JusChek®

RSV Rapid Test Cassette (Nasopharyngeal swab/Nasal Aspirate) Package Insert

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

INTENDED USE

The RSV Rapid 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.

SUMMARY

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 RSV Rapid Test cassette (Nasopharyngeal swab/Nasal Aspirate) 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 Influenza RSV Rapid Test Cassette (Nasopharyngeal swab/Nasal Aspirate) 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 regions of the test cassette. During testing, the extracted specimen reacts with the antibody to Respiratory Syncytial Virus that are 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 lines in the test regions. The presence of this colored line in the test regions 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 cassette contains anti- Respiratory Syncytial Virus particles and anti- Respiratory Syncytial Virus coated on the membrane.

PRECAUTIONS

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

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 AND PREPARATION

• Nasopharyngeal swab sample
Insert a sterilized swab into a nasal cavity securely from a nostril and collect mucoepidermis wiping turbinate several times.
• Nasopharyngeal aspirate
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. Dip a sterilized swab into the collected nasal aspirate sample and make the specimen cling to the swab.

MATERIALS】

Materials provided

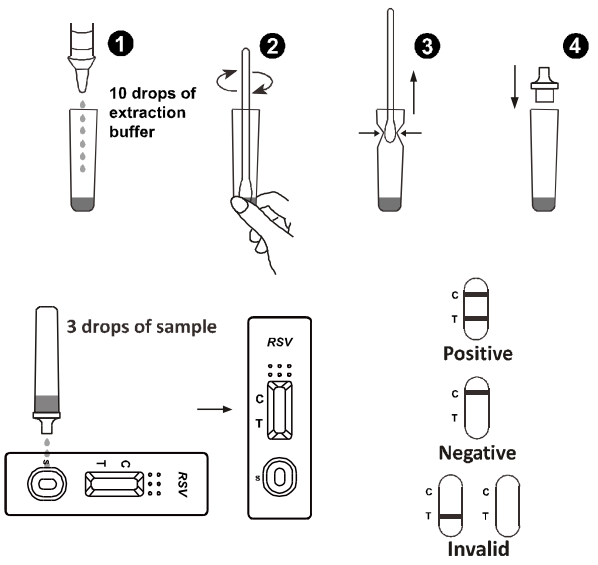
• Test cassettes
• Sterile Swabs
• Extraction Tube Tip
• Extraction Reagent
• Package insert
• Extraction Tubes
• Workstation

Materials required but not provided

• Timer
• Aspiration Device

DIRECTIONS FOR USE

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.
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 1.
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 the antigen in the swab. See illustration 2.
4. Remove the swab while squeezing the swab head against the inside of the Extraction Tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol. See illustration 3.
5. Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface. See illustration 4
6. Add three drops of the solution (approx.120μl) to the sample well and then start the timer. Read the result at 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)
POSITIVE:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T). A positive result in the test region indicates that Respiratory Syncytial Virus antigen was detected in the sample.
NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test line regions (T).
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that a positive control and a negative control be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The RSV Rapid Test Cassette (Nasopharyngeal swab/Nasal Aspirate) 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 Respiratory Syncytial Virus Antigen Rapid Test Device 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 RSV Rapid Test Cassette (Nasopharyngeal swab/Nasal Aspirate) 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 RSV Rapid Test Cassette (Nasopharyngeal swab/Nasal Aspirate) has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the RSV Rapid Test Cassette (Nasopharyngeal swab/Nasal Aspirate). 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			Nasal Aspirate Specimen		
		RT-PCR		Total	RT-PCR		Total
		Positive	Negative		Positive	Negative	
RSV Rapid Test	Positive	76	2	78	87	2	89
	Negative	6	99	105	7	128	135
Total		82	101	183	94	130	224
Relative Sensitivity		92.7%			92.6%		
Relative Specificity		98.0%			98.5%		
Accuracy		95.6%			96.0%		

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 RSV Rapid Test Cassette (Nasopharyngeal swab/Nasal Aspirate) 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 Respiratory Syncytial Virus Antigen Rapid Test Device with the following pathogens:
①Bacteria
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
②Virus
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, Tyep I simple herpes virus Parainfluenza virus Type 1～3, Poliovirus Type 1～3, Respiratory syncytial virus, Rhinovirus Type 1A,13,14, Type I simple herpes virus
③Mycoplasma 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.

Index of Symbols

	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
30°C 2°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

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DN:
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