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Rapid VIDITEST

RSV-Adeno Resp.

One step RSV-Adeno Resp. Blister Test for the detection of Respiratory Syncytial Virus and Adenovirus from nasal specimens.

Instruction manual

INTENDED USE:
The Rapid-VIDITEST RSV-Adeno Resp. test is a one step coloured chromatographic immunoassay for the qualitative detection of RSV and/or Adenovirus antigens. It can be used directly with nasal swabs or nasal wash or nasal aspirate specimens. 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). Symptoms of respiratory illness caused by adenovirus infection range from the common cold syndrome to pneumonia, croup, and bronchitis.

PRINCIPLE OF THE TEST:
The Rapid-VIDITEST RSV-Adeno Resp. is a qualitative lateral flow immunoassay for the detection of RSV and Adenovirus Respiratory antigen in human nasopharyngeal samples. The membrane is pre-coated with monoclonal antibodies against RSV and Adenovirus antigens on the test line regions. During testing, the sample reacts with the particles coated with anti-RSV antibodies and/or anti-Adenovirus antibodies which were 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 one or two coloured lines. 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:

- Blister tests
- Instructions for use
- Diluent (Sample diluent)
- Swabs

- Testing tubes or vials
- Plastic pipettes
- RSV and Adenovirus Positive Control swabs

MATERIALS REQUIRED BUT NO PROVIDED:
- Specimen collection container
- Disposable gloves
- Timer
- Shaker or vortex

SPECIMEN COLLECTION AND PREPARATION:

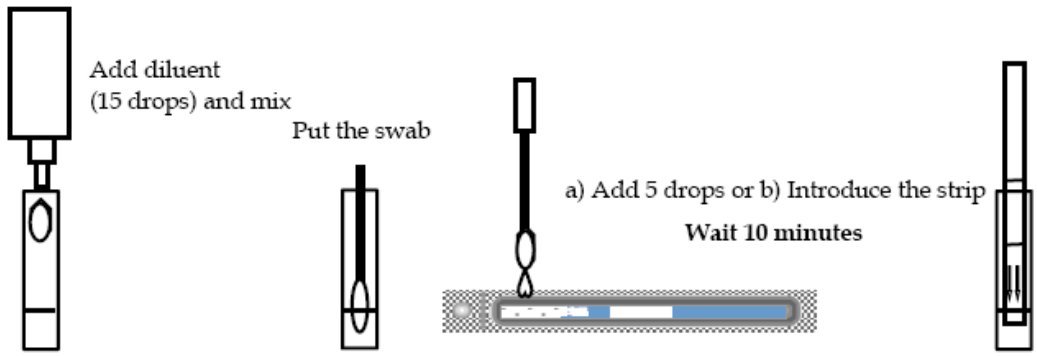
Nasopharyngeal swab method:
- Bend shaft to follow curve of nasopharynx
- Insert swab through nostril to posterior nasopharynx.
- Rotate swab a few times to obtain infected cells
- For an optimal sample, repeat procedure using other nostril

Nasopharyngeal aspirate method (suction apparatus, sterile suction catheter):
- 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-8ºC (36º-46.4ºF) during storage and transport for 8 hours prior to testing.

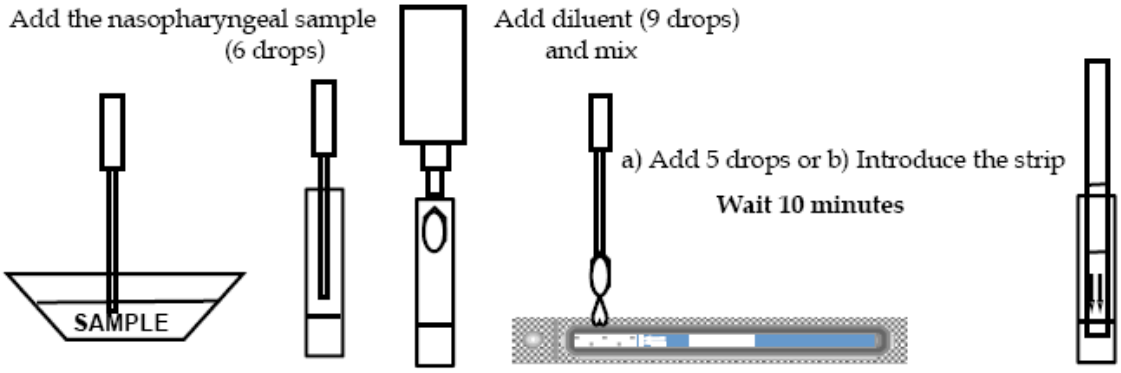
TEST PROCEDURE:
Allow the tests, swabs and controls to reach room temperature (15-30ºC) prior to testing. Do not open the package until ready to perform the assay. Only bring to room temperature the number of tests required to assay before opening it.

- Procedure A using collected nasopharyngeal swab:
1. Use a separate testing tube or vial for each sample (swab). Add the diluent (15 drops) into the testing tube or vial,
2. Put the nasopharyngeal swab, mix and extract as much liquid possible from the swab.
3. Cut the blister to obtain a test single pack, hold the non sealed side and open it peeling off the upper foil.
   a) Using the blister test single pack as a card test: Don't remove the test strip from the blister cavity and use it as soon as possible. Place the blister test single pack horizontally and identify it. Dispense exactly 5 drops on the white end of the test. Start the timer. Read the result at 10 minutes.
   b) By immersion: Leave the test strip to stand vertically in the vial, taking care of not surpassing the limit of immersion indicated with the arrows. Leave it for 1-3 minutes and place and a flat surface. Start the timer.
4. Read the result at **10 minutes**.

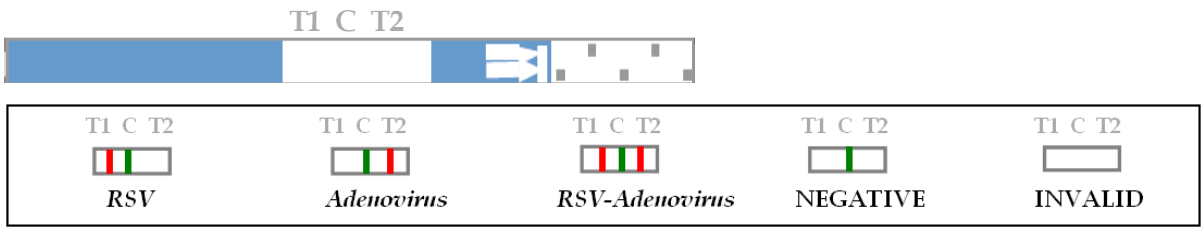


- Procedure B using nasal wash or aspirate samples:

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.
2. Add the diluent (9 drops) and mix with a shaker (1 minute).
3. Cut the blister to obtain a test single pack, hold the non sealed side and open it peeling off the upper foil.
   a) Using the blister test single pack as a card test: Don't remove the test strip from the blister cavity and use it as soon as possible. Place the blister test single pack horizontally and identify it. Dispense exactly 5 drops on the white end of the test. Start the timer. Read the result at 10 minutes.
   b) By immersion: Leave the test strip to stand vertically in the vial, taking care of not surpassing the limit of immersion indicated with the arrows. Leave it for 1-3 minutes and place and a flat surface. Start the timer.
4. Read the result at **10 minutes**.



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



POSITIVE:

***RSV* positive**: Two lines appear across the central window, a **red** test line marked with the letter T1 and a **green** control line marked with the letter C.
***Adenovirus* positive**: Two lines appear across the central window, a **red** test line marked with the letter T2 and a **green** control line marked with the letter C.
***RSV-Adenovirus* positive**: Three lines appear across the central window, the two **red** test lines (T1 and T2) and the **green** control line marked with the letter C.

NEGATIVE: Only one **green** line appears in the 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 lines. 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 coloured test lines in the result line regions (T1 and T2) 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. Rapid-VIDITEST RSV-Adenovirus Resp. will only indicate the presence of RSV and/or Adenovirus in the specimen (qualitative detection) and should be used for the detection of RSV and/or Adenovirus antigens in nasopharyngeal specimens only (from swab, aspirate or wash). Neither the quantitative value nor the rate of increase in 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 or Adenovirus infection.
3. This test provides a presumptive diagnosis of RSV and/or Adenovirus respiratory 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.
Everyone is at risk of Adenovirus infection, but patients with weak immune systems or with underlying respiratory or cardiac disease are most at risk for severe complications from any respiratory infection, including Adenovirus infections.

PERFORMANCE:

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.
Rapid-VIDITEST RSV-Adenovirus Resp. was highly specific (>99%) to detect Adenovirus and also sensitive (>99%) compared with the results of an immunochromatographic test (Adenovirus Respi, CorisBioConcept) and an inmunofluorescence test (PathoDx®Adenovirus, Remel).

Cross-Reactivity
It was performed an evaluation to determine the cross reactivity of Rapid-VIDITEST RSV-Adenovirus Resp. There is not cross reactivity with common respiratory pathogens, other organisms and substances occasionally present in nasopharyngeal samples:
- Influenza type A
- Influenza type B

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.

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.

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.

SYMBOLS FOR IVD COMPONENTS AND REAGENTS:

IVD	*In vitro* diagnostic device	LOT	Batch code
	Use by		Manufacturer
	Number of tests		

Last Revision: August 2014/A