RSV Antigen Rapid Test Cassette (Swab)

English

For professional and in vitro diagnostic use only.

[INTENDED USE]

The RSV Antigen Rapid Test Cassette is a lateral flow immunoassay for the qualitative detection of Respiratory Syncytial Virus (RSV) antigens in human nasopharyngeal swab or oropharyngeal swab. It is recommended that negative test results be confirmed by cell culture.

[SUMMARY]

Respiratory syncytial virus is a member of the Paramyxoviridae family and is the most significant respiratory pathogen for infants and children. Infection usually causes mild to moderate severe upper respiratory illness that may lead to life threatening pneumonia or bronchiolitis. RSV infections are seasonal and are most prominent from December to March in the northern hemisphere. The virus is spherical in shape with a lipoprotein envelope synthesized from the plasma membrane of the infected host cell. The virus is spread rapidly through droplets dispersed in the air or secretions from the respiratory tract of infected individuals. The incubation period is 3-7 days. Specimens from patients are obtained by using nasopharyngeal aspiration, washes and swabs.

Several methods have been developed for the detection of RSV. This includes direct and indirect immunofluorescence on exfoliated cells, enzyme immunoassay (EIA) from nasopharyngeal samples, and isolation of the virus from cell culture. Cell culture has remained historically the "gold standard" used for diagnosis, but requires specialized equipment, highly trained personnel, specialized care in specimen collection and transportation, and long periods of time to obtain results. Rapid immunodetection methods have provided a cost effective detection option, which allows for timely patient treatment to prevent possible nosocomial spread.

[PRINCIPLE]

The RSV Antigen Rapid Test Cassette is a qualitative membrane strip based immunoassay for the detection of Respiratory Syncytial Virus (RSV) F-protein antigens in human nasopharyngeal swab or oropharyngeal swab. In this test procedure, mouse anti-syncytial virus monoclonal antibody is immobilized in the T line. After a specimen is placed in the specimen well, it reacts with mouse anti-syncytial virus monoclonal antibody coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized antibody. If the specimen contains RSV antigen, a colored line will appear in the T line region indicating a positive result. Absence of T lines suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

[WARNINGS AND PRECAUTIONS]

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as if they contain infectious agents.
- Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Follow standard biosafety guidelines for handling and disposal of potential infective material.
- Hot and humid environment can adversely affect results.

[COMPOSITION]

The test cassette contains a membrane strip coated with mouse anti-syncytial virus monoclonal antibody on the test line, rabbit anti polypeptide C antibody on the control line, and a dye pad which contains colloidal gold coupled with mouse anti-syncytial virus monoclonal antibody and polypeptide C.

The quantity of tests was printed on the labeling.

Materials Provided

- Test Cassette
- Sterilized Swab
- Extraction Reagent
- Extraction Tube
- Package Insert
- Work Station

Materials Required But Not Provided

- Timer

[STORAGE AND STABILITY]

- Store as packaged in the sealed pouch at temperature (4-30℃ or 40-86℉). The kit is stable within the expiration date printed on the labeling.
- Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
- The LOT and the expiration date were printed on the labeling.

[SPECIMEN]

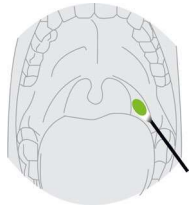
Specimens obtained early during symptom onset will contain the highest viral titers; specimens obtained after five days of symptoms are more likely to produce negative results. Inadequate specimen collection, improper specimen handling and/or transport may yield a falsely negative result; therefore, training in specimen collection is highly recommended due to the importance of specimen quality for generating accurate test results.

Nasopharyngeal Swab Specimen Collection

Insert minitip swab with a flexible shaft (wire or plastic) through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions. 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 minitip 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.

Oropharyngeal Swab Specimen Collection

Insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.

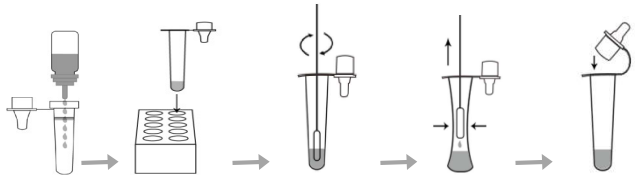


Sample Transport and Storage

- After swab specimens were collected, swab can be stored in extraction reagent provided with the kit. Swab also can be stored by immersing the swab head in a tube containing 2 to 3 mL of virus preservation solution (or isotonic saline solution, tissue culture solution, or phosphate buffer).
- Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection. Specimen collected may be stored at 2-8℃ (36-46℉) for no more than 24 hours; Store at -70℃ (-94℉) for a long time, but avoid repeated freeze-thaw cycles.

[SPECIMEN PREPARATION]

1. Add 0.3 mL (10 drops) of the specimen extraction reagent into the extraction tube, and put it on the work station.
2. Insert the swab into the extraction tube which contains 0.3 mL (10 drops) of the extraction reagent. Rotate the swab inside the tube using a circular motion to roll the side of the extraction tube so that the solution is expressed and reabsorbed from the swab. **Leave the swab in the reagent tube for one minute.**
3. Pinch the extraction tube with fingers and remove the solution from the swab as far as possible. The extracted solution will be used as test specimen.
4. Cover the extraction tube with the connected dropper tip tightly.

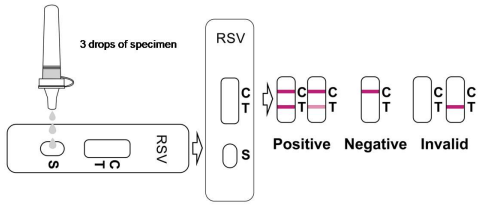


(The picture is for reference only, please refer to the material object.)

[TEST PROCEDURE]

Allow the test device and specimens to equilibrate to temperature (15-30℃ or 59-86℉) prior to testing.

1. Remove the test cassette from the sealed pouch.
2. Reverse the specimen extraction tube, hold the specimen extraction tube upright, transfer 3 drops (approximately 100 µL) to the specimen well (S) of the test cassette, then start the timer. See illustration below.
3. Wait for colored line(s) to appear. Interpret the test results at 15 minutes. Do not read results after 20 minutes.



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[INTERPRETATION OF RESULTS]

Positive: Two lines appear. One colored line should be in the control region (C), and another apparent colored line adjacent should be in the test region (T). This positive result indicates the presence of Respiratory Syncytial Virus antigen.

Negative: One colored line appears in the control region (C). No line appears in the test region (T). This negative result indicates Respiratory Syncytial Virus antigen are not present or present below the detectable level.

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 using a new test cassette. If the problem persists, discontinue using the lot 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 considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

[LIMITATIONS]

- The RSV Antigen Rapid Test Cassette is for *in vitro* diagnostic use only. The test should be used for the detection of Respiratory Syncytial Virus (RSV) F-protein antigens in nasopharyngeal swab or oropharyngeal swab. Neither the quantitative value nor the rate of increase in Respiratory Syncytial Virus can be determined by this qualitative test.
- The results obtained from this test are intended to be an aid in diagnosis only. Each physician must interpret the results in conjunction with the patient's history, physical findings, and other diagnostic procedures.
- A negative test result indicates that RSV antigens are either not present or at levels undetectable by the test.

[PERFORMANCE CHARACTERISTICS]

Accuracy

Agreement with Commercial RSV Antigen Rapid Test

Two hundred and eighty-one (281) patient samples were obtained from several laboratories. Each sample was thawed and a RSV Antigen Rapid Test and other commercial test were performed.

		Commercial RSV Antigen Rapid Test		Total
		Positive	Negative	
	Positive	138	1	139
	Negative	2	140	142
Total		140	141	281

The agreement between these two devices is 98.57% for positive specimens, and 99.29% for negative specimens. This study demonstrated that the RSV Antigen Rapid Test is substantially equivalent to the commercial device.

Agreement with Cell Culture

Two hundred and eighty-one (281) patient samples were obtained from several laboratories. Each sample was thawed and an RSV viral culture and a RSV Antigen Rapid Test were performed.

		Cell Culture		Total
		Positive	Negative	
	Positive	138	1	139
	Negative	7	135	142
Total		145	136	281

The agreement between these two devices is 95.17% for positive specimens, and 99.26% for negative specimens. This study demonstrated that the RSV Antigen Rapid Test is substantially equivalent to the commercial device.

Cross-Reactivity and Interference

1. Cross-reactivity with following organisms has been studied. The following organisms were found negative when tested with the RSV Antigen Rapid Test:
   Influenza c virus, Influenza a virus, Influenza b virus, Adenovirus, Cytomegalovirus, Enterovirus, Parainfluenza, Coronavirus, Measles virus, Human partial lung virus, Mumps virus, Streptococcus pyogenes, Chlamydia pneumoniae, Rhinovirus, Pertussis bacillus, Streptococcus salivarius, Mycoplasma pneumoniae, Haemophilus influenzae, Mycobacterium tuberculosis, Staphylococcus aureus, Streptococcus pneumoniae, Neisseria meningitidis.
2. Potentially cross-reactive endogenous substances including common components, such as lipids, hemoglobin and bilirubin, were spiked at high concentrations into the positive and negative specimens and tested, separately. No cross-reactivity or interference was observed to the device.

Analytes	Conc.	Specimens	
		Positive	Negative
Albumin	20 mg/mL	+	-
Bilirubin	20 μg/mL	+	-
Hemoglobin	15 mg/mL	+	-
Glucose	20 mg/mL	+	-
Uric Acid	200 μg/mL	+	-
Lipids	20 mg/mL	+	-

Reproducibility

Reproducibility studies were performed for the RSV Antigen Rapid Test at three physician office laboratories (POL). Sixty (60) clinical nasopharyngeal swab specimens, 20 negative, 20 borderline positive and 20 positive, and Sixty (60) clinical oropharyngeal swab specimens, 20 negative, 20 borderline positive and 20 positive,were used in this study. Each specimen was run in triplicate for three days at each POL. The intra-assay agreements were > 99%, the inter-site agreement was > 99% for clinical nasopharyngeal and oropharyngeal swab specimens.

[BIBLIOGRAPHY]

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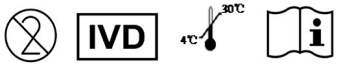

Index of Symbol

	Do not reuse	IVD	*In vitro* diagnostic medical device
4℃ 30℃	Store between 4-30℃		Consult instructions for use
	Caution	LOT	Lot number
	Use by	Σ	Contains sufficient for <n> tests
	Keep away from sunlight		Keep dry
	Manufacturer		Do not use if package is damaged

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Effective Date: Apr. 03, 2024