QuickStripe™ RSV

A rapid, one step test for the qualitative detection of *RSV* antigens from human nasopharyngeal specimens (swab, nasopharyngeal wash and aspirate).

Instruction Manual

Test kit for 25 determinations
(Catalog No. 41209)

For professional in vitro diagnostic use only
Store at 2-30°C. **Do Not Freeze**

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INTENDED USE

The QuickStripe™ RSV is a rapid qualitative immunochromatographic assay for the detection of respiratory syncytial virus (*RSV*) antigens in human nasopharyngeal specimens to aid in the diagnosis of *RSV* infection.

SUMMARY AND EXPLANATION

Respiratory syncytial virus (*RSV*) is the most important cause of pneumonia and bronchiolitis in infants and small children. *RSV* causes a range of respiratory illness, the most common being a cold with profuse rhinorrhea. [1] Of infants infected for the first time, 25-40% develops some lower respiratory tract disease. [2] Between 1 and 2% of infected infants require hospitalization. Because of its high infectivity and because hospital staff as well as patients are susceptible, *RSV* has emerged as the most frequent cause of nosocomial infections on pediatric wards. [1]
RSV belongs to the family Paramyxoviridae and the genus Pneumovirus. It is morphologically similar to other paramyxoviruses with the exception that the diameter of its helical nucleocapsid is smaller, 13 to 14 nm rather than 18 nm. *RSV* is an antigenically heterogeneous species, with strain differences, which are due primarily to differences in one of the two antigenically active surface components. These differences between strains are probably of little or no practical importance from a diagnostic point of view, since available reagents, including monoclonal antibodies, react equally with all clinical isolates. [3]

PRINCIPLE OF THE PROCEDURE

The QuickStripe™ RSV is a qualitative lateral flow immunoassay for the detection of *RSV* antigen in human nasopharyngeal samples. The QuickStripe™ RSV contains monoclonal antibody-dye conjugate pre-dried on the test strip and monoclonal solid phase antibodies pre-coated on the test membrane. As the test sample flows through the strip, the labelled antibody-dye conjugate binds to the *RSV* antigen forming an antibody-antigen complex. This complex binds to the anti-*RSV* antibody in the test zone producing a red color band. In the absence of *RSV* there is no line in the test zone.
The reaction mixture continues flowing through the absorbent device. Unbound conjugate binds to the control zone producing a green color band, indicating that proper volume of specimen has been added, the flow is appropriate and that the membrane and the reagents are functioning correctly.

MATERIALS PROVIDED

- 25 aluminium pouches, each containing one strip of QuickStripe™ RSV and a desiccant bag
- 25 disposable test tubes
- 1 dropper containing sample diluent B
- 1 Instruction for Use

WARNING AND PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use beyond the expiration date. The test should remain in the sealed pouch until use. Do not use the test if pouch is damaged.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled as an infectious agent. The test should be discarded in a proper biohazard container after use.
- The test must be carried out within 2 hours of opening the sealed bag.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC). 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.**

SPECIMEN COLLECTION AND HANDLING

Nasopharyngeal swab method:

- Bend shaft to follow curve of nasopharynx;
- Insert swab through the nostril to the posterior nasopharynx.
- Rotate swab a few times to obtain infected cells
- For an optimal sample, repeat procedure using other nostril

Nasopharyngeal aspirate method (suction apparatus, sterile suction catheter):

- Instill several drops of solution saline into each nostril
- Place catheter through nostril to posterior nasopharynx;
- Apply gentle suction. Using rotating motion, slowly withdraw catheter

- For an optimal sample, repeat procedure using other nostril
- Send specimen to lab immediately (testing sensitivity decrease over time)
- Cool specimen to 2º-4ºC during storage and transport.

PROCEDURE

Allow the tests, samples and buffer to reach room temperature (15-30ºC) prior to testing. Do not open pouches until ready to perform the assay.

To process the collected nasopharyngeal wash or aspirate samples (see illustration 1):

1. Use a separate testing tube or vial for each sample. Add 300µL of the nasopharyngeal wash or aspirate sample. Add 3 (150µL) drops of diluent B and mix.
2. Remove the Strip from its sealed pack and use it as soon as possible. Use a separate test strip for each sample.
3. Immerse the Strip vertically into the extracted specimen solution with the white end pointing toward the specimen and then start the timer.
4. Read the result at 10 minutes.

To process the collected nasopharyngeal swab (see illustration 2):

1. Use a separate test tube or vial for each sample (swab). Add 15 drops (500µL) of diluent B into the test tube.
2. Insert the nasopharyngeal swab, mix and extract as much liquid as possible from the swab. Discard the swab into hazardous waste container.
3. Remove the Strip from its sealed pack and use it as soon as possible. Use a separate strip for each sample.
4. Immerse the Strip vertically into the extracted specimen solution with the white end pointing toward the specimen and then start the timer.
5. Read the result at 10 minutes.

Illustration 1 Nasopharyngeal aspirate or wash

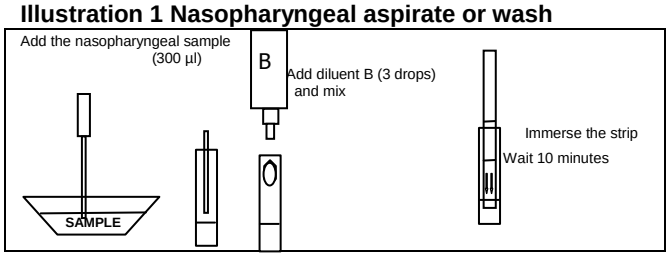
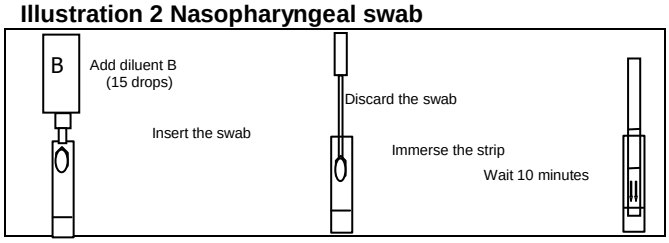
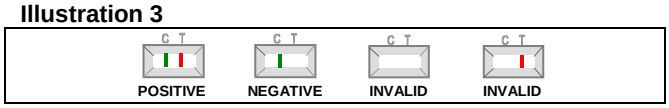


Illustration 2 Nasopharyngeal swab



INTERPRETATION OF RESULTS

Illustration 3



Negative: Only one green band appears in the Control window. No band is visible in the Test window.

Positive: In addition to the Control band a clearly distinguishable red band also appears in the Test window.

Invalid: A total absence of the green control band regardless of the appearance or not of the red test line. Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact your local distributor.

NOTES ON THE INTERPRETATION OF RESULTS

The intensity of the red band in the result line region (T) will vary depending on the concentration of antigens in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

QUALITY CONTROL

Internal procedural control is included in the test:

- A green line appearing in the control line region (C). It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS OF THE PROCEDURE

1. The QuickStripe™ RSV will only indicate the presence of *RSV* in the specimen (qualitative detection) and should be used for the detection of *RSV* antigens in nasopharyngeal specimens only (from swab, aspirate or wash). Neither the quantitative value nor the rate of increase in *RSV* antigens concentration can be determined by this test.
2. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *RSV* infection.
3. This test provides a presumptive diagnosis of *RSV* infections. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

EXPECTED VALUES

RSV is generally considered the most frequent cause of pneumonia, bronchiolitis, and tracheobronchitis among infants and young children. It is now known to be the etiologic cause in 14-27% of cases of pneumonia in the elderly during the winter season.

PERFORMANCE CHARACTERISTICS

Sensitivity and specificity

Different virus extract dilutions were tested directly in the sample diluent or spiked in a negative nasal specimen in accordance with the kit instructions.

The detection of *RSV* showed >95% of sensitivity compared with another commercial rapid test and showed >99% of specificity compared with the commercial rapid test.

Cross-Reactivity

There is no cross reactivity with common respiratory pathogens, other organisms and substances occasionally present in nasopharyngeal samples:

- Influenza A&B
- Adenovirus

REFERENCES

1. Hall, CB. 2000. Nosocomial respiratory syncytial virus infections: The “cold war” has not ended. Clin. Inf. Diseases 31:590-596.
2. Domachowske, JB and Rosenberg, HF. 1999. Respiratory syncytial virus infection: Immune response, immunopathogenisis, and treatment. Clin. Microbiol. Reviews 12:298-309.
3. Talis, A and McIntosh, K. 1991 Respiratory Syncytial Virus in Manual of Clinical Microbiology, Fifth ed., Am. Soc. Microbiol. pp 883-6.

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