CE

IVD

Rapid-VIDITEST

Adeno Resp. CARD

One step Adenovirus respiratory Card Test.

Instruction manual

INTENDED USE:

The Rapid-VIDITEST Adeno Resp. Card is a one step coloured chromatographic immunoassay for the qualitative detection of Adenovirus antigens. It can be used directly with nasal swabs or nasal wash or nasal aspirate specimens.

INTRODUCTION:

Adenoviruses most commonly cause respiratory illness; however, depending on the infecting serotype, they may also cause various other illnesses, such as gastroenteritis, conjunctivitis, cystitis, and rash illness. Symptoms of respiratory illness caused by Adenovirus infection range from the common cold syndrome to pneumonia, croup, and bronchitis. Patients with compromised immune systems are especially susceptible to severe complications of Adenovirus infection. Adenovirus is transmitted by direct contact, fecal-oral transmission, and occasionally waterborne transmission. Some types are capable of establishing persistent asymptomatic infections in tonsils, adenoids, and intestines of infected hosts, and shedding can occur for months or years.

PRINCIPLE OF THE TEST:

The Rapid-VIDITEST Adeno Resp. Card is a qualitative immunochromatographic assay for the determination of Adenovirus in nasal samples. The membrane is pre-coated with mouse monoclonal antibodies, on the test band region, against viral antigens.
During testing, the sample is allowed to react with the coloured conjugate (anti-Adenovirus mouse monoclonal antibodies-blue microspheres) which was pre-dried on the test. The mixture then moves upward on the membrane by capillary action. As the sample flows through the test membrane, the coloured particles migrate. In the case of a positive result the specific antibodies present on the membrane will capture the coloured conjugate. The mixture continues to move across the membrane to the immobilized antibody placed in the control band region, a GREEN coloured band always appears. The presence of this GREEN band serves as 1) verification that sufficient volume is added, 2) that proper flow is obtained and 3) as an internal control for the reagents.

MATERIALS PROVIDED:

- Rapid-VIDITEST Adenovirus Resp. Card tests
- Reagent B (sample diluent)
- Testing tubes
- Sterile Swabs

- Disposable pipettes
- Instructions for use

MATERIALS REQUIRED BUT NO PROVIDED:

- Disposable gloves
- Timer

SPECIMEN COLLECTION AND PREPARATION:

Nasal swab specimen:

Collect specimen with a sterile swab from one nostril. Insert the swab approximately 3 cm into the nostril rotating against the nasal wall. Process the swab as soon as possible after collecting the specimen.

Nasal Wash or Aspirate specimen:

For Adult: Place the irrigator up to the nose. Let the sterile saline water run into the nose (2.5 mL). It will run out the opposite side. Tilt and twist the irrigator side to side and up and down directing the water flow into all portions of the nasal cavity. Collect the wash in a clean specimen container, tilt the head forward and allow the water with mucus to run out of the nostril into the specimen container. Repeat the mucus collection for the other nostril and collect it into the same container.

For children: use an aspiration bulb or bulb syringe to instil the saline water into one nostril leaning the children head. Aspirate the mix of mucus-saline water into the bulb and transfer it into a clean container. Repeat for the other nostril and transfer the fluid into the same specimen container.

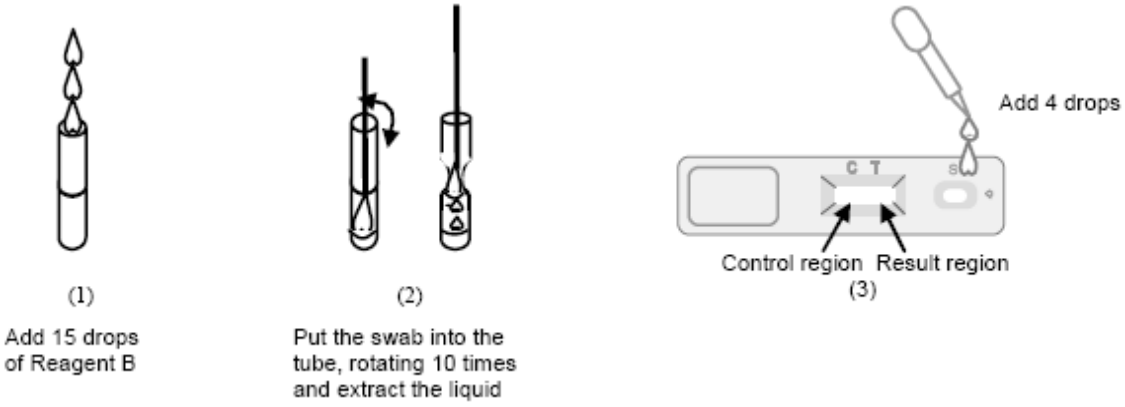
Samples should be process as soon as possible after collection. The samples can be stored in the refrigerator (2-4 ºC) for 8 hours prior to testing.

TEST PROCEDURE

Allow the tests, swabs and controls to reach to 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.

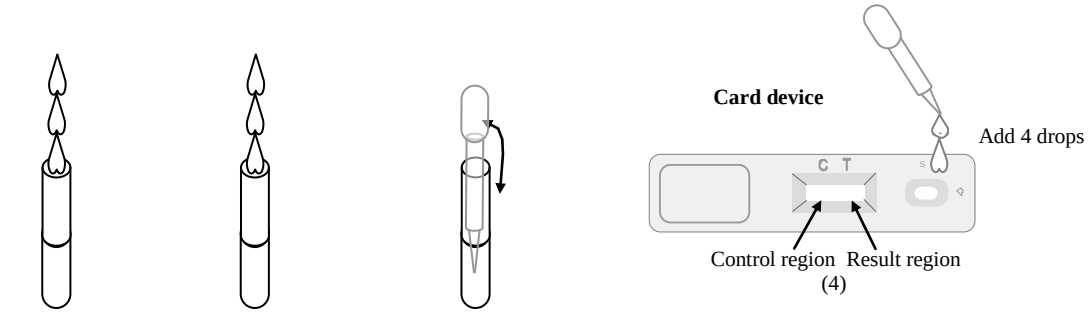
- Procedure A using nasal swab samples:

1. Add 15 drops (1) Reagent B and immediately put the swab into the tube.
2. Mix the solution by rotating the swab forcefully against the side of the tube at least 10 times. Best results are obtained when the specimen is vigorously extracted in the solution (2). Extract as much liquid as possible from the swab, squeezing the sides of the tube as the swab is withdrawn. Discard the swab.
3. Remove the Rapid-VIDITEST Adeno Resp. Card device from its sealed bag just before using.
4. Place the test on a flat surface. Use a separate pipette and device for each sample or control. Dispense 4 drops from the testing tube, into the circular window marked with an arrow (3).
5. Read the result at 10 minutes.

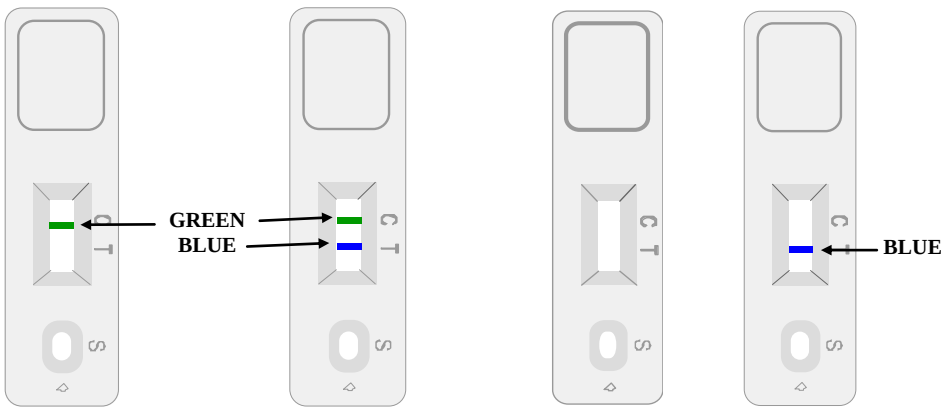


- Procedure B using nasal wash or aspirate samples:

1. Add 6 drops (1) of the nasal wash or aspirate samples with a pipette and 3 drops (2) of Reagent B in a testing tube.
2. Remove the Rapid-VIDITEST Adeno Resp. Card device from its sealed bag just before using. Place the test on a flat surface.
3. Mix the solution with the pipette at least 10 times. Best results are obtained when the specimen is vigorously extracted in the solution (3).
4. Dispense exactly 4 drops from the testing tube, into the circular window marked with an arrow (4).
5. Read the result at 10 minutes.



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



***NEGATIVE*:** Only one GREEN band appears across the central window in the site marked with the letter C (control line).

***POSITIVE*:** In addition to the GREEN control band, a BLUE band (test line) also appears in the site marked with the letter T (result line).

***INVALID*:** A total absence of the control coloured band (GREEN) regardless the appearance or not of the result line (BLUE). 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 you local distributor.

NOTES ON THE INTERPRETATION OF RESULTS:

The intensity of the blue coloured 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 controls are included in the test. A green line appearing in the control region (C) is an internal control. It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS:

1. The test must be carried out within 2 hours of opening the sealed pack.
2. This test provides a presumptive diagnosis for Adenovirus respiratory infections. A confirmed infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
3. The Rapid-VIDITEST Adeno Resp. Card test should be used only with nasal swabs, nasal wash and nasal aspirate samples. The use of swab specimens taken from other sites or the use of other samples such as saliva, sputum or urine has not been established. The quality of the test depends on the quality of the sample; proper nasal specimens must be obtained.
4. A negative result may be obtained if the specimen is inadequate or antigen concentration is below the sensitivity of the test.

PERFORMANCE:

Sensitivity:

Different evaluated nasal samples (positive and negative samples) were tested in accordance with the kit instructions of three commercial assays to detect the Adenovirus respiratory infection.

The detection of Adenovirus showed a >99% of concordance in sensitivity with a commercial immunochromatographic assay Adenovirus Respi rapid Test (CorisBioConcept) and an immunofluorescence assay PathoDx®Adenovirus (Remel).

Specificity:
The use of mouse monoclonal antibodies in the elaboration of Rapid-VIDITEST Adeno Resp. Card test assures high degree of specificity for the detection of Adenovirus antigens.
The detection of Adenovirus showed a >99% of concordance in specificity with a commercial immunochromatographic assay Adenovirus Respi rapid Test (CorisBioConcept) and an immunofluorescence assay PathoDx®Adenovirus (Remel).

STORAGE AND STABILITY:

Store as packaged in the sealed pouch at 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.

PRECAUTIONS:

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The tests should be discarded in a proper biohazard container after testing.

REFERENCES:

1. MARCELA ECHAVARRIA, JOSE L. SANCHEZ, et al. "Rapid Detection of *Adenovirus* in Throat Swab Specimens by PCR during Respiratory Disease Outbreaks among Military Recruits", *Journal of Clinical Microbiology*, Feb. 2003, Vol. 41, No. 2, p. 810–812
2. MARILYN J. AUGUST' AND ANN L. WARFORD; "Evaluation of a Commercial Monoclonal Antibody for Detection of *Adenovirus* Antigen" *Journal of Clinical Microbiology*, Nov. 1987, Vol. 25, No. 11; p. 2233-2235

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

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

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