Adenovirus Rapid Test Cassette (Feces)
Package Insert

REF IAD-602 | **English**

A rapid, one step test for the qualitative detection of Adenovirus in human feces.
For professional in vitro diagnostic use only.

INTENDED USE

The Adenovirus Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the qualitative detection of Adenovirus in human feces specimens to aid in the diagnosis of adenovirus infection.

SUMMARY

Acute diarrheal disease in young children is a major cause of morbidity worldwide and is a leading cause of mortality in developing countries.[1] Research has shown that enteric adenoviruses, primarily Ad40 and Ad41, are a leading cause of diarrhea in many of these children, second only to the rotaviruses.[2,3,4,5] These viral pathogens have been isolated throughout 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.[1,2,3,4,5]

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.

The Adenovirus Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the qualitative detection of adenovirus in human feces specimen, providing results in 10 minutes. The test utilizes antibody specific for adenovirus to selectively detect adenovirus from human feces specimens.

PRINCIPLE

The Adenovirus Rapid Test Cassette (Feces) is a qualitative, lateral flow immunoassay for the detection of adenovirus in human feces specimens. In this test, the membrane is pre-coated with anti-adenovirus antibody on the test line region of the test. During testing, the specimen reacts with the particle coated with anti-adenovirus antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-adenovirus antibody on the membrane and generate a colored line in the test line region. The presence of this colored line in the test region indicates a positive result, while its 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.

REAGENTS

The test contains anti-adenovirus antibody coated particles and anti-adenovirus antibody coated on the membrane.

PRECAUTIONS

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

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch containing desiccant until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

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 adenovirus 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.
2. The feces specimen must be collected in a clean, dry, waterproof container containing no detergents, preservatives or transport media.
3. Bring the necessary reagents to room temperature before use.

MATERIALS

Materials Provided

- Test cassettes
- Specimen collection tubes with extraction buffer
- Package insert
- Droppers

Materials Required But Not Provided

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

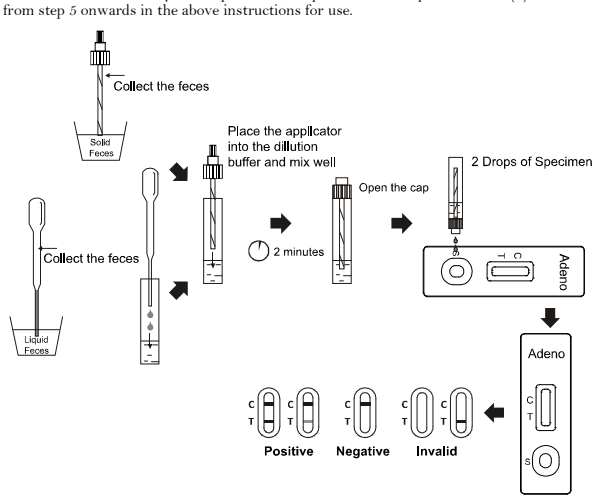
DIRECTIONS FOR USE

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 (1-2mL or 1-2g) 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 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.
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 tip** of the specimen collection tube. 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 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 above)

POSITIVE:* Two distinct colored lines appear. One colored line should be in the control line region (C) and another apparent colored 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 Adenovirus 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 apparent line appears in the test line region (T).

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.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

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

1. The Adenovirus Rapid Test Cassette (Feces) is for *in vitro* diagnostic use only. The test should be used for the detection of Adenovirus in human feces specimens only. Neither the quantitative value nor the rate of increase in adenovirus concentration can be determined by this qualitative test.
2. The Adenovirus Rapid Test Cassette (Feces) will only indicate the presence of adenovirus in the specimen and should not be used as the sole criteria for the conforming 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 adenovirus infection with low concentration of virus particles.

EXPECTED VALUES

The Adenovirus Rapid Test Cassette (Feces) has been compared with latex agglutination method, demonstrating an overall accuracy of 96.8%.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The performance of the Adenovirus Rapid Test Cassette has been evaluated with 381 clinical specimens collected from children and young adults in comparison with latex agglutination method. The results show that the relative sensitivity of the Adenovirus Rapid Test Cassette (Feces) is 95.2% and the relative specificity is 97.7%.

Adenovirus Rapid Test Cassette vs. Latex Agglutination

Method		Latex Agglutination		Total Results
Adenovirus Rapid Test Cassette	Results	Positive	Negative	
	Positive	118	6	124
	Negative	6	251	257
Total Results		124	257	381

Relative Sensitivity: 95.2% (95%CI:*89.8%-98.2%)
Relative Specificity: 97.7% (95%CI:*95.0%-99.1%)
Overall Accuracy: 96.8% (95%CI:*94.6%-98.4%) *Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 10 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 10 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.

Cross-Reactivity

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

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

Interfering Substances

The following potentially Interfering Substances were added to Adenovirus negative and positive specimens.

Ascoribic acid: 20mg/dl	Oxalic acid: 60mg/dl	Bilirubin: 100mg/dl
Uric acid: 60mg/dl	Aspirin: 20mg/dl	Urea: 2000mg/dl
Glucose: 2000mg/dl	Caffeine: 40mg/dl	Albumin: 2000mg/dl

BIBLIOGRAPHY

1. Wadell, G. Laboratory Diagnosis of Infectious Diseases: Principles and Practices. New York: Springer-Verlag, Volume II, 1988: 284-300.
2. Wood, D. J. and A. S. Bailey. Detection of Adenovirus Types 40 and 41 in Stool Specimens by Immune Electron Microscopy. Journal of Medical Virology, 1987; 21: 191-199.
3. Nishio, Osamu, M. Ooseto, K. Takagi, Y. Yamasita, Y. Ishihara, and S. Isomura. Enzyme-Linked Immunosorbent Assay Employing Monoclonal Antibodies for Direct Identification of Enteric Adenoviruses (Ad40, 41) in Feces. Microbiol. Immunol. 1990; 34(10): 871-877.
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

	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		Consult Instructions for Use

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