AG- NOROVIRUS Ag RAPID TEST KIT

INSTRUCTION FOR USE

AstraGene – Norovirus Ag Rapid Test kit is a is a rapid chromatographic immunoassay for the qualitative detection of Norovirus in human fecal specimens to aid in the diagnosis of Norovirus infection.

PRINCIPLE

AstraGene – Norovirus Ag Rapid Test kit is a qualitative, lateral flow immunoassay for the detection of Norovirus in human fecal specimens. The assay uses Genogroup 1 and Genogroup 2 specific monoclonal antibodies coated on the test membrane. During testing, the stool specimen reacts with conjugate antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with Genogroup 1 and 2 antibodies on the membrane and generates a colored line at the level of the T1 and T2 region respectively. The presence of a colored line in T1 region indicates a positive result for Genogroup 1 and in T2 region for Genogroup 2 respectively, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control reaction region (C) 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
Specimen collection tube with extraction buffer	10	1
IFU	1	1

Catalogue Number	10 tests	1 test
Cassette Model	AG/RTK/NORAg/23/01	AG/RTK/NORAg/23/02

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Clock or Timer
- Droppers
- Specimen collection containers
- 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 Norovirus in the feces of patients with gastroenteritis occurs 3-13 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 fecal specimen must be collected in clean, dry, waterproof container containing no detergents, preservatives or transport media.
- Bring the necessary reagents to room temperature before use.times.

PROCEDURE

Allow the test, specimen, buffer and/or controls to reach room temperature (15- 30°C) prior to testing.

1. 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.

2. 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 50 uL 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.

3. Bring the pouch to room temperature before opening it. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.

4. Hold the specimen collection tube upright and unscrew the small cap of the specimen collection tube. Invert the specimen collection tube and transfer 2 full drops of the extracted specimen (approximately 80 uL) to the specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.

5. Read the results at 15 minutes after dispensing the specimen. Do not read results after 20 minutes.

Note: If the specimen does not migrate (presence of particles), centrifuge the diluted sample 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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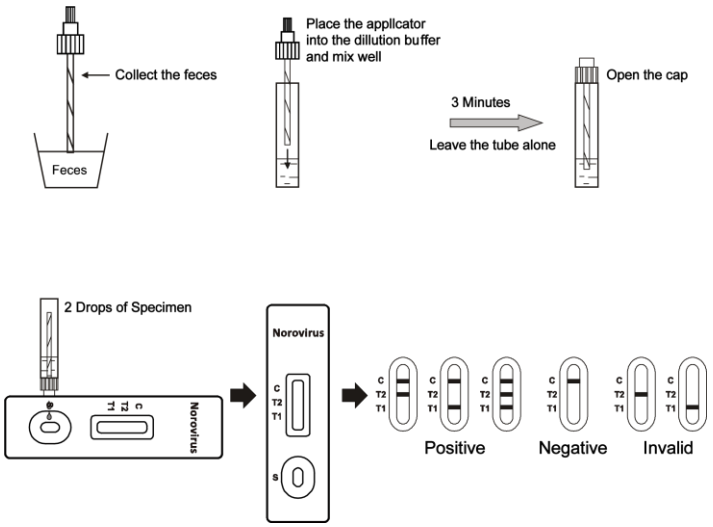

RESULT INTERPRETATIONS

- **Genogroup 1 POSITIVE:*** Two colored lines appear. One colored line should be in the control line region (C) and another colored line should be in the Genogroup 1 region (T1).
- **Genogroup 2 POSITIVE:*** Two colored lines appear. One colored line should be in the control line region (C) and another colored line should be in the Genogroup 2 region (T2).
- **Genogroup 1 & Genogroup 2 POSITIVE:* Three** colored lines appear. One colored line should be in the control region (C) and two colored lines should be in the Genogroup 1 region (T1) and Genogroup 2 region (T2). A positive result in the Genogroup 1 region and Genogroup 2 region indicates that Genogroup 1 antigen and Genogroup 2 antigen were detected in the sample.
  *NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of Norovirus antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.
- **NEGATIVE**: One colored line appears in the control line region (C). No line appears in the test line regions (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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATION OF THE PROCEDURE

- This test should be used for detection of Norovirus antigens in human stool only.
- AstraGene – **Norovirus** Ag Rapid Test kit only indicates the presence of Norovirus antigen in the specimen and should not be used as the sole criteria for the diagnosis of Norovirus infection.
- Stool sample from infant under one year old can produce a false positive result.
- As with all diagnostic tests, result must be considered together with other clinical information available to the physician.
- If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Norovirus infection.evaluated.

SENSITIVITY & SPECIFICITY

The relative sensitivity of the AstraGene – **Norovirus** Ag Rapid Test kit is 95.7%, and the relative specificity is 91.7%, and the relative accuracy is 94.3% in clinical specimens collected from children and young adults in comparison with RT-PCR method.

WARNING AND PRECAUTION

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- The test cassette 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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