istruzioni per l'uso / Skaitykite naudojimo instrukcijas / Se i bruksanvisningen / Zobacz instrukcja użytkowania / Consulte as instruções de utilização / Pozri Pokyny na používanie / Consultar las instrucciones de uso / Se bruksanvisningen / Направете справка в инструкциите за употреба / Consultaţi instrucţiunile de utilizare / Kullanım Talimatları'na başvurun / Pogledajte uputstvo za upotrebu / См. руководство по эксплуатации / Пайдалану нұсқаулығымен танысып алыңыз / Koristi upute za upotrebu

Do not reuse / Nepoužívejte opakovaně / Må ikke genbruges / Niet opnieuw gebruiken / Mitte kasutada korduvalt / Ei saa käyttää uudelleen / Usage unique / Nicht wiederverwenden / Μην το ξαναχρησιμοποιείτε / Egyszer használatos / Non riutilizzare / Tik vienkartiniam naudojimui / Må ikke gjenbrukes / Nie stosować powtórnie / Não reutilizar / Nepoužívajte opakovane / No reusar / Får ej återanvändas / Не използвайте отново / A nu se reutiliza / Tekrar kullanmayın / Ne upotrebljavajte ponovo / Не использовать повторно / Пайдаланбаңыз / Ne koristiti ponovo

CONTROL Control / Kontrola / Kontrol / Controle / Kontroll / Kontrolli / Contrôle / Kontrolle / Έλεγχος / Controllo / Kontrolė / Controlo / Управление / Etalon Etalon / Контроль / Бақылау

Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152 USA
800-638-8663
www.bd.com/ds

EC REP Benex Limited
Rineanna House
Shannon Free Zone
Shannon, County Clare, Ireland