

DIRECTIGEN™ EZ RSV

For the direct detection of Respiratory Syncytial Virus (RSV)

I. INTENDED USE

The **Directigen**™ EZ RSV test is a rapid chromatographic immunoassay for the direct and qualitative detection of Respiratory Syncytial Virus (RSV) antigen in nasopharyngeal washes, nasopharyngeal aspirates, nasopharyngeal swabs and nasopharyngeal swab/washes from patients suspected of having a viral respiratory infection. This test is intended for *in vitro* diagnostic use to aid in the diagnosis of Respiratory Syncytial Virus (RSV) infections in neonatal and pediatric patients under the age of 20. It is recommended that negative test results be confirmed by cell culture.

II. 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 in young children during the cold season.¹ RSV has also been implicated in severe respiratory infections in the elderly and immunocompromised.^{2,3} More recently, RSV has been identified as causing 20% of “influenza-like” illness in people 15–44 years of age.⁴

Traditional methods for detection of respiratory viruses have included cell culture and direct fluorescent antibody (DFA).⁵⁻⁷ More recently, PCR has shown clinical utility for the detection of respiratory viruses including RSV.⁸ Enzyme immunoassay (EIA) and rapid manual systems are available for specific viruses such as Influenza A/B and RSV. Rapid tests allow for 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 specimens collected for RSV testing include nasopharyngeal washes, nasopharyngeal aspirates and nasopharyngeal swabs. Nasopharyngeal washes and aspirates have been shown to be superior to swabs and are the specimens of choice.¹⁰

The **Directigen** EZ RSV antigen detection test is a chromatographic assay to detect RSV antigens extracted from various specimens of symptomatic patients. The speed and workflow of the **Directigen** EZ RSV test make it applicable as a “STAT” RSV antigen detection test, providing rapid, relevant information to assist with antiviral intervention and other clinical or support decisions.

III. PRINCIPLES OF THE PROCEDURE

The **Directigen** EZ RSV test is a chromatographic assay to qualitatively detect RSV antigen in samples extracted from respiratory specimens. When extracted specimens are added to the test device, RSV A and/or B antigens bind to the antibody-colloidal gold conjugate in the test strip forming an antigen-antibody complex. This complex migrates

across the test strip to the reaction area and is captured by the line of RSV antibody on the membrane. Excess conjugate binds to a second line consisting of inactivated RSV antigen that serves as a functional control. A positive result is indicated by the appearance of two reddish-purple lines in the read window, one line next to the Test “T” and the other next to the Control “C”. The absence of a reddish-purple line next to the “T” and the presence of a reddish-purple line next to the “C” indicate a negative result. The test is considered uninterpretable if no visible reddish-purple line is present next to the “C”.

IV. REAGENTS

The following are included in the **Directigen** EZ RSV kit.

BD RSV Devices	30	Each device containing a control line of inactivated RSV antigen and a test line of monoclonal RSV antibody on the membrane.
Extraction Reagent E	4.0 mL	Detergent with 0.2% sodium azide (preservative).
Control + Swab	1 ea.	Positive Control, detergent-treated RSV infected HEp-2 cells with 0.1% sodium azide (preservative).
Control – Swab	1 ea.	Negative Control with 0.1% sodium azide (preservative).
DispensTube™ Tubes	30	Tubes for specimen extraction and sample delivery into device.
DispensTube Tips	30	Tips to filter sample when delivered into device.

Materials Required But Not Provided: Pipette (capable of delivering 250 µL), vortex, timer and Transport Media (see Specimen Collection and Handling).

Warnings and Precautions:

For *in vitro* Diagnostic Use.

1. The RSV Control (+) swab and the control line on the **BD 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.
2. Do not use the kit if the Controls do not yield appropriate results.
3. Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. “Standard Precautions”¹¹⁻¹⁴ and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids.
4. Do not use kit components beyond the expiration date.
5. Do NOT mix reagents from different kit lot numbers. Do not reuse the device.
6. Reagents contain sodium azide, which is harmful by inhalation, in contact with skin and if swallowed. Contact with acids liberates 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.

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

V. SPECIMEN COLLECTION AND PREPARATION

Specimen Transport and Storage: Transport fresh specimens to the laboratory as rapidly as possible in a suitable liquid transport system. Process specimens as soon as possible after collection. If necessary, specimens may be stored at 2-8°C for up to 72 hours or at -20°C for up to seven days after collection.

It is essential that the correct specimen collection and preparation methods be followed. Do not centrifuge specimens prior to use with the **Directigen** EZ RSV, as the removal of cellular material will adversely affect the sensitivity of the test.

Transport Media: The following transport media have been tested and found to be compatible with the **Directigen** EZ RSV Test:

Normal Saline	Trypticase TM Soy Broth + 0.5% gelatin*
Phosphate Buffered Saline (PBS)	Trypticase Soy Broth + 0.5% BSA
PBS + 0.5% gelatin*	Earle's Minimal Essential Medium (EMEM)
PBS + 0.5% (BSA) Bovine Serum Albumin	EMEM + 0.5% BSA
Veal Infusion Broth (VIB)	EMEM + 1% BSA
VIB + 0.5% BSA	EMEM + 0.5% lactalbumin hydrolysate
Hanks Basal Salt Solution	EMEM + 1.0% lactalbumin hydrolysate
M4 Media*	Modified Stuart's (liquid) CultureSwab TM
M4-RT Media*	Amies (liquid) CultureSwab
M5 Media	Starplex Multitrans TM *
Bartels ViraTrans TM Media	BD TM Universal Viral Transport Medium*
Sucrose Phosphate (2-SP)	BD TM ESwab

* Medium contains gelatin.

Specimen Collection and Preparation: Nasopharyngeal washes and aspirates have been shown to be superior to nasopharyngeal swabs and are the specimens of choice.^{9,10}

Acceptable specimens for testing with the **Directigen** EZ RSV test include nasopharyngeal washes, nasopharyngeal aspirates, nasopharyngeal swabs and nasopharyngeal swab/washes.

Note: For nasopharyngeal swabs (NPS), polyester or rayon-tipped swabs with an aluminum wire are recommended. Flocked swabs have been analytically tested and have been found to be compatible with the **Directigen** EZ RSV test.¹⁵ Calcium alginate-tipped swabs are not acceptable for collection of viral specimens.¹⁶

Procedure for Nasopharyngeal Washes and Nasopharyngeal Swab/Washes:

1. Sample volumes of 2–3 mL are recommended.
2. Excessive wash or lavage volumes should be avoided as they may result in decreased test sensitivity.
3. Process specimen as described in “Test Procedure.”

Procedure for Nasopharyngeal Swabs:

1. Swab specimens may be added to 350 µL–2 mL of transport medium.
2. Vortex the swab and transport medium.
3. Remove as much liquid from the swab as possible.
NOTE: Alternatively swab may be left in tube.
4. Dispose the swab into appropriate container.
5. Process specimen as described in “Test Procedure.”

Procedure for Nasopharyngeal Aspirates:

1. Specimens may be dispersed in 1–3 mL of transport medium or saline prior to processing.
2. Process specimen as described in “Test Procedure.”

VI. PROCEDURE

Test Procedure

NOTES:

- Reagents, specimens and **BD** RSV devices must be at room temperature (15–30°C) when used for testing.
 - Thoroughly mix all specimens prior to removal of an aliquot for extraction. Do not centrifuge specimens prior to use with **Directigen** EZ RSV test, as the removal of cellular material will adversely affect the sensitivity of the test.
 - To assure proper delivery, **DispensTube** tubes and reagent bottles must be held vertically (approximately one inch from the **BD** RSV device sample well or **DispensTube**), while gently dispensing one drop at a time, in quick succession.
1. Remove a **BD** RSV device from its foil pouch immediately before use.
 2. Label a **BD** RSV device and a **DispensTube** tube for the control or specimen to be tested.
 3. Place the labeled **DispensTube** in the designated area of the workstation or rack.
 4. Gently mix Extraction Reagent E by inversion. Dispense 3 drops into the **DispensTube**. Hold reagent bottle vertically (approximately one inch from the **DispensTube**) while dispensing drops.
 5. Process specimens and controls as directed below:
 - a. For specimens:
 1. Vortex or thoroughly mix specimen. Do not centrifuge.
 2. Pipette 250 µL of specimen into **DispensTube** (containing Reagent E)

- b. For Controls:
 1. Add 250 µL of normal saline to the DispensTube tube (containing Reagent E)
 2. Insert control swab and express by rotating swab 6-8 times while pinching tube.
 3. Remove control swab while pinching tube to remove excess fluid from the swab tip.
6. Insert a **DispensTube** Tip into each **DispensTube**.
NOTE: Do not use tips from other Directigen products.
7. Vortex or mix thoroughly.
8. Invert the **DispensTube** and holding the tube on the upper half, away from the tip, gently squeeze three (3) drops of the extracted specimen into the appropriately labeled **BD RSV** sample well.
NOTE: Squeezing the tube close to the tip may result in ejection of the tip and leakage of the contents from the tube.
9. Read results at 15 minutes or up to 60 min. Positive results may be reported as soon as 5 min. as long as the test and control line are visible.
NOTE: If using a gelatin-containing transport medium, results must be read at 15 min. See “Limitations of the Procedure.”
10. Read in a well-lighted area and record 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. It is recommended that the user refer to CLSI (formerly NCCLS) EP12-A¹⁷ and 42 CFR 493.1202 (c)¹⁸ for guidance on appropriate Quality Control practices.

Each **BD RSV** device contains built-in controls. Built-in control features include:

Internal Control: The appearance of a reddish-purple control line provides an internal antigen control (positive internal control) that serves as a reagent check for the conjugate and capture antibody as well as ensuring sufficient capillary flow has occurred. The absence of this line indicates an uninterpretable test.

Test Membrane Control (negative internal control): The unreactive membrane surface surrounding the positive internal control and test lines contrasts with a positive reaction and therefore serves as a background reference for interpreting reaction color.

External Positive and Negative Controls:

Positive and Negative controls are supplied with each kit. These controls are provided as a means of additional quality control to demonstrate a positive or negative reaction. The external controls should be run as a quality control procedure for each new lot or shipment received. The formation of the reddish-purple line

in the read window next to the “T” when the Control (+) is employed further indicates that the RSV antigen binding property of the membrane is functional. Do not report results if either the Control + or the Control – do not give appropriate results.

If expected control results are not obtained, do not report patient results. Contact your local **BD** representative or Technical Services for assistance.

VII. INTERPRETATION OF RESULTS

Positive Test (antigen present) – A visible reddish-purple line appears in the read window next to the Test “T”, and a reddish-purple line next to the Control “C”. This indicates RSV antigen was detectable in the specimen. The background area should be white to light pink.

Negative Test (no antigen detected) – No reddish-purple line is visible next to the Test “T”. This indicates RSV antigen was not detectable in the specimen. A reddish-purple line next to the Control “C” indicates proper performance of test procedure and reagents. The background area should be white to light pink.

Uninterpretable Test – If a reddish-purple line next to the Control “C” is not visible or the background color interferes with interpretation of the test or control lines, the test is uninterpretable. An uninterpretable test must be repeated, a new specimen obtained and retested, or the specimen sent to the clinical laboratory for culture isolation.

REPORTING OF RESULTS

Positive	Positive for the presence of RSV antigen. A positive result may occur in the absence of viable virus.
Negative	Negative for the presence of RSV antigen. Infection due to RSV cannot be ruled-out since the antigen present in the sample may be below the detection limit of the test. Culture confirmation of negative samples is recommended.

VIII. LIMITATIONS OF THE PROCEDURE

1. The **Directigen** EZ RSV test is capable of detecting both viable and non-viable RSV particles. The **Directigen** EZ RSV test performance depends on antigen load and may not correlate with tissue culture performed on the same specimen. The etiology of respiratory infection caused by microorganisms other than Respiratory Syncytial Virus cannot be established with this test.
2. Inadequate specimen collection, improper sample handling/transport or low levels of virus shedding may yield a false-negative result. Accordingly, a negative test result does not eliminate the possibility of an RSV infection. As with all diagnostic procedures, the results obtained with the **Directigen** EZ RSV test

- should be used in conjunction with other clinical information available to the physician.
3. In chromatographic immunoassays, weakly visible lines are more likely to be false positives than are strongly visible lines. As with all diagnostic procedures, the results obtained with the **Directigen** EZ RSV test should be used in conjunction with other clinical information available to the physician.
 4. The validity of the **Directigen** EZ RSV test has not been proven for identification/confirmation of tissue culture isolates and should not be used in this capacity.
 5. Contents of the transport medium being used should be carefully reviewed to determine whether or not it contains gelatin. If using a gelatin-containing transport medium, results must be read at 15 min. Extending read time beyond 15 min. may result in the appearance of faint lines in the test (T) position of the read window.
 6. Amies Gel **CultureSwab**TM Plus medium is not compatible with the **Directigen** EZ RSV test. Storing specimens in this medium over time may cause a potential false negative result.
 7. Cross-reactivity of this assay with human metapneumovirus has not been studied.
 8. Monoclonal antibodies may not detect all antigenic variants or new strains of RSV.
 9. The **Directigen** EZ RSV test has not been evaluated with a sufficient number of lower respiratory specimens, lower nasal swabs, nose/throat swabs and pharyngeal swabs to estimate performance characteristics with these specimen types.

IX. 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. The prevalence observed with culture during the clinical study ranged from 4.2%–46.5%.

X. PERFORMANCE CHARACTERISTICS

Performance characteristics for the **Directigen** EZ RSV test were established in a multi-center study conducted at seven clinical centers during the 2001–2002 RSV season. The clinical centers were located in Canada and geographically diverse areas within the United States.

All specimens were collected and transported to the laboratory according to each laboratory's procedure. Each specimen was evaluated with the **Directigen** EZ RSV test, cell culture and the laboratory's routine method (i.e., DFA, EIA). Any remaining specimen was archived at or below –20°C.

For cell culture, a portion of the specimen was inoculated into cell lines appropriate for respiratory viral culture according to each laboratory's procedure. Cells were examined for the appearance of cytopathic effects (CPE). Infected cells were confirmed for RSV by immunofluorescent staining. Specimens negative for CPE at fourteen days were stained for negative confirmation by species-specific immunofluorescent staining.

A total of 1176 specimens, consisting of nasopharyngeal wash, nasopharyngeal aspirate, nasopharyngeal swab and nasopharyngeal swab/wash, from patients suspected of having RSV were evaluated with the **Directigen** EZ RSV test.

Clinical Performance: For all specimens evaluated, the overall sensitivity and specificity of the **Directigen** EZ RSV test for RSV when compared to culture were 80% and 91%, respectively. The overall uninterpretable rate was 0%. The performance characteristics of the **Directigen** EZ RSV as compared to cell culture for each specimen type are shown in Table 1. The performance characteristics as compared to cell culture by clinical site are shown in Table 2.

Table 1: Summary of the Performance of the Directigen EZ RSV (EZ) Test Compared to Culture for all Specimen Types

Specimen Type	n	Culture/EZ				Sensitivity (%) (95% CI)	Specificity (%) (95% CI)
		+/+	-/+ ^a	+/-	-/-		
Nasopharyngeal Wash (NPW)	348	129	29	19	171	87.2 (80.7-92.1)	85.5 (79.8-90.1)
Nasopharyngeal Aspirate (NPA)	401	90	24	27	260	76.9 (68.2-84.2)	91.6 (87.7-94.5)
Nasopharyngeal Swab/Wash (NPSW)	160	28	6	11	115	71.8 (55.1-85.0)	95.0 (89.7-98.2)
Nasopharyngeal Swab (NPS)	267	20	20	10	217	66.7 (47.2-82.7)	91.6 (87.3-94.8)

(+) = RSV positive (-) = RSV negative

^a The PCR method used to test the culture negative, **Directigen** EZ RSV positive specimens is not an FDA-cleared method.

There were 79 specimens that were culture negative, **Directigen** EZ RSV test positive. PCR testing was performed on 73 of the 79 specimens; a total of 46 of the 73 specimens were positive by PCR.

Table 2: Summary of the Performance of the Directigen EZ RSV (EZ) Test Compared to Culture by Clinical Site

Site	Specimen Type	n	Culture/EZ				Sensitivity (%) (95% CI)	Specificity (%) (95% CI)
			+/+	-/+	+/-	-/-		
Site 1	50% NPW 45% NPA 5% NPS	38	11	2	0	25	100 (71.5-100)	92.6 (83.8-99.4)
Site 2	100% NPW	173	56	18	15	84	78.9 (67.6-87.7)	82.4 (73.6-89.2)
Site 3	59% NPA 37% NPW 4% NPS	195	79	24	13	79	85.9 (77.1-92.3)	76.7 (67.3-84.5)
Site 4	100% NPS	207	4	17	5	181	44.4 (13.7-78.8)	91.4 (86.6-94.9)
Site 5	73% NPSW 24% NPS 2% NPW 1% NPA	219	46	8	15	150	75.4 (62.7-85.5)	94.9 (90.3-97.8)
Site 6	100% NPW	77	31	0	3	43	91.2 (76.3-98.1)	100 (91.8-100)
Site 7	100% NPA	267	40	10	16	201	71.4 (57.8-82.7)	95.3 (91.5-97.7)

(+) = RSV positive (-) = RSV negative

Directigen EZ RSV positive test results were distributed over a range of weakly visible to strongly visible lines. Of the 70 **Directigen** EZ RSV positive specimens with weakly visible lines, 39 were culture positive and a total of 58 were positive by one or more methods (i.e., culture, DFA EIA, or PCR^a). Of the 170 **Directigen** EZ RSV positive specimens with visible lines, 130 were culture positive while a total of 166 were positive by one or more methods (i.e., culture, DFA, EIA, or PCR^a). Of the 106 **Directigen** EZ RSV positive specimens with strongly visible lines, 98 were culture positive while a total of 106 were positive by one or more methods (i.e., culture, DFA, EIA, or PCR^a).

^a The PCR method used to test the culture negative, **Directigen** EZ RSV positive specimens is not an FDA-cleared method.

Reproducibility: The reproducibility of the **Directigen** EZ RSV test was evaluated at three sites. The reproducibility panel was composed of 12 simulated RSV samples and included four replicates of a low positive level (near the Limit of Detection [LOD]) and four replicates of a moderate positive level of RSV antigen seeded into the negative control diluent. The panel also included four simulated RSV negative samples that were the unseeded negative control diluent. The overall reproducibility for the **Directigen** RSV EZ test was 99.1%.

Analytical Studies

Analytical Sensitivity (Limit of Detection)

The limit of detection (LOD) for the **Directigen** EZ RSV test was established for a total of five RSV strains; two RSV A and three RSV B strains.

Type	RSV Viral Strain	LOD (TCID ₅₀)*
A	RSV (Long)	3.95 x 10 ³
A	RSV (A-2)	7.9 x 10 ³
B	RSV (9320)	4.05 x 10 ²
B	RSV (Washington)	7.03 x 10 ³
B	RSV (Wild-type)	5.56 x 10 ²

*TCID₅₀ = Tissue Culture Infectious Dose at which 50% of cells are lysed.

Analytical Specificity

The **Directigen** EZ RSV test was evaluated using a total of 99 microorganisms (58 bacteria, two yeasts and 39 viruses). Bacteria and yeasts were tested at concentrations of 10⁸ CFU/mL. *Mycoplasma orale* was tested at >10⁷ CFU/mL. *Mycoplasma pneumoniae* was tested at >10⁶ CCU/mL (CCU – color changing units). *Mycobacterium tuberculosis* was tested at 7.0 x 10⁶ CFU/mL. Viral isolates were tested at titers between 10^{3.5} to 10^{9.5} TCID₅₀/0.20 mL. Influenza viruses were tested at titers of 10^{3.5} to 10^{9.5} CEID₅₀ ** /0.20 mL. None of the microorganisms listed gave a positive result in the **Directigen** EZ RSV test.

** CEID₅₀ = Chick Embryo Infectious Dose at 50% of the chick embryo infected.

Bacteria and Yeast Panel		
<i>Acinetobacter baumannii</i> (<i>calcoaceticus</i>)	<i>Klebsiella pneumoniae</i>	<i>Proteus mirabilis</i>
<i>Actinobacillus suis</i>	<i>Lactobacillus casei</i>	<i>Proteus vulgaris</i>
<i>Bacteroides fragilis</i>	<i>Lactobacillus fermentum</i>	<i>Pseudomonas aeruginosa</i>
<i>Bordetella pertussis</i>	<i>Lactobacillus plantarum</i>	<i>Salmonella choleraesuis</i> subsp <i>minnesota</i>
<i>Candida albicans</i>	<i>Legionella pneumophila</i>	<i>Serratia marcescens</i>
<i>Candida glabrata</i>	<i>Listeria monocytogenes</i>	<i>Staphylococcus aureus</i>
<i>Cardiobacterium hominis</i>	<i>Moraxella catarrhalis</i>	<i>Staphylococcus aureus</i> - Cowan
<i>Chlamydia psittaci</i>	<i>Mycobacterium</i> <i>intracellulare</i>	<i>Staphylococcus epidermidis</i>
<i>Chlamydia trachomatis</i> LGVII	<i>Mycobacterium</i> <i>tuberculosis</i>	<i>Streptococcus bovis</i> II Group D
<i>Corynebacterium</i> <i>diphtheriae</i>	<i>Mycoplasma orale</i>	<i>Streptococcus mutans</i>
<i>Eikenella corrodens</i>	<i>Mycoplasma pneumoniae</i>	<i>Streptococcus oralis</i>
<i>Enterococcus faecalis</i>	<i>Neisseria gonorrhoeae</i>	<i>Streptococcus</i> <i>pneumoniae</i>
<i>Enterococcus gallinarum</i>	<i>Neisseria meningitidis</i>	<i>Streptococcus pyogenes</i>
<i>Escherichia coli</i>	<i>Neisseria mucosa</i>	Group A
<i>Fusobacterium nucleatum</i>	<i>Neisseria sicca</i>	<i>Streptococcus sanguis</i>
<i>Gardenerella vaginalis</i>	<i>Neisseria subflava</i>	<i>Streptococcus sp.</i> Group B
<i>Haemophilus aphrophilus</i>	<i>Peptostreptococcus</i> <i>anaerobius</i>	<i>Streptococcus sp.</i> Group B
<i>Haemophilus influenzae</i>	<i>Porphyromonas</i>	<i>Streptococcus sp.</i> Group B

<i>parainfluenzae</i>	<i>assachrolyticus</i>	C
<i>Haemophilus</i>	<i>Prevotella oralis</i>	<i>Streptococcus</i> sp. Group
<i>paraphrophilus</i>		F
<i>Kingella kingae</i>		<i>Streptococcus</i> sp. Group
		G
		<i>Veillonella parvula</i>

VIRAL PANEL

Adenovirus, Type 3	Influenza B/GL/1739/54
Adenovirus, Type 5	Influenza B/Hong Kong/5/72
Adenovirus, Type 7	Influenza B/Lee/40
Adenovirus, Type 10	Influenza B/Allen/45
Adenovirus, Type 18	Influenza B/Maryland/1/59
Coronavirus	Influenza B/Taiwan/2/62
Coxsackievirus Type A9 (Griggs)	Influenza C/Taylor/1233/47
Coxsackievirus Type A9 (P.B. Bozek)	Measles Virus
Coxsackievirus Type B5	Mumps virus
Coxsackievirus Type B6	Parainfluenza Type 1
Coxsackievirus Type A21	Parainfluenza Type 2
Cytomegalovirus	Parainfluenza Type 3
Echovirus Type 2	Rhinovirus Type 1A
Echovirus Type 3	Rhinovirus Type 2
Echovirus Type 6	Rhinovirus Type 13
Echovirus Type 11	Rhinovirus Type 15
Herpes Simplex Virus Type 1	Rhinovirus Type 16
Herpes Simplex Virus Type 2	Rhinovirus Type 37
Influenza A (H1N1)	Varicella-Zoster Virus
Influenza A (H3N2)	

Interfering substances

Various substances were tested in the **Directigen** EZ RSV test including whole blood at 2%, over the counter (OTC) drugs and prescription drugs. No interference was noted in the assay for any substance at the levels tested.

Non-Prescription Medications (OTC)

Three OTC mouthwashes at 25%	Diphenhydramine HCl at 5 mg/mL
Three OTC throat drops at 25%	Pseudoephedrine HCl at 20 mg/mL
Three OTC nasal sprays at 10%	Guaiacol Glyceryl Ether at 20 mg/mL
4-Acetamidophenol at 10 mg/mL	Ibuprofen at 10 mg/mL
Acetylsalicylic acid at 20 mg/mL	Oxymetazoline at 0.5 mg/mL
Chlorpheniramine maleate at 5 mg/mL	Phenylephrine at 1 mg/mL
Dextromethorphan at 10 mg/mL	

Prescription Medications

Zanamavir at 1 mg/mL
Amantadine at 500 ng/mL
Rimantadine at 500 ng/mL

Ribavirin at 500 ng/mL
Synagis™ at 0.1 mg/mL
Albuterol Sulfate at 0.083 mg/mL

XI. AVAILABILITY

Cat. No.	Description
256030	Directigen™ EZ RSV Test Kit
220115	BBL™ CultureSwab™ Sterile Single Swab, Pkg. of 100
220131	BBL™ CultureSwab™ Liquid Amies, Flexible Aluminum Wire, pkg. of 50
220134	BBL™ CultureSwab™ Liquid Stuart, Flexible Aluminum Wire, pkg. of 50
220220	BD™ Universal Viral Transport 3 mL Vial, Ctn. of 50
220244	BD™ Universal Viral Transport 1mL Vial, Ctn. of 50
220526	BD™ Universal Viral Transport Kit, 1mL Vial and a sterile nylon flocked flexible minitip swab, Ctn. of 50
220531	BD™ Universal Viral Transport Kit, 3mL Vial and a sterile nylon flocked flexible minitip swab, Ctn. of 50
220532	BD™ Eswab Colleciton Kit, 1mL Liquid Amies and a sterile nylon flocked flexible minitip swab, Ctn. of 50
256034	Directigen™ EZ RSV Control Kit, Box of 10

XII. REFERENCES

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XIII. TECHNICAL INFORMATION

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