TOYO DIAGNOSTICS

INSTRUCTIONS FOR USE

ONE STEP TEST
Adenovirus Antigen
Detection in Feces

Only for professional *in vitro* diagnostic use

Product Code: TADV01
Adenovirus Test Device detects Adenovirus antigens in human feces.

INTENDED USE

Adenovirus Test Device is a rapid chromatographic immunoassay for the qualitative detection of Adenovirus antigens in human feces samples.

BACKGROUND INFORMATION

Adenoviruses are common pathogens that are often associated with respiratory and gastrointestinal illness and/or conjunctivitis in young persons.
In the world, acute diarrheal diseases in young children are major causes for morbidity and the most important causes for mortality in developing countries. After Rotavirus infections, especially Ad40 and Ad41 are enteric Adenoviruses causing diarrhea in many of the children according to research results. These viruses have been isolated all over the world and can cause diarrhea in every term of the year. Infections frequently affect the children less than two years of age, but there are patients of all ages. Further research show that Adenoviruses are associated with 4 - 15 % of all hospitalized cases of viral gastroenteritis. Rapid and accurate diagnosis of gastroenteritis due to Adenovirus infections 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, such expensive and labor intensive tests may not be necessary.

REAGENTS

The test contains coated particles with anti-adenovirus antibodies and anti-adenovirus antibodies immobilized on the membrane.

METHOD

Adenovirus Test Device is a rapid, qualitative, immunochromatgraphic assay for the detection of adenovirus in human feces samples. Immobilized anti-adenovirus antibodies on the “T” test area of this test. While performing the test; sample dropped to the sample well reacts with the particles coated with anti-adenovirus antibodies. This complex migrates to the other end of the membrane by capillary action.
If there is Adenovirus antigen in the sample, they bind to anti-adenovirus antibodies in the “T” test area and create a visible, colored signal that means the test result is positive. If the sample does not contain Adenovirus antigen, colored line does not appear in the “T” test area. This means the test result is negative. As a procedural control, colored line always appears in the “C” control area indicating that proper volume of sample has been introduced and membrane wicking has occurred.

PRECAUTIONS AND LIMITATIONS

1. For professional and *in vitro* diagnostic use only.
2. Do not use test kit beyond expiry date. The test device is single use. Do not reuse.
3. The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
4. Wear disposable gloves while performing the test.
5. Use a new dropper for each sample.
6. All patient samples should be handled as taking capable of transmitting disease into consideration. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
7. This test will indicate only the presence or absence of Adenovirus antigen in the sample, and should not be used as the only basis for the diagnosis of Adenovirus infection.
As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.
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.

STORAGE

Test device should be kept away from direct sunlight, moisture, heat and radiation sources.
Store at 4 - 30°C (39 - 86°F). Do not freeze.
The test in the original packaging retains stable until expiry date at storage conditions. The test device should be used in maximum one hour after the foil is opened.

Kit components : Test devices, droppers, sample collection tubes with dilution buffer and instructions for use.

Additional materials required but not provided : Sample collection containers, centrifuge and timer.

Additional materials recommended but not provided : Micropipettes to deliver mentioned amount of sample in the test procedure, negative and positive control materials.

TEST PROCEDURE

Take the test device out of its pouch. Bring the tests, dilution buffer and samples to room temperature.
1. Feces sample :
Feces sample must be collected in clean, dry, waterproof container containing no detergents, preservatives and transport media. Take 1 - 2 ml or 1 - 2 g feces sample to the container to collect sufficient quantity of antigen (if present). Best results will be obtained if the assay is performed within 6 hours after collection. Collected samples may be stored 3 days at 2-8°C if not tested within 6 hours. For long term storage samples should be kept below -20°C.
2. To process fecal samples :
For solid samples ;
Unscrew the cap of the sample collection tube. Stab the sample collection applicator randomly into the fecal sample in at least 3 different sites to collect approximately 50 mg of feces. Screw the applicator to the sample collection tube with the sample on it.
For liquid samples ;
Hold the dropper vertically and draw feces sample into the dropper. Put 2 drops (approximately 50 µl) of sample in the sample collection tube.
3. Screw the cap of the sample collection tube and shake well to mix the sample and the dilution buffer. Wait for two minutes.
4. Hold the sample collection tube upright and break off the tip. Transfer 2 drops of extracted sample (approximately 80 µl) to the sample well of the cassette. Avoid the formation of any air bubbles.
5. Depending on the adenovirus concentration in the sample, the test can react even in 5 minutes. Results should be read at 10 minutes as shown below. Results forming after 20 minutes should be regarded as invalid.

NOTE : If the extracted sample does not migrate in the test because of the particles, centrifuge the extracted sample in the sample collection tube. Then collect 80 µl supernatant and dispense it to the sample well of a new test device and follow the instruction from step 5.

INTERPRETATION OF RESULTS

Negative: Only one colored line is visible in “C” area, indicating that Adenovirus antigen does not exist.
Positive : Two colored lines are visible in “C” and “T” areas, indicating that Adenovirus antigen exists.
Low concentration of Adenovirus antigen may cause a faint line in “T” area. Even such a faint line in “T” area should be regarded as “positive”.
Invalid : No colored line is visible or only one colored line is visible in “T” area; test should be repeated using a new test device.

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QUALITY CONTROL

Tests have built in procedural quality control features. When the test is complete, the user will see a colored line in the “C” area of the test on negative samples and a colored line in the “T” and “C” area on positive samples. The appearance of the control “C” line is considered as an internal procedural control. This line indicates that sufficient volume of sample was added as well as valid test result. It is recommended that a negative control and a positive control be used to verify proper test performance as an external control. Users should follow appropriate federal, state and local guidelines concerning the external quality controls..

PERFORMANCE EVALUATION

Adenovirus Test Device has been evaluated with clinical samples from children and young adults. Latex agglutination method is used as a reference and following results obtained. .

Sensitivity : 99,9 % **Specificity : 99,3 %** **+ Predictive V : 99 %** **- Predictive V : 99,9 %**

Confidence interval : 95 %

		Reference	
		+ Result	- Result
Test	+ Result	99	1
	- Result	0	150

Intra Assay
Within-run precision of the same test has been confirmed with 100 replicates of negative, adenovirus low positive, adenovirus medium positive and adenovirus high positive samples. Negative, adenovirus low positive, adenovirus medium positive and adenovirus high positive values were correctly determined for each trial.

Inter Assay
Between-run presicion of the same test has been confirmed with 20 independent assays with the same negative, adenovirus low positive, adenovirus medium positive and adenovirus high positive samples. Negative, adenovirus low positive, adenovirus medium positive and adenovirus high positive values were correctly determined for each trial.

CROSS REACTIVITY

Cross reactivity has been tested with below samples (1.0×10^9 microorganism/ml), no cross reactivity was found with the Adenovirus Test Device.

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 calcoacetius*	*Hemophilus influenzae*
Branhamella	*E.coli*	*Neisseria meningitidis*
Candida albicans	*Chlamydia trachomatis*	*Rotavirus*

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SYMBOLS USED

Manufacturer
Authorized European Representative
Attention, see instruction for use
Consult instruction for use
In vitro diagnostic medical device
Number of test
For single use only
Storage temperature
Lot number
Catalog number
Expiry date