

tru<sup>®</sup>  
RSV

(US Patent No. US D560,281S; US D561,344S; US 744,9775 B2)

**A Rapid Immunoassay for the Detection of Respiratory Syncytial Virus (RSV) Antigens  
in Nasal Wash, Nasopharyngeal Aspirate, Nasopharyngeal Swab and Nasal Swab Samples**

REF 751330

IVD

Rx Only

**INTENDED USE**

TRU RSV is a rapid, qualitative, lateral-flow immunoassay for the detection of Respiratory Syncytial Virus (RSV) antigens (fusion protein or nucleoprotein<sup>1,2</sup>) in human nasal wash, nasopharyngeal aspirate, and nasal and nasopharyngeal swab samples. It is designed to be used by clinical laboratories to test specimens from symptomatic patients aged five years or less. A negative result does not preclude RSV infection. It is recommended that all negative test results be confirmed by cell culture. The results of this test are used in combination with other clinical tests and the patients' conditions to diagnose RSV-associated infections.

**SUMMARY AND EXPLANATION OF THE TEST**

Respiratory Syncytial Virus (RSV) is the most important cause of pneumonia and bronchiolitis in infants and small children. Approximately 90,000 children are hospitalized each year due to RSV in the USA alone.<sup>3</sup> Hospitalization due to RSV is more frequently associated with children that have underlying disease or premature birth.<sup>4</sup> Mortality rates are estimated to be between 1 and 3% for children that are hospitalized with RSV.<sup>3</sup> RSV is also being recognized more frequently as a cause of significant respiratory disease in the elderly.<sup>5</sup> RSV causes a wide range of respiratory symptoms that can be difficult to distinguish clinically from symptoms caused by other respiratory viruses such as influenza.<sup>3</sup> Because of its high infectivity, the potential for prolonged patient shedding and the ability of the virus to survive for hours on environmental surfaces, RSV has emerged as a serious cause of nosocomial infection.<sup>3,6</sup> RSV can be detected in human respiratory samples by a variety of methods including tissue culture, immunofluorescent assay and enzyme immunoassay. Although tissue culture is still considered the diagnostic test standard, it requires tissue culture facilities and may take a week to complete. Immunofluorescent antibody-based tests are reasonably sensitive, yet highly dependent on specimen quality and preparation. Enzyme and microparticle-based immunoassays have become one of the most frequently used methods for the detection of RSV.<sup>6</sup> TRU RSV is a lateral flow-based immunoassay for the rapid detection of RSV in human respiratory samples. The results from this test are used to support data available from the patient's clinical evaluation and assist the physician in determining a course of action.

**BIOLOGICAL PRINCIPLES**

TRU RSV is a single use capture immunoassay to detect RSV antigen in human samples. The test consists of a Conjugate Tube, a Test Strip and Sample Diluent. The Conjugate Tube contains a lyophilized bead of colloidal gold-linked monoclonal antibodies to RSV fusion and nucleoproteins (detector antibodies). The Test Strip carries a nitrocellulose membrane with dried capture antibodies placed at a designated Test Line for RSV. The Test Strip holder caps the Conjugate Tube during testing and subsequent disposal to reduce exposure to potential pathogens.

The conjugate bead is first rehydrated in the Conjugate Tube with Sample Diluent. Patient sample is then added, the contents mixed and the Test Strip added. If RSV antigens are present, they first bind to the monoclonal antibody-colloidal gold conjugate. When the sample migrates up the Test Strip to the Test Line, the antigen-conjugate complex is bound to the capture antibody, yielding a pink-red line. When no antigen is present, no complexes are formed and no pink-red line appears at the Test Line. An internal control line helps determine whether adequate flow has occurred through the Test Strip during a test run. A visible pink-red line at the Control position of the Test Strip should be present each time a specimen or control is tested. If no pink-red control line is seen, the test is considered invalid.

**REAGENTS/MATERIALS PROVIDED**

*The maximum number of tests obtained from this test kit is listed on the outer box.*

1. **Test Strip:** A test strip attached to a plastic holder enclosed in a foil pouch with desiccant. The test strip carries monoclonal anti-RSV capture antibodies (to fusion and nucleoproteins<sup>1,2</sup>) for the test lines. The holder is used to stopper the Conjugate Tube. The strip frame portion of the holder indicates where test and control lines should appear. Store the pouch at 2-25 C when not in use. Do not use the device if the desiccant indicator (line in center of desiccant) changes from blue to pink.
2. **Conjugate Tube:** A capped plastic tube containing a conjugate bead. The tube is enclosed in a foil pouch. The conjugate consists of gold-conjugated anti-RSV (to fusion and nucleoprotein), which serves as the detector antibodies. Store the foil pouch at 2-25 C when not in use. Do not store in the freezer. Do not remove the cap before use.
3. **Sample Diluent/Negative Control:** A buffered protein solution provided in a plastic vial. Sodium azide (0.094%) added as a preservative. Use as supplied. Store at 2-25 C when not in use.
4. Plastic transfer pipettes with 100, 200 and 300 µL volume marks (see diagram below).
5. TRU RSV Conjugate Tube labels (to differentiate TRU RSV Conjugate Tubes from Conjugate Tubes of other TRU assays).

**MATERIALS NOT PROVIDED**

1. Disposable latex gloves (Respiratory samples are considered potentially biologically hazardous material.)
2. Vortex for suspending the specimen in the Sample Diluent (optional)
3. Interval timer
4. Meridian Bioscience FLU/RSV Positive Control, (Product Code 751110). Inactivated RSV, influenza A, and influenza B viruses in a buffered diluent containing sodium azide (0.094%) as a preservative. The reagent is supplied ready to use. Store at 2-8 C when not in use. (This adjunct External Control is sold separately.)
5. Marking pen

**PRECAUTIONS**

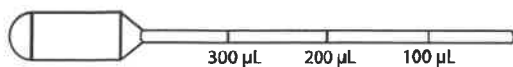
1. All reagents are for in vitro diagnostic use only.
2. Do not use reagents beyond their expiration dates.
3. Test Strips and Conjugate Tubes are packaged in foil pouches that exclude moisture during storage. Inspect each foil pouch before use. Do not use Test Strips or Conjugate Tubes in pouches that have holes or where the pouch has not been completely sealed. Do not use the Test Strip if the desiccant indicator has changed from blue to pink. The change in the desiccant color is an indicator the Test Device has been exposed to moisture. False-negative reactions may result if Test Strips or Conjugate Tubes are exposed to moisture.
4. Do not use the Sample Diluent Buffer if it is discolored or turbid. Discoloration or turbidity may be a sign of microbial contamination.
5. Directions should be read and followed carefully.
6. The Positive Control reagent vial should be held vertically when dispensing drops to ensure consistent drop size and delivery.
7. Some patient specimens contain infectious agents; therefore all patient specimens should be handled and disposed of as if they are biologically hazardous.
8. Meridian's FLU/RSV Positive Control (sold as an adjunct reagent) contains inactivated RSV and influenza antigens and should be handled as if it were potentially infectious. This reagent contains 0.094% sodium azide. Sodium azide is a skin irritant. Avoid skin contact. Disposal of reagents containing sodium azide into drains consisting of lead or copper plumbing can result in the formation of explosive metal oxides. Eliminate build-up of oxides by flushing drains with large volumes of water during disposal.
9. All respiratory samples must be mixed thoroughly before testing, regardless of consistency, to ensure a representative sample prior to testing.
10. Failure to bring specimens and reagents to room temperature (20-25 C) before testing may decrease assay sensitivity.
11. RSV antigens are relatively unstable. Care should be taken to store samples as indicated in this document. Even when samples are stored in the frozen state, the rate at which antigen deterioration occurs varies from sample to sample and cannot be predicted. Caution should be taken when assigning a negative result to samples frozen for longer than two weeks at ≤ -20 C, as such results may be a false-negative.
12. Swab samples can be transported in 0.5 to 3 mL of an approved transport medium. Stronger positive reactions may be obtained if the transport medium volume is 0.5 to 1.5 mL.
13. Sample Diluent must be added to the Conjugate Tube within one minute after removing the cap from the tube.

**HAZARDS and PRECAUTIONARY STATEMENTS**

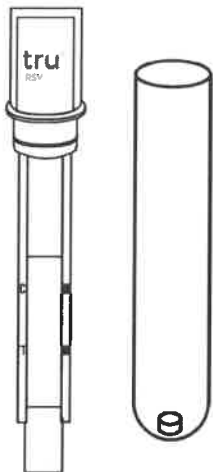
There are no known hazards associated with this product.

**PROCEDURAL NOTES**

The TRU RSV transfer pipette is diagrammed below.



The TRU RSV Test Strip and Conjugate Tubes are diagrammed below.



**SPECIMEN COLLECTION**

**Warning:** Whole blood at concentrations greater than 2.5% may lead to falsely positive test results. Do not use specimens that are obviously contaminated with blood.

- Specimens should be collected and transported in standard containers and stored at 2-8 C until tested. The specimen should be tested as soon as possible, but may be held up to 72 hours at 2 -8 C prior to testing. If testing cannot be performed within this time frame, specimens should be frozen immediately on receipt and stored frozen ( $\leq -20$  C) for up to two weeks until tested. (See section on PRECAUTIONS.) A single freeze/thaw cycle should not affect test results.
- The following liquid transport media and swabs are acceptable for collection of specimens:  
**Transport media:** M4, M4-RT, M5, UTM-RT, Stuart's, Hank's Balanced Salt, Amies, Dulbecco's PBS, 0.85% saline, Meridian Viral Transport Medium (Product code 505021). The volume of transport medium should not exceed 3 mL or false-negative results may occur due to sample dilution.  
**Swabs (Swab/Handle):** cotton/plastic, rayon/plastic, flocked nylon/plastic, foam/plastic, polyester/metal, polyester/plastic, rayon/metal, cotton/m etal. Do not use calcium alginate swabs. The chemical decreases positive reactions. Specimens collected with approved plastic shafted swabs should be processed within 60 minutes. Specimens collected with approved metal shafted swabs should be processed immediately. If testing cannot be performed within the appropriate timeframe, place the swabs in an acceptable transport medium.

**SPECIMEN PREPARATION**

Bring specimens and reagents to room temperature (20-25 C) before testing.

**Nasal wash, nasopharyngeal aspirate or swab specimens in transport media:**

- Remove 1 Conjugate Tube from its foil pouch and discard the pouch. Label the tube with the patient's name. Apply a TRU RSV label to the tube.
- Remove the cap from the Conjugate Tube and discard the cap.
- Using a transfer pipette supplied with the kit, immediately add 100 µL (first mark from the tip of the pipette) of Sample Diluent to the Conjugate Tube. Dispense directly into the center of the tube. Vortex or swirl the contents of the Conjugate Tube for 10 seconds.  
**Warning:** Dilution errors may affect test performance. Failure to add sufficient respiratory sample to the Sample Diluent may result in falsely negative tests. Failure to add the full amount of Sample Diluent may result in falsely positive tests. Addition of too much sample may result in invalid test results due to the inhibition of proper sample flow.
- Mix patient sample regardless of consistency. Use 1 of the transfer pipettes supplied with the kit to mix the sample gently but thoroughly by squeezing the pipette bulb 3 times. Alternatively, mix for at least 10 seconds using a vortex mixer.
- Using the same pipette, draw 100 µL of specimen (first mark from the end of the pipette) and add it to the Conjugate Tube.
- Using the same pipette, mix the sample and conjugate thoroughly but gently by squeezing the pipette bulb 3 times. Alternatively, mix for at least 10 seconds using a vortex mixer. Discard the pipette.

**Nasal and nasopharyngeal swab specimens collected without transport media:**

**NOTE:** Swabs constructed of plastic shafts with flocked nylon or foam absorbent materials are recommended for collecting swab specimens without transport media.

- Remove 1 Conjugate Tube from its foil pouch and discard the pouch. Label the tube with the patient's name. Apply a TRU RSV label to the tube.
- Remove the cap from the Conjugate Tube and discard the cap.
- Using a transfer pipette supplied with the kit, immediately add 300 µL (third mark from the end of the pipette tip) of Sample Diluent to the Conjugate Tube. Dispense directly into the center of the tube. Vortex or swirl the contents of the Conjugate Tube for 10 seconds. For heavily viscous samples, up to 500 µL of Sample Diluent can be added. [To deliver 500 µL with the transfer pipette supplied with the kit, draw and deliver 300 µL (third mark from the pipette tip) into the Conjugate Tube.] Using the same pipette, draw and deliver an additional 200 µL (second mark from the pipette tip) into the same Conjugate Tube.  
**Warning:** Dilution errors may affect test performance. Failure to add sufficient respiratory sample to the Sample Diluent may result in falsely negative tests. Failure to add the full amount of Sample Diluent may result in falsely positive tests. Addition of too much sample may result in invalid test results due to the inhibition of proper sample flow.
- Dip the swab into the Conjugate Tube and rotate it 3 times in the liquid. Press the swab against the side of the tube as it is removed to squeeze out as much fluid as possible. Discard the swab.

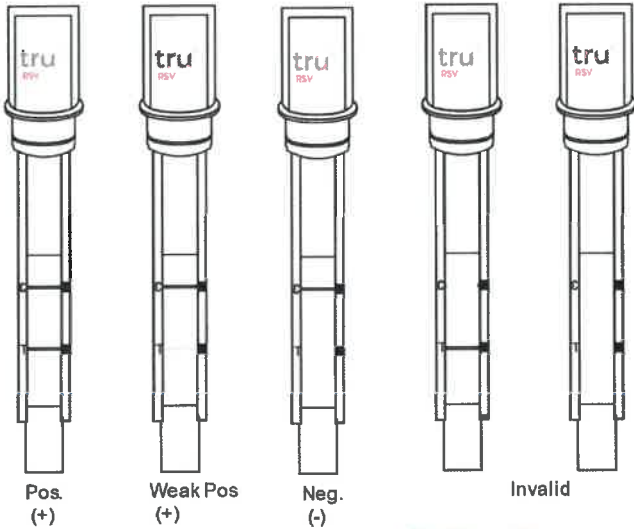
**TEST PROCEDURE**

- Remove the Test Strip from its foil pouch and discard the pouch.
- Insert the narrow end of the Test Strip into the Conjugate Tube and firmly press down on the cap to close the tube.
- Incubate at 20-25 C for 15 minutes.
- Read the results on the test strip within 1 minute. Do not read results beyond this period. (NOTE: Remove the Test Strip from the Conjugate Tube if Test or Control Lines are difficult to read. Recap the Conjugate Tube with the Test Strip holder and discard when testing is completed.)

**EXTERNAL CONTROL TESTS**

- Bring all test components, reagents and samples to room temperature (20-25 C) before testing.
- Use 1 Conjugate Tube and 1 Test Strip for positive control testing and 1 Conjugate Tube and 1 Test Strip for negative control testing.  
 Remove the Conjugate Tubes from their foil pouches and label accordingly. Discard the pouches.
- Remove the caps from the Conjugate Tubes and discard the caps.
- Add exactly 5 drops of the Positive Control reagent to the Conjugate Tube marked for the Positive Control. The drops should be dispensed directly into the center of the tube.
- Using 1 of the transfer pipettes supplied with the kit, add 200 µL (second mark from the end of the pipette tip) of Sample Diluent/Negative Control to the Conjugate Tube marked for the Negative Control. The drops should be added directly to the center of the tube.
- Vortex or swirl the contents of the tubes for 10 seconds.
- Remove 2 Test Strips from their foil pouches and discard the pouches.
- Insert the narrow end of a Test Strip to each Conjugate Tube and firmly press down on the caps to close each tube.
- Incubate both tubes at 20-25 C for 15 minutes.
- Read the results on the test strip within 1 minute. Do not read results beyond this period. (NOTE: Remove the Test Strip from the Conjugate Tube if test or control lines are difficult to read. Recap the Conjugate Tube with the Test Strip holder and discard when testing is completed.)

INTERPRETATION OF RESULTS



**Negative test:** A PINK-RED band at the Control Line position. No other bands are present.

**Positive test:** PINK-RED band at the Control and RSV Test Line positions. The color of the Test Line can be lighter than that of the Control Line. Test Lines may appear strongly visible or may appear less strongly visible.

**Weakly Positive Test:** PINK-RED band at the Control position and the appearance of a very faintly visible RSV Test Line (equal to or less in PINK-RED band color intensity compared to the "Weakly Positive" Test Line depicted in the colored illustration given in the procedure card.) TRU RSV weak positive Test Lines should be interpreted with caution since weakly positive test results may represent false-positive tests. In the TRU RSV clinical trials, 35% (23/66) of weak-positive tests were false-positive tests when compared to tissue culture results. (See also LIMITATIONS section.) Weak-positive tests should be considered presumptive positives and should be confirmed by tissue culture or DFA tests.

**Invalid test results:**

1. No band at the designated position for the Control Line. The test is invalid since the absence of a control band indicates the test procedure was performed improperly or that deterioration of reagents has occurred.
2. A PINK-RED band appearing at the Test Line position of the device after 16 minutes of incubation, or a band of any color other than PINK-RED. Falsely positive results may occur if tests are incubated too long. Bands with colors other than PINK-RED may indicate reagent deterioration.

*If any result is difficult to interpret, the test should be repeated with the same sample to eliminate the potential for error. Obtain a new sample and retest when the original sample repeatedly produces unreadable results.*

REPORTING OF RESULTS

**Negative test:** Report test results as "RSV antigens not detected. This result does not exclude viral infection. Negative tests should be confirmed by tissue culture."

**RSV Positive test:** Report test result as "Positive for RSV antigen. This result does not rule out coinfection with other pathogens."

QUALITY CONTROL

*This test should be performed per applicable local, state, or federal regulations or accrediting agencies.*

At the time of each use, kit components should be visually examined for obvious signs of microbial contamination, freezing or leakage. Do not use contaminated or suspect reagents.

**Internal procedural controls:** Internal procedural controls are contained within the Test Strip and therefore are evaluated with each test.

1. A PINK-RED band appearing at the Control Line serves as a procedural control and indicates the test has been performed correctly, that proper flow occurred and that the test reagents were active at the time of use.
2. A clean background around the Control or Test Lines also serves as a procedural control. Control or Test Lines that are obscured by heavy background color may invalidate the test and may be an indication of reagent deterioration, use of an inappropriate sample or improper test performance.

**External Control reagents should be tested according to the requirements of the laboratory or applicable local, state or accrediting agencies:**

1. See section EXTERNAL CONTROL TESTS for instructions on performing these control tests.
2. The reactivity of each new lot and each new shipment of TRU RSV should be verified on receipt using external Positive and Negative Control reagents. The number of additional tests performed with external controls will be determined by the requirements of local, state or federal regulations or accrediting agencies.
3. The external controls are used to monitor reagent reactivity. Failure of the controls to produce the expected results can mean that one of the reagents or components is no longer reactive at the time of use, the test was not performed correctly, or that reagents or samples were not added. If the positive and negative external controls fail, do not report test results to the clinician.
4. The results expected with the Controls are described in the section on INTERPRETATION OF RESULTS.

The kit should not be used if control tests do not produce the correct results. Repeat the control tests as the first step in determining the root cause of the failure. If control failures are repeated please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor.

Positive and Negative Control reagents manufactured for this assay are prepared in the matrix of the Sample Diluent, which may not mimic test specimens. If control materials that are identical in composition to test specimens are preferred, the user can prepare those by diluting known positive and negative specimens in Sample Diluent according to the SPECIMEN PREPARATION section of this insert.

EXPECTED VALUES

The positivity rate for each laboratory will be dependent on several factors including the method of specimen collection, the handling and transportation of the specimen, the time of year, the age of the patient and the prevalence of RSV at the time of testing. The Centers for Disease Control reports that outbreaks of RSV infections occur annually, usually during late fall, winter and spring months. The timing and severity of an outbreak in a community varies from year to year. The prevalence of RSV infection in the US during TRU RSV trials (December 2006 to March 2007) as reported by CDC, ranged from a high of approximately 15% in December to a low of approximately 4% in March. The monthly prevalence rates at the clinical trial sites, based on the results of prospective samples, were December 43%, January 37%, February 7% and March 5%.

LIMITATIONS OF THE PROCEDURE

1. The test is qualitative and no quantitative interpretation should be made with respect to the intensity of the positive line when reporting the result.
2. The performance of TRU RSV has not been established in patients greater than five years of age.
3. Test results are to be used in conjunction with information available from the patient clinical evaluation and other diagnostic procedures.
4. Overincubation of tests may lead to false-positive test results. Incubating tests at reduced temperatures or times may lead to falsely negative results.
5. Anti-microbials, anti-virals and interferon were not evaluated for potentially interfering properties.
6. TRU RSV detects both viable and non-viable RSV. The appearance of TRU RSV positive tests depend on RSV antigen load in the specimen; therefore a TRU RSV positive test may not correlate with the results of tissue culture performed on the same specimen.
7. The antibodies used in the test may not detect all antigenic variants or new strains of RSV.
8. A negative test result does not exclude infection with RSV nor does it rule out other microbial-caused respiratory infections. A positive test result does not rule out coinfection with other microbes.
9. Dry swab specimens are not as stable as swab specimens in transport medium. Studies performed at Meridian suggest deterioration occurs more rapidly on metal shafted swabs, than on plastic-shafted swabs.
10. In all immunochromatographic assays, faintly visible or weak test lines are more likely to be falsely positive than are strongly positive test lines. As with any diagnostic procedure, the result of a TRU RSV test should be used in conjunction with other tests and the patient's clinical picture.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

Clinical studies evaluated the performance of TRU RSV in the laboratory setting. Four independent laboratories in different geographic regions of the US and the manufacturer's laboratory tested a total of 625 samples from symptomatic patients under five years of age and that had been submitted for RSV testing. Three hundred four of the samples were collected during the 2006-07 season and tested fresh, while 321 were tested as frozen/thawed samples. Frozen samples were collected during the 2006-07 and earlier seasons and tested by tissue culture before freezing. Samples were evenly distributed among male and female patients. Samples that produced different test results in TRU RSV than in tissue culture were either tested by direct specimen fluorescence assay (DSFA) or by a polymerase chain reaction (PCR) assay. Those found to be RSV positive on reculture or by DSFA or PCR are indicated in the postscripts to the tables below.

**Table 1. Distribution of TRU RSV data by sample type**

Fresh Wash/Aspirate	Tissue Culture	TRU RSV**		
		Positive	Negative	Total
	Positive	64	8	72
	Negative	21*	90	111
	Total	85	98	183
		<b>95% CI</b>		
	Sensitivity	64/72	88.9%	79.3-95.1%
	Specificity	90/111	81.1%	73.8-88.4%
	Correlation	154/183	84.2%	78.9-89.4%

\* Of the 21 TRU RSV false-positive results three were positive by DSFA

\*\* One TRU RSV invalid test

Fresh Swab	Tissue Culture	TRU RSV		
		Positive	Negative	Total
	Positive	12	1	13
	Negative	7*	100	107
	Total	19	101	120
		<b>95% CI</b>		
	Sensitivity	12/13	92.3%	64.0-99.8%
	Specificity	100/107	93.5%	87.3-97.3%
	Correlation	112/120	93.3%	87.3-97.1%

\* Of the seven TRU RSV false-positive results, four were positive by PCR

Frozen Wash/Aspirate	Tissue Culture	TRU RSV		
		Positive	Negative	Total
	Positive	79	9	88
	Negative	12*	149	161
	Total	91	158	249
		<b>95% CI</b>		
	Sensitivity	79/88	89.8%	81.5-95.2%
	Specificity	149/161	92.5%	87.3-96.1%
	Correlation	228/249	91.6%	87.4-94.7%

\* Of the 12 TRU RSV false-positive results, two were positive by DSFA

Frozen Swab	Tissue Culture	TRU RSV		
		Positive	Negative	Total
	Positive	33	13	46
	Negative	1	25	26
	Total	34	38	72
		<b>95% CI</b>		
	Sensitivity	33/46	71.7%	56.5-84.0%
	Specificity	25/26	96.2%	80.4-99.9%
	Correlation	58/72	80.6%	69.5-88.9%

NOTE: As the data in Table 1 indicates, the performance characteristics generated from prospective frozen specimens might not be the same as the performance characteristics generated from prospective fresh specimens.

**Table 2. Distribution of test results by test site**

Fresh Wash/Aspirate	Site ID	TRU/Culture	Positive Samples		TRU/Culture	Negative Samples	
			Sensitivity %	95% CI		Specificity %	95% CI
	1	7/8	87.5%	47.3-99.7%	31/45	68.9%	53.4-81.8%
	2	3/3	100%	29.2-100%	2/2	100%	15.8-100%
	4	54/61	88.5%	77.8-95.3%	57/64	89.1%	78.8-95.5%
Frozen Wash Aspirate	Site ID	TRU/Culture	Positive Samples		TRU/Culture	Negative Samples	
			Sensitivity %	95% CI		Specificity %	95% CI
	2	5/5	100%	47.8-100%	0/0	N/A	N/A
	3	40/47	85.1%	71.7-93.8%	112/122	91.8%	85.4-96.0%
	4	34/36	94.4%	81.3-99.3%	37/39	94.9%	82.7-99.4%
Fresh Swab	Site ID	TRU/Culture	Positive Samples		TRU/Culture	Negative Samples	
			Sensitivity %	95% CI		Specificity %	95% CI
	2	8/9	88.9%	51.8-99.7%	11/15	73.3%	44.9-92.2%
	4	3/3	100%	29.2-100%	37/37	100%	80.5-100%
	5	1/1	N/A	N/A	53/55	96.4%	87.5-99.6%
Frozen Swab	Site ID	TRU/Culture	Positive Samples		TRU/Culture	Negative Samples	
			Sensitivity %	95% CI		Specificity %	95% CI
	2	1/1	100%	N/A	2/2	100%	15.8-100%
	3	27/39	69.2%	52.4-83.0%	14/15	93.3%	68.0-99.8%
	4	5/6	83.3%	35.9-99.6%	9/9	100%	66.4-100%

**ANALYTICAL SENSITIVITY**

The analytical sensitivity of this assay was established in tests with dilutions of three RSV A strains (VR-26, VR-1302, VR-1540) and three RSV B strains (VR-955, VR-1400, VR-1401). The lower limit of detection (see table below) is dependent on factors such as cell culture lines used, the number of passages performed and the effectiveness of the isolation methods. For these reasons, assay limit of detection levels may vary if other strains or samples are used.

Strain ID	Strain Type	Limit of Detection (LoD) TCID <sub>50</sub> /mL
VR-26	A	2.49 x 10 <sup>2</sup>
VR-1302	A	4.47
VR-1540	A	5.52 x 10 <sup>1</sup>
VR-955	B	4.47
VR-1400	B	1.10 x 10 <sup>1</sup>
VR-1401	B	2.47

**REPRODUCIBILITY**

Assay precision, intra-assay variability and inter-assay variability were assessed with a reference panel prepared from pools of negative samples spiked with specific virus. The reproducibility panel consisted of high positive (n=2), low negative (n=2), and low positive (n=3) and high negative specimens (n=3). The latter were prepared near the assay limit of sensitivity. Each sample was evaluated twice per day for three consecutive days by three different laboratories. Reproducibility was 100% with no intra-assay and inter-assay variability for samples prepared above or below the limit of analytical sensitivity.

**CROSSREACTIVITY**

The specificity of TRU RSV was tested utilizing the following bacterial, viral and yeast strains. RSV positive and negative respiratory specimens were spiked with  $\geq 4 \times 10^7$ /mL bacteria or yeast. Viruses were tested at levels  $\geq 6.7 \times 10^4$  TCID<sub>50</sub>/mL. None of the microorganisms tested yielded a positive result in the RSV-negative sample or interfered with detection of the RSV-positive sample. The RSV-negative respiratory sample was positive when spiked with RSV strain VR-26.

Adenovirus Types 1, 5 and 7A, Coxsackie Type A9, Human Coronavirus Types 229E and OC43, Cytomegalovirus, Influenza A (2 strains), Influenza B (1 strain), Human metapneumovirus, Measles, Parainfluenza Types 1, 2 and 3, Rhinovirus Type 39, *Bacillus cereus*, *Bacillus subtilis*, *Bordetella parapertussis*, *Bordetella pertussis*, *Branhamella catarrhalis*, *Candida albicans*, *Candida glabrata*, *Citrobacter freundii*, *Enterobacter cloacae*, *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Listeria monocytogenes*, *Legionella pneumophila*, *Neisseria cinerea*, *Neisseria gonorrhoeae*, *Neisseria meningitidis*, *Nocardia asteroides*, *Proteus vulgaris*, *Pseudomonas aeruginosa*, *Pseudomonas fluorescens*, *Serratia liquefaciens*, *Staphylococcus aureus*, *Staphylococcus aureus* (Cowan I), *Staphylococcus epidermidis*, *Streptococcus* (not typed), *Streptococcus* Groups A, B, D, F, and G, *Streptococcus pneumoniae*.

A clinical sample containing Epstein Barr virus at  $2.32 \times 10^6$  genome equivalents/mL was nonreactive with TRU RSV.

**TESTS FOR INTERFERING SUBSTANCES**

The following substances, when introduced directly into nasal samples, do not interfere with testing at the concentrations identified: Acetaminophen (10 mg/mL), Acetylsalicylic acid (20 mg/mL), Albuterol (9.1% v/v), Halls® Throat Drops (20 mg/mL), Ludens® Throat Drops (20 mg/mL), Chlorpheniramine maleate (1.7 mg/mL), Clemastine fumarate (5 mg/mL), Diphenhydramine HCl (5 mg/mL), Dextromethorphan (9.1% v/v), Naproxen sodium (10 mg/mL), Phenylephrine hydrochloride (9.1% v/v), Oxymetazoline (9.1% v/v), Guaifenesin (9.1% v/v), Pseudoephedrine HCl (20 mg/mL), Listerine® Mouthwash (9.1% v/v).

Whole blood at concentrations greater than 2.9% interfered with test interpretation. Chlorpheniramine maleate at concentrations greater than 1.7 mg/mL may cause false-positive test results.