Adenovirus Rapid Test (Cassette)

Cat. No.:DTS551
Pkg.Size:

Intended use

The Adenovirus Test Device is a rapid chromatographic immunoassayfor the qualitative detection of adenovirusin human feces specimen,providing results in 10 minutes. The test utilizes antibody specific for Adenovirus to selectively detect Adenovirus from human feces specimens.

General Description

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 diarrhoea in many of these children, second only to Rotavirus. The viral pathogens have been isolated throughout the world, and can cause diarrhoea in children year round. Infections are most frequently seen in children less than two years of age,but have also 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 Of The Test

The Adenovirus Rapid Test(Cassette) is a qualitative, lateral flow immunoassay for the detection of Adenovirus in human feces specimen. In this assay Adenovirus is detected with the aid of specific antibodies against Adenovirus. After the addition of the sample(feces diluted in buffer) a color-labelled antibody specifically binds to the virus if it is presentin the sample. When this complex migrates upward on the membrane by capillary action,it is captured with the aid of another specific antibody at the test result line region of the test. A red test result line is generated. If no virusis present the color labelled antibody can not bind at the test result line region. No red test result line is formed. So the presence of a colored test result line 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 And Materials Provided

1. Individually pouched test cassettes
2. Specimen collection tubes with dilution buffer for sample collection and dilution
3. Disposable pipettes for sample collection of extremely liquid specimen
4. Package insert

Materials Required But Not Supplied

1. Absorbent tissue paper to prevent solution from splashing.
2. stool specimen collection units
3. Timer

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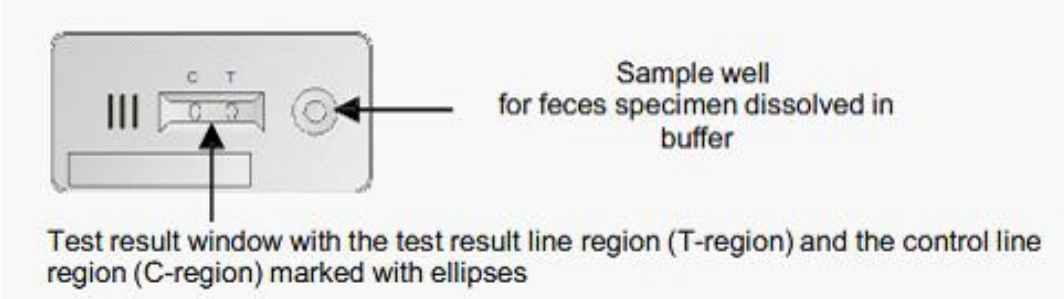
When to Start Testing

SET-UP OF THE TEST DEVICE



Storage

Store kit as packaged either at room temperature or refrigerated (2-30°C). Under these conditions the test and the buffer is stable through the expiration date.

Specimen Collection And Preparation

Conditions for optimal sample collection

1. The Adenovirus test device is intended only for use with human fecal specimen that has been diluted in the provided buffer.
2. 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.

For collecting the stool sample the patient is given one of the specimen collection tubes of the kit and a disposable pipette. Please advice the patient to collect the stool sample in the following way:

3. Any clean and dry container/ water repellent paper might be used for sample collection. Please ensure that the stool sample has no direct contact with the water of the toilet bowl to avoid a dilution or a contamination with detergents. An amount of 1-2 ml or 1-2 g stool is sufficient.
4. Transfer a small amount of the stool into the specimen collection tube:

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).

For Liquid Specimens: If the stool is too liquid to stick to the applicator please use the provided disposable pipette. Hold the pipette vertical y, aspirate some stool, and then transfer 2 drops (approximately 50 ul) into the specimen collection tube containing the dilution buffer.

5. Place the applicator back into the tube and screw the cap tightly. Shake the specimen collection tube to mix the specimen and the dilution buffer. Be careful not to break the tip of the collection tube.
6. Wrap the sample in a plastic bag and store it in a cool place. Return the sample to the doctor’s office within the next 24 hours.

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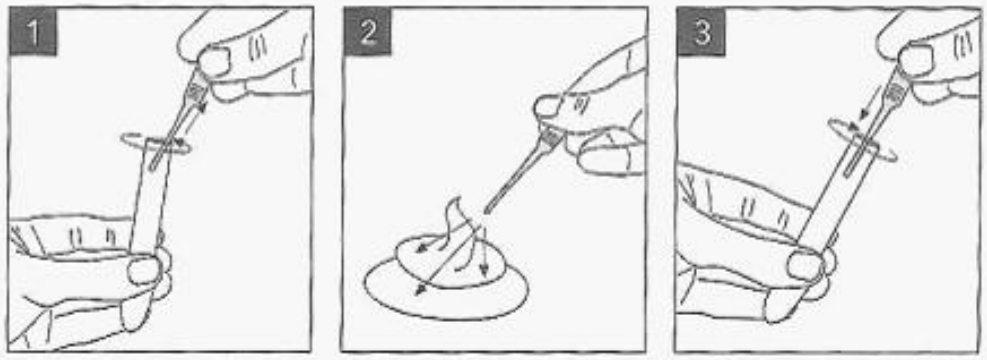
Please ensure that patients will pay attention to the following instructions for the collection of the stool samples.



Specimen Stability

The test must remain in the sealed pouch containing a desiccant until use. DO NOT FREEZE. Do not use beyond the expiration date.

Assay Procedure

1. Allow the test device and the diluted stool sample to reach room temperature (15-30°C) prior to testing.
2. Remove the test device from its pouch when ready to perform the test. The device must have room temperature to avoid condensation of moisture on the membrane. Label the device on the provided space with patient or control identification.
3. Shake the collection tube thoroughly to ensure proper mixing of the fecal sample with the extraction solution.
4. Using a piece of tissue paper, break the tip of the collection tube with a twisting motion. Hold the collection tube verticaly and dispense 2-3 drops of solution into the round sample well of the test device by applying a gentle pressure to the walls of the tube. Avoid air bubbles in the sample well or splashes of liquid into the oval result window.
5. Start the timer. As the test begins to work, you wil see a reddish coloured liquid front moving across the membrane.
6. Wait for the coloured lines to appear. The result should be read after 10 minutes. Strong positive results may be observed sooner. Do not interpret the result after 20 minutes.

Quality Control

An internal procedural control is included in the test. A coloured 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 are tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Interpretation of Results

For the interpretation of the test result the line(s) that has(ve) appeared in the test result window are visually interpreted.
Only one colored line appears in the control line region (C). No line appears in the test line region (T). The absence of the test result line (T) indicates that no Adenovirus has been detected by the assay.
Two distinct colored lines appear on the membrane. One colored line forms in the control line region (C) and another apparent colored line appears in the test result line region(T).
INVALID: The control line (C) fails to appear. Results from anytest that has not produced a control line at the specified reading

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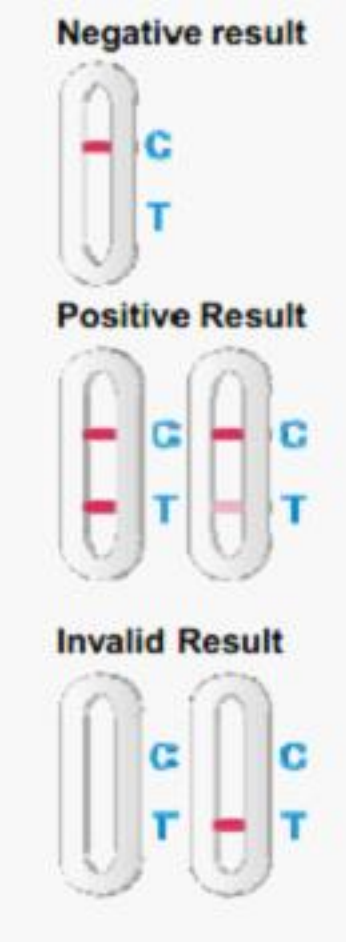
time should be discarded. Insufficient specimen volume, insufficient specimen migration, or incorrect procedural techniques are the most likely reasons for control line failure.



Sensitivity

Relative Sensitivity: 99.9%(95.6%- 99.9%)

Specificity

Relative Specificity: 99.4%(96.5%- 99.9%)

Cross-Reactivity

Cross reactivity with following organisms has been studied at 1.0 x 109 organisms/ml. The following organisms were found negative when tested
with the Adenovirus Test Device.
Acinetobacter calcoaceticus; Enterococcus faecium; Neisseria meningitides; Acinetobacter spp; Gardnerela vaginalis; Proteus mirabilis; Branhamella catarrhalis; Group B Streptococcus; Proteus vulgaris; Candida albicans; Group C Streptococcus; Pseudomonas aeruginosa; Chlamydia trachomatis; Hemophilus influenzae; Salmonela choleraesius; E.coli; Klebsiela pneumoniae; Staphylococcus aureus; Enterococcus faecalis; Neisseria gonorrhea

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Precautions

1. Please follow the instructions for use carefully. Please inform your patients how to collect and dilute the stool sample.
2. For single use. Do not reuse tests
3. Do not interchange or mix reagents from different lots.
4. Do not use test if its foil pouch has been damaged. Do not use after expiration date.
5. Handle all specimens as if they contain infectious agents. Do not eat, drink or smoke in the area where the specimens or kits are handled. Protective clothing such as laboratory coats, disposable gloves and eye protection are recommended. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens in accordance with local regulations.
6. The dilution buffer contains low amounts of sodium azide.
7. Humidity and temperature can adversely affect results.
8. The components of the test (e.g. antibodies/chemicals) do not cause any danger if the test is used according to the instructions.

Limitations

1. The Adenovirus Rapid Test Device (Feces) 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 result 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.

REFERENCES

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