ADEN-F23

Adenovirus
Rapid Test Device (Feces)

INTENDED USE

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

INTRODUCTION

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 of diarrhea in many of these children, second only to the rotaviruses. 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.
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 Adenovirus Rapid Test Device (Feces) has been designed to detect adenovirus through visual interpretation of color development in the internal strip. The membrane was immobilized with anti-adenovirus monoclonal antibody on the test region. During the test, the specimen is allowed to react with colored anti-adenovirus monoclonal antibody 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 adenovirus in specimens, a colored band will form at the test region of the membrane. Presence of this 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

Materials Provided

- Individually packed test devices
- Specimens dilution tube with buffer
- Package insert
- Disposable pipettes

Materials Required but Not provided

- Centrifuge
- Specimens collection container
- Timer

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.
- Buffered Saline contains sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of buffered saline or extracted samples, always flush with copious quantities of water to prevent azide build up.
- 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 Adenovirus Rapid Test Device (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 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.
- 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) Use the specimens collection container provided in the kit for specimens collection. Follow the operation procedure written on it for instructions. Other clean dry containers could also be used for the same purpose. 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 20 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: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read 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. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or 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 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 Adenovirus Rapid Test Device (Feces) is for professional *in vitro* diagnostic use, and should be used for the qualitative detection of 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 adenovirus infection with low concentration of virus particles.

PERFORMACE CHARACTERISTICS

Table 1: Adenovirus Rapid Test vs. ELISA

Relative Sensitivity: >98.8%
Relative Specificity: >99.9%
Overall Agreement: >99.5%

		Adenovirus Rapid Test		
		+	-	Total
ELISA	+	82	1	83
	-	0	127	127
		82	128	210

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 Adenovirus Rapid Test Device (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	

LITERATURE REFERENCES

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.

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer		Contains sufficient for <n> tests
	Do not reuse	EC REP	Authorized representative in the European Community
CE	CE marking according to IVD Medical Devices Directive 98/79/EC		