

ROTA-ADENO Virus Combo Test Device

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 diarrhea 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

Rota-Adeno Combo Test Device is a qualitative immunochromatographic assay for the determination of Rotavirus and Adenovirus in stool samples. The membrane is pre-coated with monoclonal antibodies, on the test band region, against viral antigens. During testing, the sample is allowed to react with the colored 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 colored particles migrate. In the case of a positive result the specific antibodies present on the membrane will capture the colored conjugate. Different colored 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 colored 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.

STORAGE

Store as packaged at 2-30°C. Do not freeze.

PRECAUTIONS

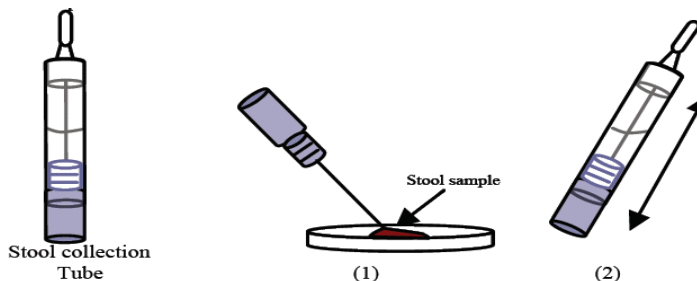
- For professional *in vitro* diagnostic use only.
- Do not use after expiration date.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test should be discarded in a proper biohazard container after testing.

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 °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:

1. Unscrew the tap and use the stick to pick up a little sample. Close the tube with the diluent and stool sample.
2. Shake the tube in order to assure good sample dispersion.



MATERIALS PROVIDED

- Test Devices
- Stool collection tubes containing sample diluent.
- Package Insert

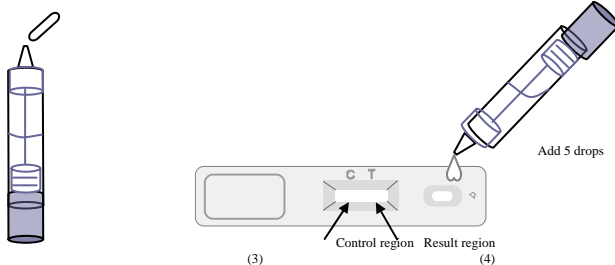
MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Disposable gloves
- Timer

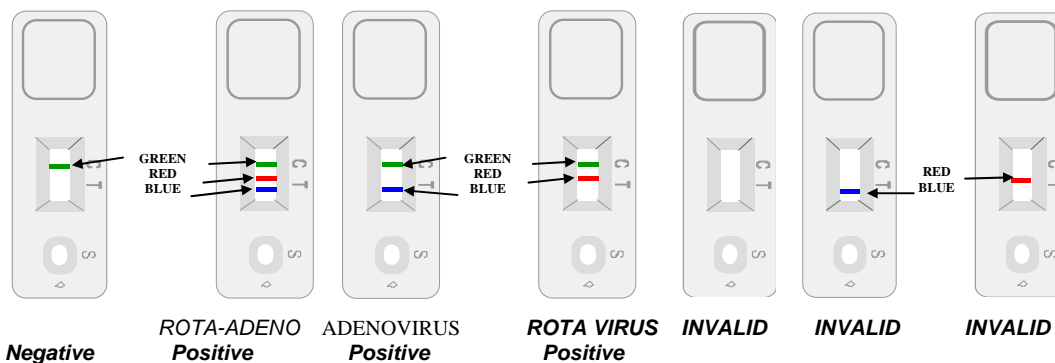
TEST PROCEDURE

Allow the test , stool samples and controls to reach room temperature (15-30 °C) 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 3.
2. remove the Rota-Adeno Card device from it's 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 4.
4. read the result at 10 minutes .



INTERPRETATION OF RESULTS (please refer to the illustration below)



NEGATIVE: Only one GREEN band (control line) appears in the white central zone of the reaction test (control region).

ROTA VIRUS POSITIVE: In addition to the GREEN control band, a distinguishable RED band (Rotavirus result line) also appears in the white central zone of the reaction test (result region).

ADENOVIRUS POSITIVE: In addition to the GREEN control band, a distinguishable BLUE band (Adenovirus result line) also appears in the white central zone of the reaction test (result region).

ROTA VIRUS-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 colored band (GREEN) regardless of the appearance or not of the result line (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 performance using a new test. If the problem persists, discontinue using the test kit and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A green line appearing in the control region 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. 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 Adenovirus and Rota virus infections. A confirmed infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE

Under process

REFERENCES

1. CUKOR G., and BLACKLOW N. R., "Human Viral Gastroenteritis", Microbiological 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 bu 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.

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Revision A (06.10.2007)
PPI489A01