Rapid Response™

RSV Test Cassette
(Nasopharyngeal Swab/Nasal Aspirate)

REF RSV-19C, RSV-19C20, RSV-19C30 Product Insert

A rapid test for the qualitative detection of Respiratory Syncytial Virus Antigen in nasopharyngeal swab or nasal aspirate specimens.
For laboratory *in vitro* diagnostic use only

Intended Use

The Rapid Response™ RSV Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of Respiratory Syncytial Virus antigen in nasopharyngeal swab or nasal aspirate specimens. It is intended to aid in the rapid differential diagnosis of respiratory syncytial virus viral infections.

Introduction

Respiratory Syncytial Virus (RSV), which causes infection of the lungs and breathing passages, is a major cause of respiratory illness in young children. In adults, it may only produce symptoms of a common cold, such as a stuffy or runny nose, sore throat, mild headache, cough, fever, and a general feeling of being ill. But in premature babies and kids with diseases that affect the lungs, heart, or immune system, RSV infections can lead to other more serious illnesses.[1] RSV is highly contagious and can be spread through droplets containing the virus when someone coughs or sneezes. It also can live on surfaces (such as countertops or doorknobs) and on hands and clothing, so it can be easily spread when a person touches something contaminated. RSV can spread rapidly through schools and childcare centers. Babies often get it when older kids carry the virus home from school and pass it to them. Almost all kids are infected with RSV at least once by the time they're 2-3 years old.[2] RSV infections often occur in epidemics that last from late fall through early spring. Respiratory illness caused by RSV - such as bronchiolitis or pneumonia - usually lasts about a week, but some cases may last several weeks.
The Rapid Response™ RSV Test Cassette qualitatively detects the presence of Respiratory Syncytial Virus antigen in nasopharyngeal swab or nasal aspirate specimens, providing results within 15 minutes. The test uses antibodies specific for Respiratory Syncytial Virus to selectively detect Respiratory Syncytial Virus antigen in nasopharyngeal swab or nasal aspirate specimens.

Principle

The Rapid Response™ RSV Test Cassette is a qualitative, lateral flow immunoassay for the detection of Respiratory Syncytial Virus nucleoproteins in nasopharyngeal swab or nasal aspirate specimens. In this test, antibody specific to the Respiratory Syncytial Virus nucleoproteins is coated on the test line region of the test cassette. During testing, the extracted specimen reacts with the antibody to Respiratory Syncytial Virus that is coated onto particles. The mixture migrates up the membrane to react with the antibody to Respiratory Syncytial Virus on the membrane and generate one colored line in the test region. The presence of this colored line in the test region indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

Reagents

The test contains anti- Respiratory Syncytial Virus particles and anti-Respiratory Syncytial Virus coated on the membrane.

Precautions

- Please read all the information in this product insert before performing the test.
- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until ready to use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

Materials

Materials provided

- Test cassettes
- Sterile swabs
- Extraction tube tips
- Extraction reagent
- Product insert
- Extraction tubes
- Workstation

Materials required but not provided

- Timer
- Aspiration device

Storage and Stability

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

Specimen Collection

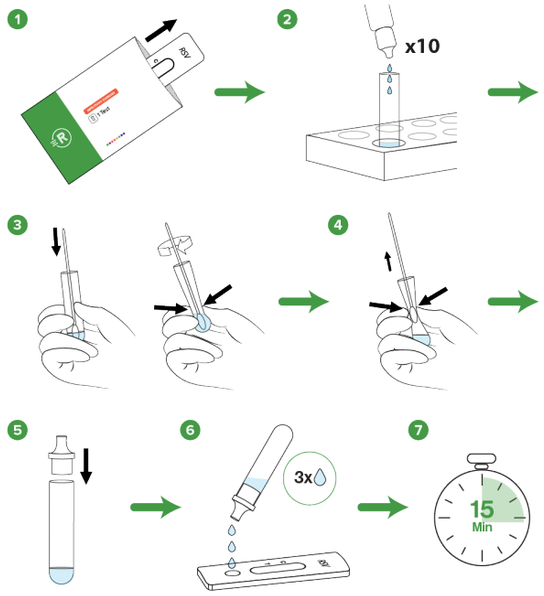
Nasopharyngeal swab sample

1. Insert swab through the nostril parallel to the palate (not upwards). The distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx or until resistance is encountered. Swab should reach depth equal to distance from nostrils to outer opening of the ear.
2. Gently rub and roll the swab. Leave swab in place for several seconds to saturate tip with secretions.
3. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the swab is saturated with fluid from the first collection. If a deviated septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

Nasal Aspirate

1. Connect an aspiration catheter to an aspiration trap that is attached to an aspiration device, insert the catheter to nasal cavity from a nostril, start the aspiration device and then collect nasal aspirate sample.
2. Dip a sterilized swab into the collected nasal aspirate sample and make the specimen cling to the swab.

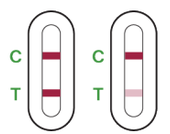
Test Procedure



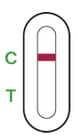
Allow the test, specimen, extraction buffer to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch. See illustration 1.
2. Place the extraction tube in the workstation. Hold the extraction reagent bottle upside down vertically. Squeeze the bottle and let the solution drop into the extraction tube freely without touching the edge of the tube**. Add 10 drops of solution** (approx. 500µl) to the extraction tube. See illustration 2.
3. Place the swab specimen in the extraction tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release sample from the swab. See illustration 3.
4. Remove the swab while squeezing the swab head against the inside of the extraction tube to expel as much liquid as possible from the swab. See illustration 4. Discard the swab in accordance with your biohazard waste disposal protocol.
5. Fit the dropper tip on top of the extraction tube. See illustration 5.
6. Place the test cassette on a clean and level surface. Invert the tube and **add 3 drops of the solution** (approx.120µl) to the sample well (S) and then start the timer. See illustration 6.
7. **Read the result at 15 minutes**. Do not interpret the result after 20 minutes.

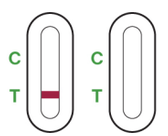
Results Interpretation



POSITIVE: Two colored lines appear on the membrane. One colored line appears in the control region (C) and another colored line appears in the test region (T). A positive result in the test region indicates that Respiratory Syncytial Virus antigen was detected in the sample.



NEGATIVE: **Only one colored line appears in the control region (C). No line in the test region (T).** The negative result indicates that there are no Respiratory Syncytial Virus in the sample, or the virus is below the detectable range.



INVALID: No colored line appears in the control region (C). The test is invalid even if there is a line on test region (T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.

Quality Control

- Internal procedural controls are included in the test. A

colored line appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.

- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations

1. The Rapid Response™ RSV Test Cassette is for professional *in vitro* diagnostic use only. The test should be used for the detection of Respiratory Syncytial Virus in nasopharyngeal swab or nasal aspirate specimens. Neither the quantitative value nor the rate of increase in Respiratory Syncytial Virus concentration can be determined by this qualitative test.
2. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
3. The Rapid Response™ RSV Test Cassette is an acute-phase screening test for qualitative detection. Sample collected may contain antigen titles below the reagent's sensitivity threshold, so a negative test result does not exclude infection with Respiratory Syncytial Virus.
4. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result.
5. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
6. The use of over-the-counter and prescription nasal sprays at high concentrations can interfere with results, leading to either invalid or incorrect test results.

Expected Values

The Rapid Response™ RSV Test Cassette has been compared with a leading commercial RT-PCR test. The correlation between these two systems is over 95%.

Performance Characteristics

Sensitivity, Specificity and Accuracy

The Rapid Response™ RSV Test Cassette has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the Rapid Response™ RSV Test Cassette. Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result.

		Nasopharyngeal Swab Specimen		
		RT-PCR		
		Positive	Negative	Total
Rapid Response™ Respiratory Syncytial Virus (RSV) Test Cassette	Positive	76	2	78
	Negative	6	99	105
Total		**82**	**101**	**183**
Relative Sensitivity		**92.7%(95%CI*: 84.8%-97.3%)**		
Relative Specificity		**98.0%(95%CI*: 93.0%-99.8%)**		
Accuracy		**95.6%(95%CI*: 91.6%-98.1%)**		

*Confidence Intervals

		Nasal Aspirate Swab Specimen		
		RT-PCR		
		Positive	Negative	Total
Rapid Response™ Respiratory Syncytial Virus (RSV) Test Cassette	Positive	87	2	89
	Negative	7	128	135
Total		**94**	**130**	**224**
Relative Sensitivity		**92.6%(95%CI*: 85.3%-97.0%)**		
Relative Specificity		**98.5%(95%CI*: 94.6%-99.8%)**		
Accuracy		**96.0%(95%CI*: 92.5%-98.1%)**		

*Confidence Intervals

Reaction with Various Serotype of Respiratory Syncytial Virus

The current test kit is able to detect the following serotype of the Respiratory Syncytial Virus: Subtype A (A2, long) Subtype B (9320, wild-type)

Precision

Intra-Assay & Inter-Assay

Within-run and Between-run precision has been determined by using three specimens of Respiratory Syncytial Virus standard control. Three different lots of the Rapid Response™ RSV Test Cassette have been tested using negative, weak positive, strong positive specimens. Ten replicates of each level were tested each day for 3 consecutive days. The specimens were correctly identified>99% of the time.

Cross-reactivity

No cross reaction has been confirmed of the Rapid Response™ RSV Test Cassette with the following pathogens:

A. Bacteria

Acinetobacter baumannii	Bordetella pertussis	Branhamella catarrhalis
Candida albicans	Candida glabrata	Cardiobacterium hominis
Eikenella corrodens	Enterococcus faecalis	Enterococcus gallinarum
Escherichia coil	Group C streptococcus	Group G streptococcus
Haemophilus aphrophilus	Haemophilus influenzae	Haemophilus paraphrophilus
Klebsiella pneumoniae	Neisseria gonorrhoeae	Peptococcus asaccharolyticus
Peptostreptococcus anaerobius	Proteus mirabilis	Proteus vulgaris
Pseudomonas aeruginosa	Serratia marcescens	Staphylococcus epidermidis
Streptococcus agalactiae (group B)	Streptococcus mutans	Streptococcus pneumoniae
Streptococcus pyogenes (group A)	Veillonella parvula.	

B. Virus

Influenza A	Influenza B	Adenovirus Type 1~8,11,19,37
Coxsackie virus Type A16, B1~5	Cytomegalovirus	Echovirus Type 3,6,9,11,14,18,30
Enterovirus Type 71	HSV-1	Mumps virus,
Type I simple herpes virus	Parainfluenza virus Type 1~3	Poliovirus Type 1~3
Rhinovirus Type 1A,13,14		

C. Mycoplasma etc.

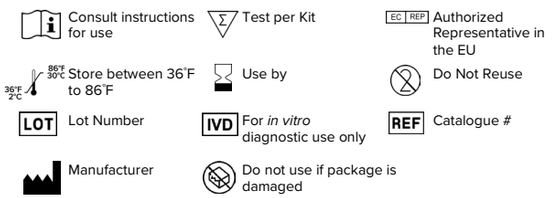
No cross reaction with

Chlamydia pneumoniae	Chlamydia psittaci	Chlamydia trachomatis
Mycoplasma pneumoniae		

Bibliography

1. Glezen, WP; Taber, LH; Frank, AL; Kasel, JA (1986). "Risk of primary infection and reinfection with respiratory syncytial virus". American journal of diseases of children (1960). 140(6): 543–6. doi:10.1001/archpedi.1986.02140200053026.PMID 3706232.
2. Hall, Caroline Breese; Weinberg, Geoffrey A.; Iwane, Marika K.; Blumkin, Aaron K.; Edwards, Kathryn M.; Staat, Mary A.; Auinger, Peggy; Griffin, Marie R.; Poehling, Katherine A.; Erdman, Dean; Grijalva, Carlos G.; Zhu, Yuwei; Szilagyi, Peter (2009). "The Burden of Respiratory Syncytial Virus Infection in Young Children". New England Journal of Medicine. 360 (6): 588–98. doi:10.1056/NEJMoa0804877. PMID 19196675.

Glossary of Symbols



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