Atlas Medical

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.

MATERIALS

MATERIALS PROVIDED

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

MATERIALS REQUIRED BUT NO PROVIDED

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

STORAGE

- Store as packaged at 2-30ºC. Do not freeze.

PRECAUTIONS

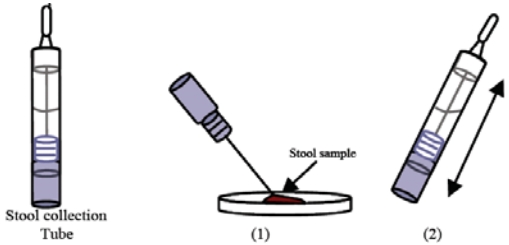
- For professional ***in vitro*** diagnostic use only.
- Do not use after expiration date.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test should be discarded in a proper biohazard container after testing.

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 (see illustration):

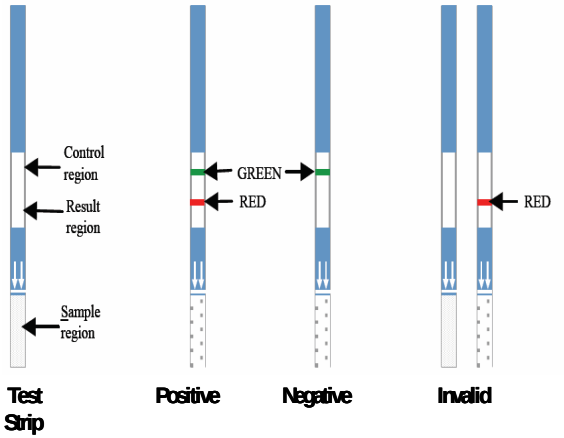
1. Unscrew the tap and use the stick to pick up a little sample. Close the tube with the diluent and stool sample.
2. Shake the tube in order to assure good sample dispersion.
3. The sample is ready now to perform the test.



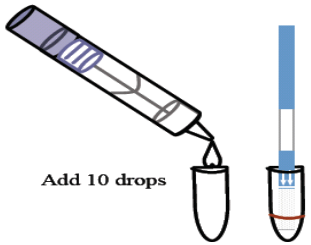
TEST PROCEDURE

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. Take the sample collection tube in which the sample had been prepared and breake the tip off.
2. .Add 10 drops into a clean test tube.
3. Take the strip out out of the pouch and place it vertically in the test tube with the white end submerged into the sample taking care of not exceeding the limit of immersion indicated with the arrows.
4. Read the result at 10 minutes.
5. 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

- The test must be carried out within 2 hours of opening the sealed pack.
- An excess of stool sample could cause wrong results (brown bands appear).
- 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.
- 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

1. SENSITIVITY

Detection Limit

A purified Rotavirus protein was diluted in the Rota buffer and tested in accordance with the kit instruction for use. We found that,under such condition ,the detection limit using the reference antigen preparation of Rotavirus is 15.6 ng\ml.

Note:

Detection limit and the reaction temperature

It is worthy to remark that the temperature has influence on the performance of the test. The sensitivity limit is slightly reduced when the sample and reaction strip are cold. The sensitivity limit improves when sample and reaction strips are kept at room temperature (20-25ºC) for a while prior to running the test. The sensitivity reaches its optimal value when this warm up period has been 20 minutes. To be sure that the samples and reaction strips have reached room temperature when performing the test, they should be taken out of the refrigerator at least 30 minutes in advance.

2. **SPECIFICITY**

Several evaluations at different hospitals are being conducted. A first small evaluation of the test gave the following results:

ROTAVIRUS LINE		ELISA evaluation		
+		+	-	Total
9	+	18	1	19
1	-	0	43	43
10	Total	18	44	62

Rotavirus:

- Sensitivity: > 99%
- Specificity: 98%
  - Positive Predictive Value: 95%
- Negative Predictive Value: >99%
-

REFERENCES

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