AG- ADENO/ROTA RAPID TEST KIT

INSTRUCTION FOR USE

AstraGene – Adeno/Rota Rapid Test kit is a rapid chromatographic immunoassay for the qualitative detection of rotavirus and adenovirus in human feces specimens to aid in the diagnosis of rotavirus or adenovirus infection.

PRINCIPLE

AstraGene – Adeno/Rota Rapid Test Kit is a qualitative, lateral flow immunoassay for the detection of rotavirus and adenovirus in human feces specimen. In this test, the membrane is pre-coated with anti-rotavirus antibody on the T1 test line region of the test and anti-adenovirus antibody on the T2 test line region of the test. During testing, the specimen reacts with a particle coated with anti-rotavirus antibody and anti-adenovirus antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-rotavirus antibody and anti-adenovirus antibody on the membrane and generate a colored line. The presence of these colored lines in the test line region indicates a positive result, while their absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred. properly.

PACKAGE CONTENTS

Description	10 tests	1 test
Test Cassettes with desiccant	10	1
Dropper	10	1
Specimen collection tube with extraction buffer	10	1
IFU	1	1

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

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Clock or Timer
- Specimen collection container
- Centrifuge
- Pipette 100ul
- Disposable Gloves

STORAGE &STABILITY

- Test device should be stored at 2-30ºC in the original sealed pouch.
- Do not freeze the test device.
- 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 the symptoms. It has been reported that the maximum excretion of rotavirus and adenovirus 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 antigen may not be sufficient to obtain a positive reaction or the antigens detected may not be linked to the diarrheic episode.
- The feces specimen must be collected in a clean, dry, waterproof container containing no detergents, preservatives or transport media.
- Bring the necessary reagents to room temperature before use.

PROCEDURE

- Allow Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.
  To collect fecal specimens:
- Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain enough virus particles. Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours. For long-term storage, specimens should be kept below -20°C.
- **To process fecal specimens:**
  - **For Solid Specimens:** Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites 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 dropper vertically, aspirate fecal specimens, and then transfer 2 drops of the liquid specimen (approximately 50 µL) into the specimen collection tube containing the extraction buffer. Tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Leave the collection tube for reaction for 2 minutes.
- Bring the pouch to room temperature before opening it. Remove the Test from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
- Hold the specimen collection tube upright and open the cap on the tip. Invert the specimen collection tube and transfer 2 full drops of the extracted specimen (approximately 80 µL) to the specimen well (S) of the Test, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
- Read the results at 10 minutes after dispensing the specimen. Do not read results after 20 minutes.
  Note: If the specimen does not migrate (presence of particles), centrifuge the extracted specimen contained in the extraction buffer vial. Collect 80 µL of supernatant, dispense into the specimen well (S). Start the timer and continue from step 5 onwards in the above instructions for use.

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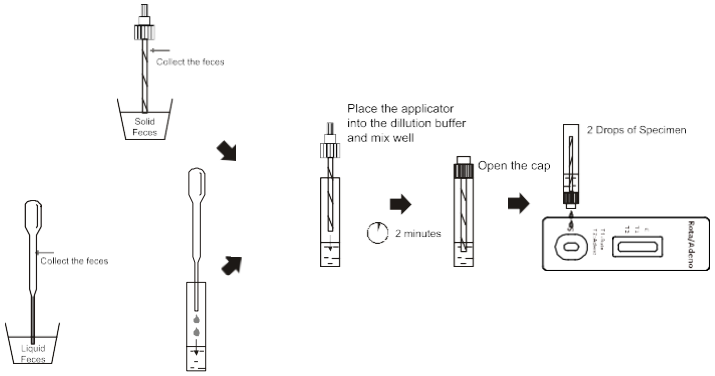


RESULT INTERPRETATIONS

Positive:

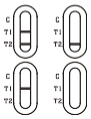
Rotavirus Positive: A colored line appears in the control line region (C) and another colored line appears in the T1 line region.

Adenovirus Positive: * A colored line appears in the control line region (C) and another colored line appears in the T2 line region.

Rotavirus and Adenovirus Positive: * A colored line appears in the control line region (C) and two other colored lines appear in T1 line region and T2 line region respectively.

*NOTE: The intensity of the color in the test line region (T1/T2) will vary depending on the concentration of rotavirus or adenovirus antigens present in the specimen. Therefore, any shade of color in the test line region (T1/T2) should be considered positive.

Negative: One colored line appears in the control line region (C). No line appears in the test line region (T1/T2).



Invalid: Control line (C) fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new Test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATION OF THE PROCEDURE

- AstraGene – Adeno/**Rota** Rapid Test kit is for *in vitro* diagnostic use only. The test should be used for the detection of human rotavirus and adenovirus in feces specimens only. Neither the quantitative value nor the rate of increase in human rotavirus and adenovirus concentration can be determined by this qualitative test.
- AstraGene – Adeno/**Rota** Rapid Test kit will only indicate the presence of rotavirus and adenovirus in the specimen and should not be used as the sole criteria for the conforming rotavirus and adenovirus to be etiological agent for diarrhea.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of rotavirus or adenovirus infection with low concentration of virus particles.

SENSITIVITY & SPECIFICITY

- The performance of AstraGene – Adeno/Rota Rapid Test kit has been evaluated the clinical specimens collected from children and young adults in comparison with latex agglutination method.
- Adeno Virus: Relative Sensitivity: 95.2% (95%CI:*89.8%-98.2%) Relative Specificity: 97.7% (95%CI:*95.0%-99.1%); Relative Accuracy: 96.8% (95%CI:*94.6%-98.4%) *Confidence Intervals
- Rota Virus: Relative Sensitivity: 97.3% (95%CI:*94.5%-98.9%); Relative Specificity: 97.1% (95%CI:*94.2%-98.8%); Relative Accuracy: 97.2% (95%CI:*95.4%-98.5%) *Confidence Intervals

WARNING AND PRECAUTION

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- The Test should remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

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SYMBOLS

Do not use if package is damaged Manufacturer Batch Code

CE mark of Conformity Refer to the instructions ISO GMP

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