Adenovirus-Rotavirus Rapid Test

Cat. No.: DTS603
Pkg. Size: 20 T

**Intended use**

Immunochromatographic card test for the qualitative detection of Adenovirus and/or Rotavirus in human faeces.

**General Description**

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 Rotavirus-Adenovirus 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.

**Reagents And Materials Provided**

Each kit contains:
1. Adenovirus-Rotavirus card (20 devices).
2. Extraction buffer (1.0 mL x 20 bottles)
3. Instruction for use (1 item)

**Materials Required But Not Supplied**

Specimen collection container
Disposable gloves and container
Timer
Plastic dropper.

**Storage**

The test must remain in the sealed pouch until use and in a dry environment. The kit must not be frozen. Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30°C/36-86°F). The test is stable through the expiration date.
Specimen Collection And Preparation

SPECIMEN COLLECTION
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 °C) for 1-2 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen at–20°C. In this case, the sample will be totally thawed, and brought to room temperature before testing.

Specimen preparation
Take out the cap of the stool collection tube.
Use the stick to pick up a little sample (approx. 100mg), if the stool sample was liquid take 100 μL using a pipette. Close the tube with the diluent and stool sample.
Shake the tube in order to assure good sample dispersion.

Assay Procedure
To process the collected stool samples
Use a separate specimen collection vial for each sample. Unscrew the cap of the vial and introduce the stick three times into the fecal specimen to pick up the sample (about 100-200 mg). Close the vial with the buffer and stool sample. This vial with the sample can be storage during 5 days. Shake the vial in order to assure good sample dispersion. For liquid stool samples, aspirate the fecal specimen with a dropper and add approx. 100-200μL into the specimen collection vial with buffer.

Test Procedure
Allow the tests, stool samples and buffer to reach to room temperature (15-30°C/59-86°F) prior to testing. Do not open pouches until ready to perform the assay.
1. Remove the Adenovirus-Rotavirus device from its sealed pouch and use it as soon as possible. Place in a clean and flat surface.
2. Shake the specimen collection vial to assure good sample dispersion. Break off the tip of the vial.
3. Use a separate device for each sample. Dispense 5-6 drops or 100 μL into the specimen well (S). Start the timer.
4. Read the result at 10 minutes after dispensing the sample.

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.

Interpretation of Results
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 your 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.

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**Expected Values**

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

**Performance Characteristics**

The evaluation was conducted comparing the results obtained using the Rotavirus-Adenovirus test to another commercial available Rotavirus-Adenovirus membrane assay.

**Sensitivity**

The detection of Rotavirus showed >99% of concordance in sensitivity. The detection of Adenovirus showed > 99% of concordance in sensitivity.

**Specificity**

The detection of Rotavirus showed a 98% of concordance in specificity. The detection of Adenovirus showed >99% of concordance in specificity. The use of mouse monoclonal antibodies in the elaboration of Rotavirus-Adenovirus test assures high degree of specificity for the detection of these viruses.

**Interferences**

Cross-reactivity to sample positive for the following pathogens was tested and found to be negative: HSV, Parainfluenza, Enterovirus, Rhinovirus, NOcardia asteroids, Streproccoccus pneumoniae, Moraxella catarrhalis, Streptococcus pyogenes, Aspergillus niger, Legionella pneumophila, Candida albicans, Haemophilus influenzae.
Precautions

All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices.
Adenovirus-Rotavirus Card is for in vitro diagnosis only.
Avoid touching the nitrocellulose with your fingers.
Wear gloves when handling the samples.
Disposable gloves, swabs, test tubes, and sensitized strips in accordance with GLP.
Never use reagents from another lot.
Discard the dilution buffer if it is contaminated with bacteria or mould.
The reagents’ quality cannot be guaranteed beyond their shelf-life date or if the reagents are stored under inappropriate conditions.

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).
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.

REFERENCES