Rotavirus and Adenovirus Combo Rapid Test Cassette (Feces)

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INTENDED USE

The Rotavirus and Adenovirus Combo Rapid Test Cassette (Feces) is a rapid visual immunoassay for the qualitative presumptive detection of rotavirus and adenovirus in human fecal specimens. This kit is intended to be used as an aid in the diagnosis of rotavirus and adenovirus infection.

INTRODUCTION

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. Rotavirus is transmitted by oro-faecal route with an incubation period of 1-3 days Although specimen collections taken within the second and fifth day of the illness are ideal for antigen detection, 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. . Acute diarrheal disease in young children is a major cause of morbidity worldwide and is a leading cause of mortality in developing countries. Research has shown that enteric adenoviruses, primarily Ad40 and Ad41, are a leading cause o diarrhea in many of these children, second only to the rotaviruses. These viral pathogens have been isolated throughoutf the world, and can cause diarrhea in children year round. Infections are most frequently seen in children less than two years of age, but have been found in patients of all ages. Further studies indicate that adenoviruses are associated with 4-15%of all hospitalized cases of viral gastroenteritis.

Rapid and accurate diagnosis of gastroenteritis due to adenovirus is helpful in establishing the etiology of gastroenteritis and related patient management. Other diagnostic techniques such as electron microscopy (EM) and nucleic acid hybridization are expensive and labor-intensive. With the self-limiting nature of adenovirus infection, such expensive and labor-intensive tests may not be necessary.

PRINCIPLE

The Rotavirus and Adenovirus Combo Rapid Test Cassette (Feces) 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 antibodies and anti-adenovirus on the test region. During the test, the specimen is allowed to react with colored anti rotavirus antibodies latex particle conjugates and anti-adenovirus antibodies latex particle 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 format the R region o themembrane. Similarily, If there were enough adenovirus in specimens, a colored band will form at the A region of thef membrane. Presence of colored band(s) 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 o specimen has been added andmembrane wicking has occurred. f

MATERIALS PROVIDED

20 Sealed pouches each containing a test cassette and a desiccant 20
Specimen collection tubes with extraction buffer, 2.0 mL
1 Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer 2. Specimen collection containers

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

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

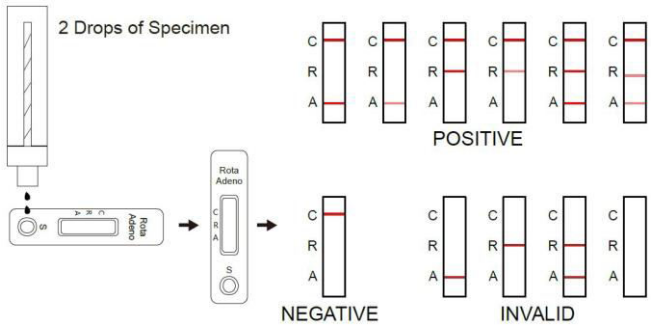
- The Rotavirus and Adenovirus Combo Rapid Test Cassette (Feces) is intended only for use with human fecal
- specimens. Viral detection is improved by collecting the specimens at the onset of the symptoms. It has been reported that the maximum excretion of rotavirus in the feces of patients with gastroenteritis 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.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 72 hours.
- Bring specimens to room temperature prior to testing.
- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.

PROCEDURE

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

1. Specimen collection and pre-treatment:
   1) Best results will be obtained if the assay is performed within 6 hours after collection.
   2) **For solid specimens:** Unscrew and remove the dilution tube applicator. Be careful not to spill or spatter solution from the tube. Collect specimens by inserting the applicator stick into at least 3 different sites of the feces to collect approximately 50 mg of feces (equivalent to 1/4 of a pea).
      For liquid specimens: Hold the pipette vertically, aspirate fecal specimens, and then transfer 2 drops (approximately 50 µL) into the specimen collection tube containing the extraction buffer.
   3) Place the applicator back into the tube and screw the cap tightly. Be careful not to break the tip of the dilution tube.
   4) Shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Specimens prepared in the specimen collection tube may be stored for 6 months at -20°C if not tested within 1 hour after preparation.
2. Testing
   1) Remove the test from its sealed pouch, and place it on a clean, level surface. Label the test with patient or control identification. To obtain a best result, the assay should be performed within one hour.
   2) Using a piece of tissue paper, break the tip of the dilution tube. Hold the tube vertically and dispense 2 drops of solution into the specimen well (S) of the test device.
      Avoid trapping air bubbles in the specimen well (S), and do not drop any solution in observation window.
      As the test begins to work, you will see color move across the membrane.
3. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 15 minutes.

Note: If the specimen does not migrate (presence of particles), centrifuge the extracted specimens contained in the extraction buffer vial. Collect 80 µL of supernatant, dispense into the specimen well (S) of a new test device and start afresh following the instructions mentioned above.



INTERPRETATION OF RESULTS

POSITIVE:
Rotavirus Positive: One colored band appears in the control line region (C) and another colored band appears in the R line region.
Adenovirus Positive: One colored band appears in the control line region (C) and another colored band appears in the A line region.
Rotavirus and Adenovirus Positive: One colored band appears in the control line region (C) and two other colored bands appear in R line region and A line region respectively.
NEGATIVE: One colored band appears in the control line region (C). No band appears in the test line region (A and R).
INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.
NOTE:

1. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control line region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

- External controls are not supplied with this kit. 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 TEST

1. The Rotavirus and Adenovirus Combo Rapid Test Cassette (Feces) is for professional *in vitro* diagnostic use, and should be used for the qualitative detection of rotavirus and adenovirus only.
2. 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.
3. 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 or adenovirus infection with low concentration of virus particles.

PERFORMANCE CHARACTERISTICS

Table: Rotavirus Rapid Test vs. Latex Agglutination

			Rotavirus Rapid Test		Total
Relative Sensitivity: 99.1% (96.8%-99.9%)*			+	-	
Relative Specificity: >99.9% (97.7%-100.0%)*	Latex Agglutination	+	224	2	226
Overall Agreement: 99.5% (98.1%-99.9%)*		-	0	156	156
***95% Confidence Interval**	Total		224	158	382

Table: Adenovirus Rapid Test vs. Latex Agglutination

			Adenovirus Rapid Test		Total
Relative Sensitivity: >99.9% (95.6%-99.9%)*			+	-	
Relative Specificity: 99.4% (96.5%-99.9%)*	Latex Agglutination	+	82	0	82
Overall Agreement: 99.6% (97.7%-99.9%)*		-	1	156	157
***95% Confidence Interval**	Total		83	156	239

Specificity:

Cross reactivity with following organisms has been studied at 1.0 x 10^9 organisms/ml. The following organisms were found negative when tested with the Rotavirus and Adenovirus Combo Rapid Test Cassette (Feces).

Staphylococcus aureus	***Proteus mirabilis***	***Neisseria gonorrhea***
Pseudomonas aeruginosa	***Acinetobacter spp***	***Group B Streptococcus***
Enterococcus faecalis	***Salmonella choleraesius***	***Proteus vulgaris***
Group C Streptococcus	***Gardnerella vaginalis***	***Enterococcus faecium***
Klebsiella pneumoniae	***Acinetobacter calcoaceticus***	***Hemophilus influenzae***
Branhamella catarrhalis	***E.coli***	***Neisseria meningitidis***
Candida albicans	***Chlamydia trachomatis***	

LITERATURE REFERENCES

1. Wadell, G. Laboratory Diagnosis of Infectious Diseases: Principles and Practices. New York: Springer-Verlag, Volume II, 1988: 284-300.
2. WILHELMI I, ROMAN E, SANCHEZ-FAUQUIER A. Viruses causing gastroenteritis. Clin Microbiol Infect. April. 2003, vol.9:247-262.
3. Cubitt, WD (1982) Rotavirus Infection: An Unexpected Hazard in Units Caring for the Elderly. Geriatric Medicine Today 1: 33-38.
4. Wood, D. J., K. Bijlsma, J. C. de Jong, and C. Tonkin. "Evaluation of a Commercial Monoclonal Antibody-Based Enzyme Immunoassay for Detection of Adenovirus Types 40 and 41 in Stool Specimens." Journal of Clinical Microbiology, June 1989; 27(6): 1155-1158.
5. Thomas, Eva. E., D. Roscoe, L. Book, B. Bone, L. Browne, and V. Mah. "The Utility of Latex Agglutination Assays in the Diagnosis of Pediatric Viral Gastroenteritis." Am. J. Clin. Pathol. 1994; 101:742-746.

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
30°C 2°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

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