Rotavirus & Adenovirus Antigen Rapid Test Cassette (Colloidal Gold)

Cassette

Package Insert

A lateral flow immunochromatographic assay for the qualitative detection of Rotavirus antigen (Rota Ag) and Adenovirus antigen (Adeno 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 & Adenovirus Antigen Rapid Test Cassette (Colloidal Gold)* is a lateral flow immunochromatographic assay for the qualitative detection of Rotavirus antigen (Rota Ag) and Adenovirus antigen (Adeno 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 and Adenovirus.The test is recommended for professional use only.All results must be interpreted together with other clinical information available to the physician.

SUMMARY

Rotavirus and Adenovirus have been identified in almost 50% of the feces of children with gastroenteritis.Adenovirus and Rotavirus infections occur frequently during the winter months. Gastroenteritis from enteric viruses can be mortal in risk populations such as children, the elderly or immunosuppressed individuals.Characteristic symptoms include vomiting, hydrodiarrhoea for between 3 and 8 days, high temperature and stomach pains.Adenovirus and Rotavirus transferred via the fecal-oral route are eliminated in large quantities into the intestine, so that hospital-borne infections from Adenoviruses and/or rotaviruses are regarded very seriously, particularly in baby stations and paediatric clinics, and are difficult to control. Early and reliable detection so that Rotavirus and Adenoviruses can be recognized and further infections avoided is therefore very important.
The Rotavirus & Adenovirus Antigen Rapid Test Cassette (Colloidal Gold) is an immunochromatographic assay that detects the presence of rotavirus and adenovirus antigen in stool specimens. The test is simple and easy to perform and the test results can be visually interpreted within 10-15 minutes.

PRINCIPLE

The Rotavirus & Adenovirus Antigen Rapid Test Cassette has been designed to detect rotavirus and adenovirus through visual interpretation of color development in the internal strip. The membrane was immobilized with anti-rotavirus(or anti-adenovirus) antibodies on the test region. During the test, the specimen is allowed to react with colored anti-rotavirus(or anti-adenovirus) antibodies colloidal gold conjugates, which were precoated on the golden 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(or adenovirus) 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 package of desiccant.
Extraction diluents
Instruction for use

MATERIALS REQUIRED BUT NOT PROVIDED

Clock or Timer
A clean container for holding stool specimen

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

Stool samples must be taken as soon as the symptoms appear.Viral particles decrease in number after one week, making the diagnosis more difficult. The samples should be collected in containers that do not contain media; preservatives, animal serum or detergents as any of these additives may interfere with the Adeno Ag and Rota Ag Test. Specimens may be stored at 2-8℃ for 1-2 days. 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.

ASSAY PROCEDURES

Test device, patient's specimens, and controls should be brought to room temperature (10-30℃) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the test device from its protective pouch. Label the device with patient or control number.
2. Remove sample probe from preparation device and coat liberally with fecal sample.Replace probe in vial and shake to disperse solid material.

For liquid or semi-solid stools,100μL of stool may be added using an appropriate pipette.

3. Allow the mixture to stand for 1-2 minutes.
4. Snap top from preparation device and invert. Add 3-4 drops to the sample well of the test cassette.
5. Start the timer. Result can be read in 10-15 minutes. **Don't read result after 20 minutes.**

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 (or adenovirus) 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

Rotavirus:
To have clinical study on the sensitivity and specificity of Rota Ag rapid test relative to a leading commercial rapid test, 361 samples from patients were studied. The results are shown in below table 1.
Table 1:

Relative Evaluation Result		Commercial Rota Ag rapid test		Total Results
		Positive	Negative	
Rota Ag Rapid Test	Positive	191	2	193
	Negative	0	168	168
Total Results		191	170	361

The study demonstrated below results for Rota Ag Rapid Test:
Sensitivity = 191/191×100% =100%
Specificity = 168/(2+168)×100% =98.8%
Accuracy=(191+168)/(191+2+168)×100% =99.4%

Adenovirus:
To have clinical study on the sensitivity and specificity of Adeno Ag rapid test relative to a leading commercial rapid test, 520 samples from patients were studied. The results are shown in below table 2.
Table 2:

Relative Evaluation Result		Commercial Adeno Ag rapid test		Total Results
		Positive	Negative	
Adeno Ag Rapid Test	Positive	65	5	70
	Negative	3	447	450
Total Results		68	452	520

The study demonstrated below results for Adeno Ag Rapid Test:
Sensitivity = 65/(65+3)×100% =95.6%
Specificity = 447/(5+447)×100%=98.9%
Accuracy=(65+447)/(65+3+8+452)×100%=98.5%

PRECISION

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 & Adenovirus Antigen Rapid Test Cassette (Feces) 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.
2. The Rotavirus & Adenovirus Antigen Rapid Test Cassette (Feces) 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 or adenovirus 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 or adenovirus infection with low concentration of virus particles.

Code:GKPD041-1 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		

Manufacturer:
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