CE

IVD

Rapid-VIDITEST

Rota-Adeno Card

One step Rotavirus-Adenovirus Card test.

Instruction manual

INTENDED USE:

The Rapid-VIDITEST Rota-Adeno Card is a one step coloured chromatographic immunoassay for the qualitative detection of Rotavirus and/or Adenovirus in stool samples.

INTRODUCTION:

Rotavirus and Adenovirus are major causes of infectious gastroenteritis in infants and young children, also observed in adults. They are transmitted by fecal-oral contact. The main symptoms of viral gastroenteritis are watery diarrhoea and vomiting. The affected person may also have headache, fever, and abdominal cramps ("stomach ache"). In general, the symptoms begin 1 to 2 days following infection with a virus that causes gastroenteritis and may last for 1 to 10 days, depending on which virus causes the illness (Rotavirus 3 days and Adenovirus 5-8 days).

PRINCIPLE OF THE TEST:

The Rapid-VIDITEST Rota-Adeno Card is a qualitative immunochromatographic assay for the determination of Rotavirus and Adenovirus in feces 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-rotavirus mouse monoclonal antibodies-red microspheres and 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 particles. Different coloured lines will be visible, depending upon the virus content of the sample. These lines are used to interpret the result.
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 Rota-Adeno Card tests
- Instructions for use
- Stool collection tubes

MATERIALS REQUIRED BUT NO PROVIDED:

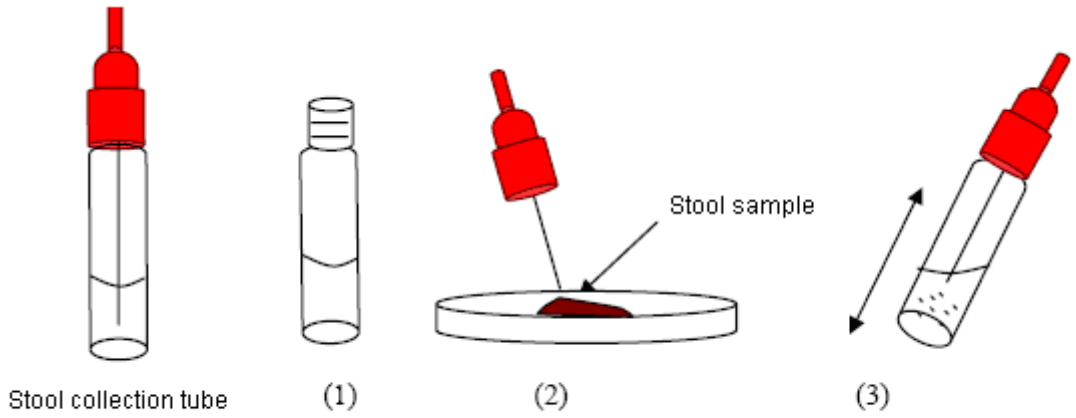
- Specimen collection container
- Disposable gloves
- Timer

SPECIMEN COLLECTION AND PREPARATION:

Stool samples should be collected in clean containers and the assay should be done right after collection. The samples can be stored in the refrigerator (2-4 ºC) for 1-2 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen at –20ºC. In this case, the sample will be totally thawed, and brought to room temperature before testing.

Specimen preparation:

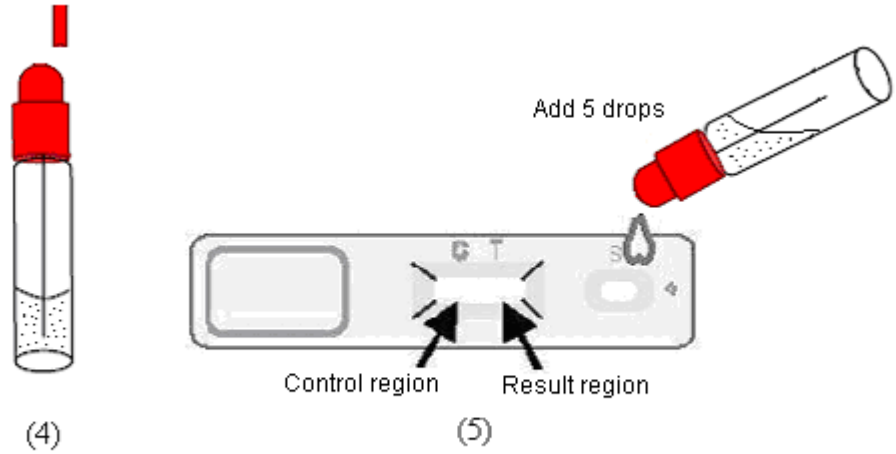
1. Take out the top of the stool collection tube (1) and use the stick to pick up a little sample (2).
2. Add the sample into the stool collection tube. Close the tube with the diluent and stool sample.
3. Shake the tube in order to assure good sample dispersion (3).



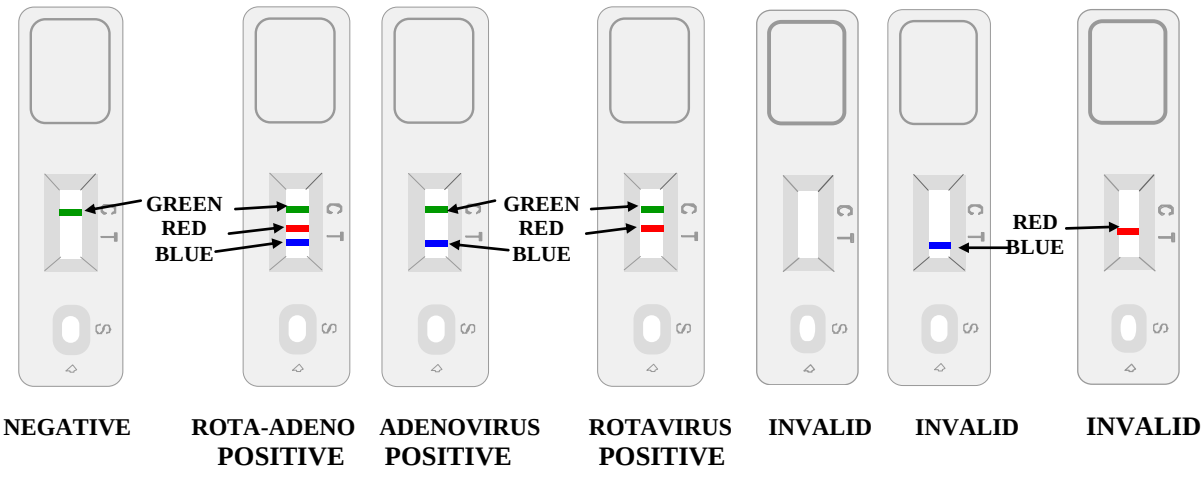
TEST PROCEDURE:

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

1. Proceed to shake the stool collection tube in order to assure good sample dispersion. Cut the end of the top (4).
2. Remove the Rapid-VIDITEST Rota -Adeno Card device from its sealed bag just before using.
3. Use a separate stool collection tube and device for each sample or control. Dispense exactly 5 drops or 150 µL into the circular window marked with an arrow, avoiding to add solid particles with the liquid (5). In case the tests did not run due to solid particles fallen into the round window, stir the sample added or dispense a drop of extraction buffer until seeing the liquid running through the reaction zone.
4. Read the result at **10 minutes** (the coloured bands appear).



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).

ROTAVIRUS POSITIVE: in addition to the GREEN control band, a RED band (Rotavirus test line) also appears in the site marked with the letter T (results lines).

ADENOVIRUS POSITIVE: in addition to the GREEN control band, a BLUE band (Adenovirus test line) also appears in the site marked with the letter T (results lines).

ROTAVIRUS-ADENOVIRUS POSITIVE: All the lines above described (a GREEN control band in the control region, a RED band and a BLUE band in the result region) could appear at the same time during the test performance due to a simultaneous infection of Rotavirus and Adenovirus.

INVALID: A total absence of the control coloured band (GREEN) regardless the appearance or not of the results lines (RED/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 red or blue coloured band 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) is the internal procedural 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 bag.
2. An excess of stool sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
3. After one week of infection, the number of viruses in feces is decreasing, making the sample less reactive. Stool samples should be collected within one week of the onset of symptoms.
4. This test provides a presumptive diagnosis for Rotavirus and/or Adenovirus infections. A confirmed infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

Negative results are expected in healthy infants and young children, also in healthy adults.

PERFORMANCE
The evaluation was conducted comparing the results obtained using the Rapid-VIDITEST Rota–Adeno Card to another commercial available Rota -Adeno membrane assay.

Sensitivity
The detection of Rotavirus showed a 100% of concordance in sensitivity.
The detection of Adenovirus showed a 90% of concordance in sensitivity.

Specificity
The detection of Rotavirus showed a 98% of concordance in specificity.
The detection of Adenovirus showed a 100% of concordance in specificity.
The use of mouse monoclonal antibodies in the elaboration of Rapid-VIDITEST Rota-Adeno Card assures high degree of specificity for the detection of these viruses.

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. CUKOR G., and BLACKLOW N. R.: „Human Viral Gastroenteritis“, *Micribiological Reviews*, Vol. 48 No 2, June 1984, pp. 157 – 179.
2. ESTES M. K. and COHEN J.: „Rotavirus Gene Structure and Function“, *Microbiological Reviews*, Vol. 53 No 4, Dec. 1989, pp. 410 – 449.
3. PAI C. H., SHAHRABADI M. S., and INCE B.: „Rapid Diagnosis of Rotavirus Gastroenteritis by a Commercial Latex Agglutination Test“, *Journal of Clinical Microbiology*, Vol. 22 No 5, Nov. 1985, pp. 846 – 850.
4. CUKOR G., PERRON D. M., and BLACKLOW N. R.: „Detection of Rotavirus in Human Stools by Using Monoclonal Antibody“, *Journal of Clinical Microbiology*, Vol, 19, 888 – 892.

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

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

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