

Rotavirus Antigen Rapid Test

Cat. No.: HROTA027G

INTENDED USE

Rotavirus Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of human Rotavirus antigen in human stool specimen. The test results are intended to aid in the diagnosis of rotavirus infection and to monitor the effectiveness of therapeutic treatment.

SUMMARY

Infantile diarrhea is a group of common pediatric diseases caused by multiple causes and factors, characterized by increased stool frequency and changes in stool characteristics. 80% of infantile diarrhea is caused by virus. The main pathogen of viral enteritis is rotavirus, followed by enterovirus, such as intestinal adenovirus.

Rotavirus is one of the main pathogens causing infantile diarrhea. It mainly infects small intestinal epithelial cells, resulting in cell damage and diarrhea. Rotavirus is prevalent in summer, autumn and winter every year. The route of infection is fecal oral route. The clinical manifestation is acute gastroenteritis and osmotic diarrhea.

PRINCIPLE

Rotavirus Antigen Rapid Test is a sandwich solid phase immunochromatographic assay. To perform the test, an aliquot of diluted stool sample is added to the sample well of the test cassette. The sample flows through a pad containing antibodies against rotavirus coupled to red-colored colloidal gold. If the sample contains rotavirus antigens, the antigen will bind to the antibody coated on the colloidal gold particles to form antigen-antibody-gold complexes. These complexes move on the nitrocellulose membrane by capillary action toward the test line region on which rotavirus specific antibodies are immobilized separately. As the complexes reach the test line, they will bind to the antibody corresponding to the virus on the membrane to form of a line. A red control line will always appear in the result window to indicate that the test has been correctly performed and the test device functions properly. If virus is not present or lower than the detection limit of the test, only the control line will be visible. If the control line dose not developed, the test is invalid.

MATERIALS

Materials Provided

- Individually packed test devices
- Assay Buffer Tube
- Disposable pipettes
- Package insert

Materials Required but Not provided

- Specimen collection container
- Timer

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or

inhale).

- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The Rotavirus Antigen Rapid Test is intended for use with human stool specimens only.
- Stool samples must be taken as soon as the symptoms appear.
- Stool specimens should be collected in containers that do not contain media, preservatives, animal serum or detergents as any of these additives may interfere with the Rotavirus Antigen Test.
- Specimens may be stored at 2-8°C for 2 days without interfering with the assay performance. For long-term storage of specimens, - 20°C or colder is recommended. Repeated freezing and thawing of specimens is not recommended and may cause erroneous results. Do not store specimens in self-defrosting freezers.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.

TEST PROCEDURE

Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.

- Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results the assay should be performed within one hour.
- SPECIMEN PREPARATION**
Unscrew the sample bottle, use the attached applicator stick attached on the cap to transfer small piece of stool (4-6 mm in diameter; approximately 50 mg – 200 mg) into the Assay Buffer Tube. For liquid or semi-solid stools, add 100 microliters of stool to the vial with an appropriate pipette. Replace the stick in the bottle and tighten securely.

Mix stool sample with the buffer thoroughly by shaking the bottle for a few seconds.

3. ASSAY PROCEDURE

3.1 Hold the Assay Buffer Tube upright with the tip point toward the direction away from the test performer, snap off the tip.

3.2. Hold the bottle in a vertical position over the sample well of the test card, deliver 3 drops (120-150 µL) of diluted stool sample to the sample well (S) and start the timer.

Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.

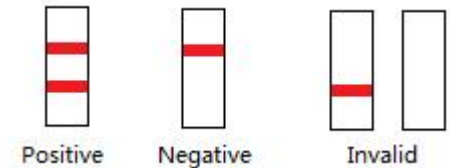
As the test begins to work, color will migrate across the result area in the center of the device.

3.3. Wait for the colored band(s) to appear. Read the result between 5 - 10 minutes. A strong positive sample may show result earlier.

Do not interpret the result after 10 minutes.

As the test begins to work, color will migrate across the result area in the center of the device.

INTERPRETATION OF RESULTS



POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

- The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
- Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The Rotavirus Antigen Combo Rapid Test is for professional in vitro diagnostic use, and should only be used for the qualitative detection of human Rotavirus.
2. The test result should be used only to evaluate with patient With signs and symptoms of the disease. A definitive clinical diagnosis should only be made by the physician after all clinical and laboratory finding have been evaluated.
3. As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the specimen. Specimens from patients who have received preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA. Such specimens may cause false positive or false negative results.
4. As all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

A Rotavirus Antigen Rapid Test detects the presence of rotavirus antigens in stool specimens. Expected values for any given population should be determined for each laboratory. The positivity rate of any given laboratory may vary depending on geographic location, season, and living environment.

PERFORMANCE CHARACTERISTICS

Table: Rotavirus Antigen Rapid Test vs. Latex Agglutination

Method		Latex Agglutination		Total Results
Rotavirus Antigen Rapid Test	Results	Positive	Negative	
	Positive	168	2	170
	Negative	1	234	235
Total Result		169	236	405

Relative Sensitivity: 99.41% (95%CI: 96.75%~99.99%)

Relative Specificity: 99.15% (95%CI: 96.97%~99.90%)

Accuracy: 99.26% (95%CI: 97.85%~99.85%)

SPECIFICITY

When the interfering substances are less than the concentrations listed in the table below, there is no significant effect on the test results:

Interfering substances	Concentration
Hemoglobin	1000mg/dL
Transferrin	100ug/mL
Lactoferrin	100ug/mL
Horseradish peroxidase	2000ug/mL














LITERATURE REFERENCES

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2. J Kaplon, L Théry, M Bidalot, N Grangier, J Frappier, L Serge Aho Glélé, A de Rougemont, K Ambert-Balay. Diagnostic Accuracy of Four Commercial Triplex Immunochromatographic Tests for Rapid Detection of

Rotavirus, Adenovirus, and Norovirus in Human Stool Samples. J Clin Microbiol, 2020 Dec 17;59(1).

3. T Kojima, M Arai, S Sadamoto, M Ikeda, K Araki. Evaluation of the diagnostic reagents which detect rotavirus and adenovirus with the immunochromatographical method. Rinsho Biseibutshu Jinsoku Shindan Kenkyukai Shi. 2000;11(2):93-8.

INDEX OF SYMBOLS

	Consult instructions for use		Store between 2-30°C		Use by
	For <i>in vitro</i> diagnostic use only		Do not reuse		Lot Number
	Manufacturer		Tests per kit	REF	Catalog No
	European union authorized representative		Keep dry		Don't use the product
	Biological risks		The product meets the basic requirements of European in vitro. diagnostic medical		



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