

HIA TEST RSV Test Cassette (Nasopharyngeal Swab/Nasal Aspirate)

Package Insert

REF FI-RSV-502 English

A Fluorescence Immunoassay test kit for the qualitative detection of Respiratory Syncytial Virus Antigen in Nasopharyngeal swab or nasal aspirate specimens with the use of Fluorescence Immunoassay Analyzer.

For professional *in vitro* diagnostic use only.

【INTENDED USE】

The RSV Test Cassette (Nasopharyngeal Swab/Nasal Aspirate) is intended for *in vitro* detection of Respiratory Syncytial Virus antigens 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 (commonly known as '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.' 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. 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 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 RSV Test Cassette (Nasopharyngeal Swab/Nasal Aspirate) detects Respiratory Syncytial Virus nucleoproteins based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains Respiratory Syncytial Virus nucleoproteins, it attaches to the fluorescent microspheres-conjugated anti-Respiratory Syncytial Virus antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of Respiratory Syncytial Virus in the sample correlates with the fluorescence signal intensity captured on the T line, which can be scanned by Fluorescence Immunoassay Analyzer. The testing result of Respiratory Syncytial Virus will display on the Fluorescence Immunoassay Analyzer screen.

【REAGENTS】

The test cassette contains anti-Respiratory Syncytial Virus conjugated fluorophores and anti-RSV coated on the membrane.

【PRECAUTIONS】

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.
- Read the entire procedure carefully prior to any testing.
- The RSV Test Cassette should only be used with the Fluorescence Immunoassay Analyzer by approved medical professionals.

【STORAGE AND STABILITY】

- The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.**
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

【SPECIMEN COLLECTION AND PREPARATION】

Preparation

Before performing the test, please make sure that all components are brought to room temperature (15-30°C). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.

Sample Handling

• Nasopharyngeal swab sample
Insert sterilized swab into nostril parallel to the palate and leave in place for a few second to absorb secretions. Collect samples with nasopharyngeal (NP) swabs for optimum results.

• Nasal Aspirate sample

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】

- | | | |
|------------------------|----------------------|--------------------|
| • Test Cassettes | • Extraction Reagent | • Sterile Swabs |
| • Package Insert | • Workstation | • Extraction Tubes |
| • Extraction Tube Tips | • ID Card | |

Materials Required But Not Provided

- Timer
- Fluorescence Immunoassay Analyzer

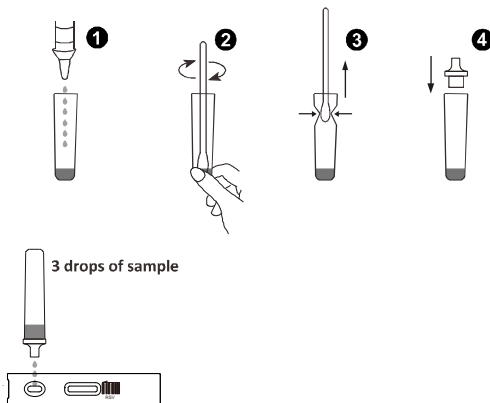
【DIRECTIONS FOR USE】

Refer to Fluorescence Immunoassay Analyzer Operation Manual for the complete instructions on use of the test. The test should be conducted in room temperature.

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

- Turn on the Analyzer power.
- Take out the ID card and insert it into the Analyzer ID Card Slot. Choose test mode and/or sample type according to needs.
- 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.
- 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 extraction reagent (Approx. 400 μ L)** to the extraction tube.
- 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.
- 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.
- Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface.
- Add **3 drops of the solution (approx.120 μ L)** to the sample well and then start the timer.(Follow the illustration as below)
- Test results should be interpreted at **15 minutes** with the use of Fluorescence Immunoassay Analyzer.

Caution: There are different test modes of the Fluorescence Immunoassay Analyzer. The difference between them is incubation of the test cassette is outside or inside the analyzer. Choose test mode accordingly and confirm sample type. Consult the user manual of the analyzer for detailed operation information.
Operator must consult the Fluorescence Immunoassay Analyzer User Manual prior to use and become familiar with the processes and quality control procedures.



【INTERPRETATION OF RESULTS】

Results read by Fluorescence Immunoassay Analyzer.

The result of tests is calculated by Fluorescence Immunoassay Analyzer and Displayed on the screen. For additional information, please refer to the user manual of Fluorescence Immunoassay Analyzer.

NOTE: The test result of each specimen is given as Pos (+) or Neg (-) with a Reference Value. This Value is calculated that a measured signal is divided by an appropriate cutoff value.

- Test results of a Value \geq 1.00 are considered positive.

- Test results of a Value < 1.00 are considered negative.

【QUALITY CONTROL】

Each RSV Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by Fluorescence Immunoassay Analyzer. An invalid result from the internal control causes an error message on Fluorescence Immunoassay Analyzer indicating that the test should be repeated. An invalid result from the internal control causes message on Fluorescence Immunoassay Analyzer. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【LIMITATIONS】

- The RSV Test Cassette (Nasopharyngeal Swab/Nasal Aspirate) is for professional *in vitro* diagnostic use only. The test should be used for the qualitative detection of RSV virus in nasopharyngeal swab or nasal aspirate specimens.
- The RSV Test Cassette (Nasopharyngeal Swab/Nasal Aspirate) will only indicate the presence of RSV virus in the specimen from both viable and non-viable RSV strains.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- The 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.
- Excess mucus on the swab specimen may interfere with test performance and may yield a false positive result.
- The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
- 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.
- The results of RSV Tests are based on measuring the levels of RSV in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

【BIBLIOGRAPHY】

- Williams, KM, Jackson MA, Hamilton M. (2002) Rapid Diagnostic Testing for URIs in Children; Impact on Physician Decision Making and Cost. *Infect. Med.* 19(3): 109-111.

Index of Symbols					
	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
	<i>In vitro</i> diagnostic medical device		Batch code		Catalogue number
	Caution		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		Authorized representative in the European Community

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