Atlas Medical

RSV Device

One Step _RSV_ Antigen Test Device

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

IVD *For In-Vitro diagnostic and professional use only*

2 30°C Store at 2-30°C CE

INTENDED USE

The *RSV* Device is a rapid chromatographic immunoassay for the qualitative detection of *RSV* antigens in human nasopharyngeal specimens to aid in the diagnosis of *RSV* infection.

SYNTHESIS

Although a wide variety of viral agents are capable of causing lower respiratory tract infections in children and adults, *influenza A & B; respiratory syncytial virus* (RSV); parainfluenza viruses 1, 2, and 3; and *adenovirus* are the most common. Of these, influenza A & B and RSV are the most important causes of medically attended acute respiratory illness. In addition to sharing a similar seasonal prevalence, it is important to remain cognizant that *influenza A & B* and *RSV* share overlapping clinical features and infection potential for certain high-risk patient groups (e.g., extremes of age, underlying cardiopulmonary disease and immunosuppression).

PRINCIPLE

The *RSV* Device is a qualitative lateral flow immunoassay for the detection of *RSV* antigen in human nasopharyngeal samples. The membrane is pre-coated with monoclonal antibodies against *RSV* antigens on the test line region. During testing, the sample reacts with the particle coated with anti-*RSV* antibodies which was pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will react with the mixture conjugate and generate a coloured line. A green coloured line always appears in the control line and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after 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 in the same manner as an infectious agent.
- The test should be discarded in a proper biohazard container after testing.
- 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/36-86ºF). 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.

MATERIALS

MATERIALS PROVIDED

- Devices.
- Sample diluent.
- Extraction Tube.
- Swabs (Optional).
- Instructions for use.

MATERIALS REQUIRED BUT NO PROVIDED

- Plastic pipettes
- RSV Positive Control swabs
- Specimen collection container.
- Disposable gloves.
- Timer.
- Shaker or vortex.

SPECIMEN COLLECTION AND PREPARATION

- Nasopharyngeal swab method:

- Bend shaft to follow curve of nasopharynx
- Insert swab through nostril to 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):

- Instil 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-8ºC (36º-46.4ºF) during storage and transport for 8 hours prior to testing.

PROCEDURES

Allow the tests, samples and buffer to reach room temperature (15-30ºC/59-86ºF) 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):

Use a separate pipette and testing tube for each sample. Add the nasopharyngeal wash or aspirate sample (200-240 µL) in a testing tube or vial. Add the diluent (7 drops approximately 360 µL) and mix with a shaker (1 minute). Remove the *RSV* Device from its sealed pouch and use it as soon as possible. Use a separate device for each sample. Dispense (6 drops approximately 160 µL) into the specimen well (S). Start the timer. Read the result at **10 minutes** after dispensing the sample.

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

Use a separate testing tube or vial for each sample (swab). Add the diluent (10 drops approximately 500 µL) into the testing tube or vial, put the nasopharyngeal swab, mix and extract as much liquid possible from the swab. Remove the *RSV* Device from its sealed pouch and use it as soon as possible. Use a separate device for each sample. Dispense exactly (6 drops approximately 160 µL) into the specimen well (S). Start the timer. Read the result at **10 minutes** after dispensing the sample.

Illustration 1 Nasopharyngeal aspirate or wash

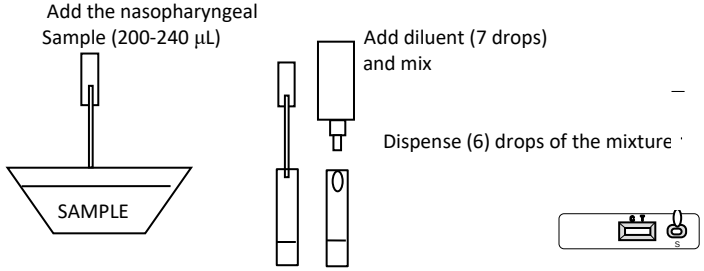
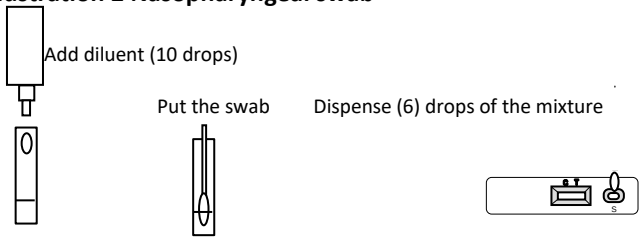


Illustration 2 Nasopharyngeal swab



INTERPRETATION OF RESULTS

Illustration 3

POSITIVE NEGATIVE INVALID INVALID

POSITIVE: Two lines appear across the central window, a **red** test line marked with the letter T and a **green** control line marked with the letter C.

NEGATIVE: Only one **green** line appears across the control line region marked with the letter C (control line).

INVALID: Total absence of the green control coloured line regardless 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. See illustration 3.

NOTES ON THE INTERPREATION OF RESULTS

The intensity of the red coloured line 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 controls are included in the test:

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

LIMITATIONS

1. *RSV* Device 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 (BinaxNow®RSV, Alere) and showed >99% of specificity compared with the commercial rapid test.

Cross-Reactivity

It was performed an evaluation to determine the cross reactivity of *RSV* Device. There is no cross reactivity with common respiratory pathogens, other organisms and substances occasionally present in nasopharyngeal samples:

- *Influenza* tipo A
- *Influenza* tipo B
- *Adenovirus*

REFERENCES

- BARENFANGER et al., “Clinical and Financial Benefits of Rapid Detection of Respiratory Viruses: an Outcomes Study”. Journal of Clinical Microbiology. August 2000, Vol 38 No 8, p. 2824-2828.

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REF	Catalogue Number		Temperature limit
IVD	In Vitro diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry