Atlas Medical

CE

ROTA-ADENO Virus Combo Test Device

IVD *For In-Vitro and professional use only*

2 30°C Store at 2-30°C

INTENDED USE

Detection of Rota-Adeno virus Antigen 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 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:

-verification that sufficient volume is added,that proper flow is obtained.as an internal control for the reagents.

MATERIALS

MATERIALS PROVIDED

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

MATERIALS REQUIRED BUT NO PROVIDED

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

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.

STORAGE

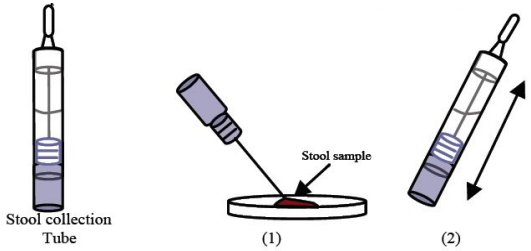
Store as packaged at 2-30ºC. Do not freeze.

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):

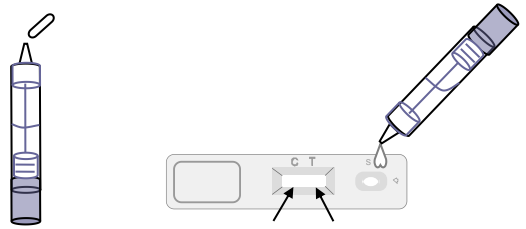
1. Unscrew the tap and use the stick to pick up a little sample. Close the tube with the diluent and stool sample.
2. Shake the tube in order to assure good sample dispersion.



TEST PROCEDURE

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

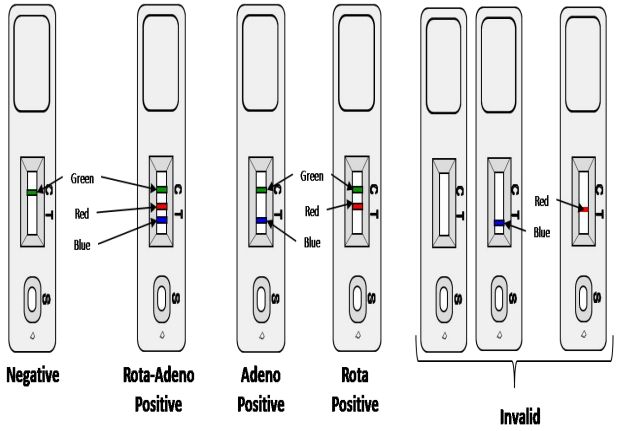
1. Using the applicator stick of the provided sample diluent vial, transfer a small portion (5mm diameter) of stool specimen into the sample diluent.
2. Shake gently in order to unstuck and facilitate the sample dispersion.
3. Hold the vial and break the tip off.
4. Add 4 drops to the sample well in the test device.
5. Read the result after 10 minutes.



(3) (4) Control region Result region

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).

ROTAVIRUS 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).

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 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

- 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 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

1. SENSITIVITY

Detection Limit: A purified Rotavirus-Adenovirus protein (Purified Rotavirus extract + Adenovirus Hexon Antigen) preparation was diluted in the Rota-Adeno buffer and tested in accordance with the kit instructions for use. We found that, under such conditions, the detection limit using the reference antigen preparation of Rotavirus and Adenovirus is 15.6 ng/mL (Rotavirus) and 31.25 ng/mL (Adenovirus).

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:

Atlas Rotavirus-Adenovirus Test ADENOVIRUS LINE	ELISA evaluation			Atlas Rotavirus-Adenovirus Test ROTAVIRUS LINE	ELISA evaluation		
	+	-	Total		+	-	Total
+	9	0	9	+	18	1	19
-	1	88	89	-	0	43	43
Total	10	88	98	**Total**	18	44	62

Rotavirus:

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

Adenovirus:

- Sensitivity: 90%
- Specificity: >99%
- Positive Predictive Value: >99%
- Negative Predictive Value: 99%

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 Commerctial 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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REF	Product Reference No.	2	Single use. Do not re-use
IVD	For in-vitro diagnostic use.		Do not use if the pouch is damaged.
ST	For Self-Testing use.		Store at
	Caution.	Σ	Number of tests in the pack.
	Read product insert before use.		Manufacturer.
LOT	Lot (batch) number.		Expiry date.
	Manufacturer telephone number.		Manufacturer fax number.