ROTA Virus Test Strip

INTRODUCTION

Rotavirus is major cause of infectious gastroenteritis in infants and young children, also observed in adults. It is 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 Rotavirus that causes gastroenteritis and may last for 3 days.

RINCIPLE OF THE TEST

Rota Test Strip is a qualitative immunochromatographic assay for the determination of Rotavirus in stool 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 colored conjugate (anti-Rotavirus mouse monoclonal antibodies-red 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. 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 2-30ºC. 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 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. Place 1ml (approximately 20 drops) of the sample diluent in a test tube.
2. Add approximately a sample portion of 5mm diameter with a swab and shake gently in order to un-stick and facilitate the sample dispersion.
3. Shake the test tube with a vortex in order to assure good sample dispersion.
4. Centrifuge the sample tube for 5 minutes.

MATERIALS PROVIDED

- Test Strips.
- Package Insert.
- Sample Diluent.

MATERIALS REQUIRED BUT NO PROVIDED

- Specimen collection container
- Test tubes or vials
- Disposable gloves
- Timer

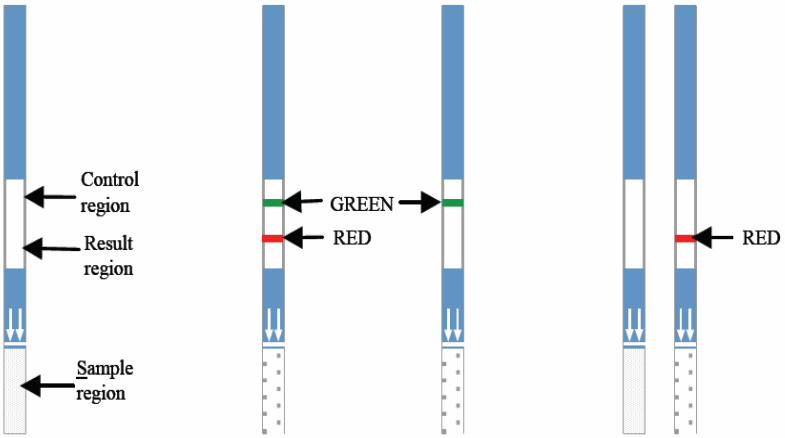
TEST PROCEDURE

Allow the test, stool samples 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.

1. Allow the test strips and samples to reach room temperature (15-30ºC) prior to testing. Do not open the package until ready to perform the assay.
2. Using the applicator stick of the provided sample diluent vial, transfer a small portion (5mm diameter) of stool specimen into the sample diluent.
3. Shake gently in order to unstuck and facilitate the sample dispersion.
4. Hold the vial and break the tip off.
5. Dispense 10 drops (approximately 0.5 ml) of the sample extract in a test tube.
6. Immerse the test strip in the liquid prepared in step 5. Do not exceed the line shown on the strip.
7. Read the result at 10 minutes.

Depending on the concentration of Rotavirus, positive results may be observed as soon as 3 minutes. However to confirm the final result, the complete reaction time of 10 minutes is required.

INTERPRETATION OF RESULTS (please refer to the illustration below)



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

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

INVALID: A total absence of the control colored band (GREEN) regardless of the appearance or not of the result line (RED). 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 Rotavirus infections. A confirmed infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE

Under process

ATLAS MEDICAL
Unit 4, William James House
Cowley Rd, Cambridge, CB4 0WX
Tel: ++44 (0) 1223 858 910
Fax: ++44 (0) 1223 858 524

PPI267A01
Revision A (31.01.2006)