Rotavirus Antigen Rapid Test Cassette (Colloidal Gold)

Cassette

Instruction for Use

A lateral flow immunochromatographic assay for the qualitative detection of Rotavirus antigen (Rota Ag) in human feces.For professional in vitro diagnostic use only.

CE IVD REF

In Vitro Diagnosis
For Professional Use

PACKAGING SPECIFICATION

1T/box,10T/box,20T/box,25T/box,40T/box,50T/box

INTENDED USE

The Rotavirus Antigen Rapid Test Cassette (Colloidal Gold) is a lateral flow immunochromatographic assay for the qualitative detection of Rotavirus antigen (Rota Ag) in human feces. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Rotavirus. The test is recommended for professional use only. All results must be interpreted together with other clinical information available to the physician.

SUMMARY

Rotavirus is the most common agent responsible for acute gastroenteritis, mainly in young children. Its discovery in 1973 and its association with infantile gastro-enteritis represented a very important advancement in the study of gastro-enteritis not caused by acute bacterial infection. The rotavirus may still be found while diarrhoea continues. Rotaviral gastroenteritis may result in mortality for populations at risk such as infants, the elderly, and immunocompromised patients. In temperate climates, rotavirus infections occur mainly in the winter months. Endemics as well as epidemics affecting some thousand people have been reported. With hospitalised children suffering from acute entric disease up to 50% of the analysed specimen were positive for rotavirus. The viruses replicate in the cell nucleus and tend to be host species specific producing a characteristic cytopathic effect (CPE). Because rotavirus is extremely difficult to culture, it is unusual to use isolation of the virus in diagnosing an infection. Instead, a variety of techniques have been developed to detect rotavirus in feces. The Rotavirus Antigen Rapid Test Cassette (Colloidal Gold) is an immunochromatographic assay that detects the presence of rotavirus antigen in feces specimens. The test is simple and easy to perform and the test results can be visually interpreted at 10 minutes.

PRINCIPLE

The Rotavirus *Antigen* Rapid Test Cassette(Colloidal Gold) has been designed to detect rotavirus through visual interpretation of color development in the internal strip. The membrane was immobilized with antirotavirus antibodies on the test region. During the test, the specimen is allowed to react with colored anti-rotavirus antibodies colloidal gold conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interact with reagents on the membrane. If there were enough rotavirus in specimens, a colored band will form at the T region of the membrane. Presence of colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS PROVIDED

Test devices. Each test cassette is packed in a foil pouch with a dropper and a package of desiccant.
Extraction diluents
Instruction for use

MATERIALS REQUIRED BUT NOT PROVIDED

Specimen collection containers
Timer
Centrifuge and pipette to dispense 80 μL if required

PRECAUTIONS

• For professional in vitro diagnostic use only.
• Do not use after expiration date indicated on the package. Do not use the test if its 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 totally guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (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 performing any tests.
• 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 the standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
• Do not interchange or mix reagents from different lots.
• Humidity and temperature can adversely affect results.
• The used testing materials should be discarded in accordance with local, state and/or federal regulations.

STORAGE AND STABILITY

Store the kit in cool and dry places at a temperature between 2-30°C. **Do not freeze.** The shelf-life of the kit under these storage conditions is 24 months. Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation.

SPECIMEN COLLECTION AND PREPARATION

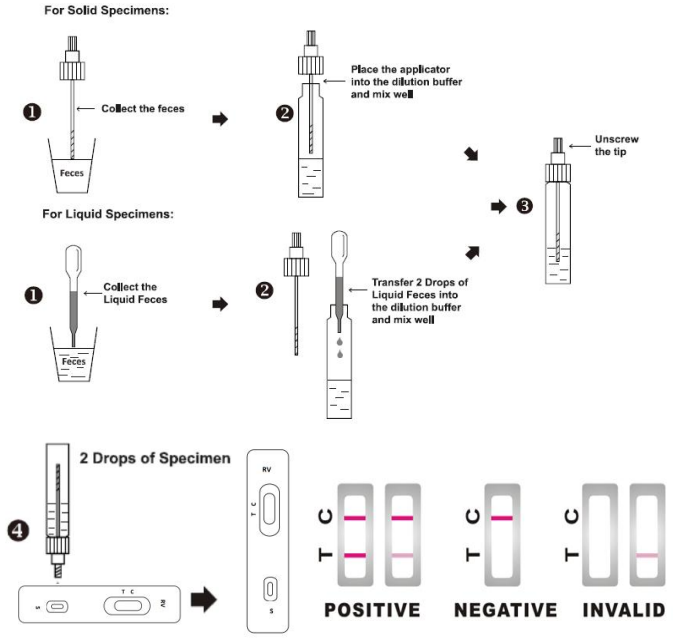
1.Viral detection is improved by collecting the specimens at the onset of the symptoms. It has been reported that the maximum excretion of rotavirus in the feces of patients with gastroenteritis occurs 3-5 days after onset of symptoms. If the specimens are collected long after the onset of diarrheic symptoms, the quantity of antigen may not be sufficient to obtain a positive reaction or the antigens detected may not be linked to the diarrheic episode.
2.The feces specimen must be collected in clean, dry, waterproof container containing no detergents, preservatives or transport media.
3.Bring the necessary reagents to room temperature before use.

ASSAY PROCEDURES

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 2 drops (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.
3. Bring the pouch to room temperature before opening it. Remove the test cassette 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.
4. Hold the specimen collection tube upright and unscrew the tip of the specimen collection tube. Invert the specimen collection tube and transfer 2

full drops of the extracted specimen (approximately 80 L) 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 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 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.



INTERPRETATION OF RESULTS

(Please refer to the illustration)
Negative: One red line appears in the control line region (C). No line appears in the test line region (T).
Positive: Two distinct red lines appear. One red line should be in the control line region (C) and another apparent red line should be in the test line region (T).
***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of rotavirus antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.
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.

PERFORMANCE

The performance of the Rotavirus Antigen Rapid Test Cassette has been evaluated with 361 clinical specimens collected from children and young adults in comparison with latex agglutination method. The results show that the relative sensitivity of the Rotavirus Antigen Rapid Test Cassette (Colloidal Gold) is >99.9% and the relative specificity is 98.8%.

Rotavirus Rapid Test Cassette vs. Latex Agglutination

Method		Latex Agglutination		Total Results
Rotavirus Rapid Test Cassette	Results	Positive	Negative	
	Positive	191	2	193
	Negative	0	168	168
Total Results		191	170	361

Relative Sensitivity: >99.9% (98.4%-100.0%)*
Relative Specificity: 98.8% (95.8%-99.9%)*
Relative Accuracy: 99.4% (98.0%-99.9%)*
*95% Confidence Intervals

Intra-Assay

Within-run precision has been determined by using 15 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. The specimens were correctly identified >99% of the time.

QUALITY CONTROL

An internal procedural control is included in the test. A red line appearing in the control line region (C) is an internal positive procedural control. It confirms adequate membrane wicking.
Control standards are not supplied with this kit; however, 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 ASSAY

1. The Rotavirus Antigen Rapid Test Cassette (Colloidal Gold) is for *in vitro* diagnostic use only. The test should be used for the detection of human rotavirus in feces specimens only. Neither the quantitative value nor the rate of increase in human rotavirus concentration can be determined by this qualitative test.
2. The Rotavirus Antigen Rapid Test Cassette (Colloidal Gold) will only indicate the presence of rotavirus in the specimen and should not be used as the sole criteria for the conforming rotavirus to be etiological agent for diarrhea.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. 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 infection with low concentration of virus particles.

Code: GKPD024-1 Effective date: May 28, 2024

Index of Symbols

IVD	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
2℃ 30℃	Temperature scope within which the product is reserved	LOT	Batch number
REF	Catalog #	Σ	Tests / box
EU REP	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

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