AG-ROTA VIRUS RAPID TEST KIT

INSTRUCTIONS FOR USE

AstraGene Rota virus rapid test kit is a rapid and convenient immunochromatographic assay for the qualitative detection of rotavirus in human fecal samples. It is intended for professional use as an aid in the diagnosis of rotavirus-associated gastroenteritis. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

PRINCIPLE

AstraGene Rota virus rapid test is an antigen-capture immunochromatographic assay, which detects the presence of rotavirus in fecal samples. Monoclonal antibodies specifically against rotavirus are 1) conjugated with colloidal gold and deposited on the conjugate pad and 2) immobilized on the test line of the nitrocellulose membrane. When a fecal sample is added, the gold-antibody conjugate is rehydrated and the rotavirus, if any in the sample, will interact with the colloidal gold conjugated antibodies. The antigen-antibody-colloidal gold complex will migrate towards the test window until the Test Zone (T) where it will be captured by immobilized antibodies, forming a visible coloured line (Test line), indicating a positive result. If rotavirus is absent in the sample, no pink line will appear in the Test Zone (T), indicating a negative result.

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a coloured control line in the Control Zone is an indication of an invalid result.

PACKAGE CONTENTS

Description	**10 tests**	1 test
Test Cassette and Desiccant	10 Cassette's	1 Cassette
Specimen collection tube	10 tubes	1 tube
IFU	1 No.	1 No.

Catalogue Number	**10 tests**	**1 test**
Cassette Model	AG/RTK/ROTA/24/01	AG/RTK/ROTA/24/02

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Clock or timer.
- Pipette
- Latex gloves

STORAGE &STABILITY

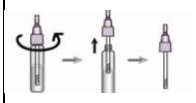
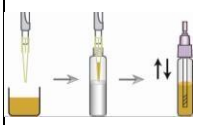
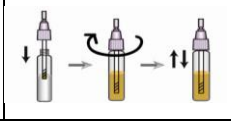
- The test device in the sealed pouch should be stored at 2-30ºC. Do not freeze the test device.
- The Fecal Specimen Collection Device containing the buffer should be stored at 2-30ºC.
- The test device should be kept away from direct sunlight, moisture and heat.

SPECIMEN COLLECTION & PREPARATION

- Viral detection is improved by collecting the specimens at the onset of symptoms. It has been reported that the maximum excretion of rotavirus in the feces of patients with gastroenteritis occurs 3-5 days after onset of symptoms. If the specimens are collected long after the onset of diarrheic symptoms, the quantity of antigens may not be sufficient to obtain a positive result or the antigens detected may not be linked to the diarrheic episode.
- Perform testing immediately after specimen collection. Best results will be obtained if the assay is performed right after collecting fecal samples. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 72 hours. Specimens prepared in the specimen collection tube may be stored for 6 months at -20°C if not tested within 1 hour after preparation.
- Bring specimens to room temperature prior to testing.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

PROCEDURE

Bring tests, specimens, the buffer and/or controls or room temperature (15-30˚C) before use.

Use clean, dry containers for specimen collection. Best results will be obtained if the assay is performed within 6 hours after collection.	
Unscrew the cap of the fecal specimen collection tube and take out specimen collection stick.	
For solid specimens: Stab the specimen collection stick into the fecal specimen in at least 3 different sites of the feces to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.	
For liquid specimens: Hold the pipette vertically, aspirate the fecal specimens, and then transfer 6 drops (approximately 300 µl) into the specimen collection tube containing the extraction buffer.	
Insert the specimen collection stick into the tube and tighten the cap. Shake the tube vigorously to ensure thorough mixture of the specimen and the assay diluents reagent.	

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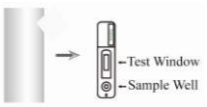
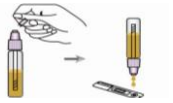
Remove the test cassette from the sealed pouch and use it as soon as possible. Caution: Do not touch the test window and the membrane inside.	
Hold the fecal specimen collection tube upright and break off the tip with hand. Invert the vial and add 3 full drops (120 µl) of specimen without air bubbles into the sample well of the cassette.	
Read the result within 15 minutes. NOTE: Specimens with high concentrations of rotavirus may produce positive results in as little as 1 minute and confirm negative results in 15-30 minutes. **DO NOT INTERPRET RESULTS AFTER 30 MINUTES**	

RESULT INTERPRETATIONS

Negative
A pink colored band appears only at the control region (C), indicating a negative result for rotavirus infections.

Positive
A clear pink control band (C) and a detectable test band (T) appear, indicating a positive result for rotavirus infections.

Invalid
No visible band at the control region (C). Repeat with a new test device. If the test still fails, please contact the distributor with the lot number.

SENSITIVITY & SPECIFICITY

AstraGene Rota virus rapid test vs. Latex Agglutination:
Relative Sensitivity: 99.1% (96.8%-99.9%)* Relative Specificity: >99.9% (97.7%-100.0%)* Overall Agreement: 99.5% (98.1%-99.9%)* *95% Confidence Interval

QUALITY CONTROL

Although the testing device contains an internal quality control (coloured band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

LIMITATION OF THE PROCEDURE

- This product is an *in vitro* diagnostic test designed for professional use only.
- Humidity and temperature can adversely affect results.
- The instructions for the use of the test should be followed during testing procedures.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- Although the test demonstrates superior accuracy in detecting rotavirus in fecal extract, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

WARNING AND PRECAUTION

- For professional *in vitro* diagnostic use only. Do not reuse.
- Do not use if the pouch seal or its packaging is compromised. Do not use after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials and performing the assay.
- Wash hands thoroughly after finishing the tests. Do not eat, drink or smoke in the area where the specimens or kits are being handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations. Keep out of children's reach.

SYMBOLS

Do not use if package is damaged Manufacturer LOT Batch Code

CE mark of Conformity Refer to the instructions ISO 13485:2016 ISO GMP

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