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Rapid-VIDITEST
RSV

One step RSV Card test for the detection of Respiratory Syncytial Virus from nasal specimens.

Instruction manual

INTENDED USE:

The Rapid-VIDITEST RSV test is one step coloured chromatographic immunoassay for the qualitative detection of RSV antigens in human nasopharyngeal specimens (swab, nasopharyngeal wash and aspirate) to aid in the diagnosis of *RSV* infection. Only for laboratory use.

INTRODUCTION:

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 OF THE TEST:

The Rapid-VIDITEST RSV test is a 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 then 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.

MATERIALS PROVIDED:

- Card tests (Plastic pipettes included)
- Diluent (sample diluent)
- Swabs
- Testing tubes or vials
- Instructions for use
- RSV positive control swabs

MATERIALS REQUIRED BUT NO PROVIDED:

- 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 during storage and transport for 8 hours prior to testing.

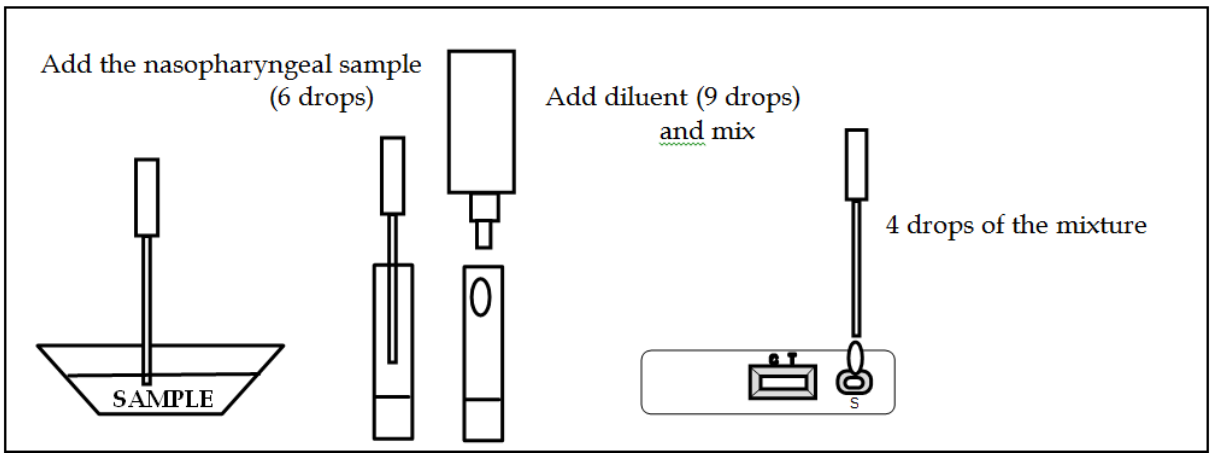
TEST PROCEDURE:

Allow the tests, samples and controls to reach to room temperature (15-30ºC) prior to testing. Do not open the package 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 (6 drops) in a testing tube or vial. Add the diluent (9 drops) 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 4 drops into the specimen well (S). Start the timer. Read the result at **10 minutes** after dispensing the sample.

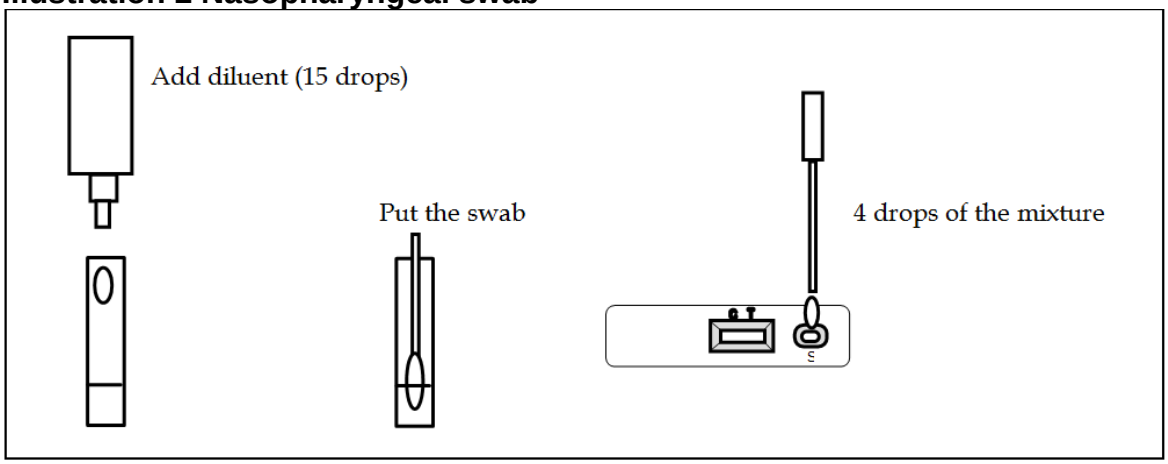
Illustration 1 Nasopharyngeal aspirate or wash



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

Use a separate testing tube or vial for each sample (swab). Add the diluent (15 drops) into the testing tube or vial, put the nasopharyngeal swab, mix and extract as much liquid possible from the swab. Discard 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 4 drops into the specimen well (S). Start the timer. Read the result at **10 minutes** after dispensing the sample.

Illustration 2 Nasopharyngeal swab



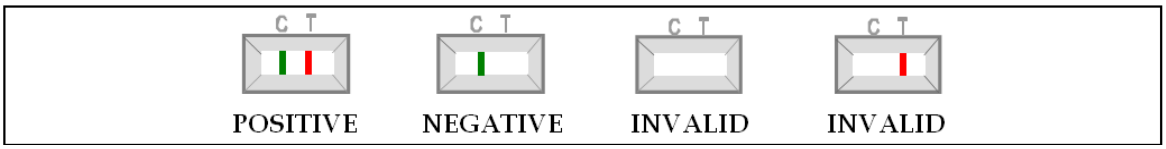
If the test does not run due to the type of sample, stir the sample added in the sample window with the plastic pipette. If it doesn´t work, dispense one or two drops maximum of diluent until seeing the liquid running through the reaction zone.

INTERPRETATION OF RESULTS (Please refer to the illustration below):

POSITIVE: Two lines appear across the result zone, a **red** test line marked in the illustration 3 with the letter T and a **green** control line marked in the illustration 3 with the letter C.
NEGATIVE: Only one **green** line appears across the control line region marked in the illustration 3 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.

Illustration 3



NOTES ON THE INTERPRETATION OF RESULTS:

The intensity of the red coloured line in the result line region (T) will vary depending on the concentration of antigens present 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 region (C). It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS:

1. RSV test 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.

STORAGE AND STABILITY:

Store as packaged in the sealed pack either at refrigerated or room temperature (2-30ºC/36-86ºF). The test is stable through the expiration date printed on the sealed pack. The test must remain in the sealed pack until use. Do not freeze.

PRECAUTIONS:

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pack until use.
- Do not use the test if pack 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.

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* Strip. There is not cross reactivity with common respiratory pathogens, other organisms and substances occasionally present in nasopharyngeal samples:
- *Influenza* type A
- *Influenza* type B
- *Adenovirus*

REFERENCES

1. 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.

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

IVD	*In vitro* diagnostic device	LOT	Batch code
	Use by		Manufacturer
	Temperature limitation	DIL	Diluent (sample diluent)
	Number of tests		

Last Revision: October 2014/A