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# DIAQUICK Adenovirus Cassette

**(en)** English

REF

**Content**

**Z09620CE**
- 5 Tests individually packed in foil pouches (5x REF Z09620B)
- 5 Collection Tubes, filled with 1.5 mL Buffer each
- 1 Package Insert

**For professional in vitro diagnostic use only.**

## INTENDED USE

The DIAQUICK Adenovirus Cassette is an *in vitro* qualitative immunochromatographic assay for the rapid detection of. adenovirus antigens in human stool specimen. The test results are intended to aid in the diagnosis of adenovirus infection and to monitor the effectiveness of therapeutic treatment.

## DIAGNOSTIC SIGNIFICANCE

Rotaviruses and adenoviruses are the main causes of severe infectious diarrhoea, especially in children under 5 years of age.
Rotavirus is the most important universal cause of dehydrating infant and childhood gastroenteritis. Annually, it causes approx. 450,000 deaths of children younger than the age of 5. Infection is universal in the first years of life and may be symptomatic or asymptomatic. Severe illness is most common between 6 months and 2 years of age. As gastroenteritis due to rotavirus is not readily distinguished from that caused by other agents on clinical grounds alone, it is important to perform diagnostic tests to decide on the further course of action in patient treatment.
Adenovirus is, after Rotavirus, the second most common cause of gastroenteritis in young children. The virus also causes febrile illness and respiratory tract infections. Adenoviruses are also ubiquitous, with most humans having serological evidence of prior infection by the age of 10. Most infections are mild and self-limited, however diagnosis is useful for the attending physician to decide on the further patient care, especially in combination with the Rotavirus test results.
Besides aiding in the diagnosis of rota- and adenovirus infections, the test results are also intended to monitor the effectiveness of therapeutic treatment. [1,2]

## TEST PRINCIPLE

The DIAQUICK Adenovirus Cassette is a qualitative, membrane based immunochromatographic lateral flow device for the detection of Adenovirus antigen in human faecal samples. The membrane is pre-coated with monoclonal antibodies against Adenovirus in the test line region. After sample application, the sample reacts with colloidal gold particles coated with anti-Adenovirus antibodies stored in the conjugate pad. The mixture migrates upward on the membrane by capillary action. In case of a positive result the specific antibodies present on the membrane will react with the conjugate mixture and generate visibly coloured lines. To serve as a procedural control, a visibly coloured line will always appear in the control line region, indicating that the proper specimen volume was added and correct membrane wicking has occurred.

## REAGENT COMPOSITION

**Adenovirus Cassette**
Strip, housed in a plastic cassette, with the following components:
- Nitro-cellulose membrane strip with coated antibodies against Adenovirus in the test line region and anti-rabbit IgG in the control line region
- Conjugate pad with anti-Adenovirus antibodies, as well as rabbit IgG conjugated to colloidal gold particles
- sample and absorbant pad

**Adenovirus Buffer**
- Tris buffer, pH 7.6
- BSA

## MATERIAL REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer

## REAGENT PREPARATION

Bring all reagents, including test device, to room temperature before use.

## STORAGE AND STABILITY

- The expiration date is indicated on the package label.
- Store Sample Collection Tubes at 4-30°C.
- Store test device at 4-30°C.

## WARNINGS AND PRECAUTIONS

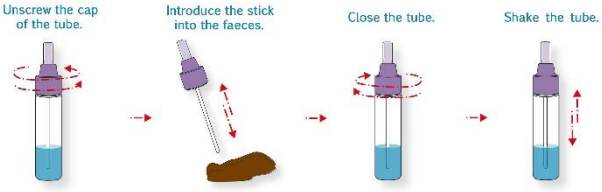
- For in vitro diagnostic use.
- Do not eat, drink or smoke in the area where the specimens or tests are handled.
- Handle all specimens as if they contained infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for the proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not use kit components beyond expiration date.

## SPECIMEN COLLECTION AND STORAGE

**Sample Collection**
- Stool samples must be taken as soon as the symptoms appear.
- Viral particles decrease in number after one week.
- Collect faeces in a clean, dry specimen collection container. Use a separate collection container for each sample. Frozen samples must be totally thawed and brought to room temperature before testing.
- Stool specimens should be collected in containers that do not contain media, preservatives, animal serum or detergents as any of these additives may interfere with the DIAQUICK Adenovirus Cassette.

**Sample Storage**
- Specimens may be stored at 2-8° C for 2 days without interfering with the assay performance.
- For long-term storage of specimens, -20° C or colder is recommended.
- may cause erroneous results.
- Do not store specimens in self-defrosting freezers.

**Sample Preparation**
- Unscrew the sample bottle, use the attached applicator stick attached on the cap to transfer small piece of stool (4-6 mm in diameter; approximately 50 mg-200 mg) into the sample bottle containing specimen preparation buffer.
- For liquid or semi-solid stool samples, add approx.100 µL of stool to the vial with an appropriate pipette.
- Replace the stick in the bottle and tighten securely. Mix stool sample with the buffer thoroughly by shaking the bottle for a few seconds.




## TEST PROCEDURE

1. Bring all materials and specimens to room temperature.
2. Remove the DIAQUICK Adenovirus Cassette from the sealed foil pouch.
3. Vigorously shake the collection tube to assure good sample dispersion.
4. Hold the sample bottle upright with the tip point towards to the direction away from the test performer, snap off the tip.
5. Hold the bottle in a vertical position over the sample well of the test card, deliver 3 drops (120 -150 µL) of diluted stool sample to the sample well.
6. Read the result at **10 minutes**. A strong positive sample may show result earlier. False positive results can appear if the test is read after >10 minutes.

**Note:** if the test does not start to run due to an excess of solid particles in the solution, try to stir the sample in the specimen well (S) with the collection stick.


## INTERPRETATION OF RESULTS

**POSITIVE RESULTS – Two distinct coloured lines appear.**
A red coloured line is visible in the test line region (T) and another one in the control line region (C). This indicates the presence of Adenovirus antigen in the tested sample.

**NEGATIVE RESULTS – Only the control line appears.**
Only the coloured line in the control line region (C) appears. This indicates that no Adenovirus antigen could be detected in the tested sample or are present below the test cut-off.

**INVALID RESULTS – The control line does not appear.**
If the coloured control line does not appear, the result is invalid. Review the package insert and repeat the test with a new device. If the problem persists, discontinue using the test kit and contact your local distributor.

**Note:** The colour intensity of the test lines will vary depending on the antigen concentration of in the sample. However, neither the quantitative value nor the rate of increase in Adenovirus antigen can be determined by this qualitative test.

## QUALITY CONTROL AND CALIBRATION

A procedural control is included in the test. A visible coloured line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and a 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.

## PERFORMANCE CHARACTERISTICS

**Analytical Sensitivity**
Adenovirus type 40 1x $10^5$ $TCID_{50}$/mL
Adenovirus type 41 2x $10^4$ $TCID_{50}$/mL

**Diagnostic Accuracy**
The DIAQUICK Adenovirus Cassette was compared to another commercially available rapid test. The following results were achieved:

| Method | | Other Rapid Test | | Total Results |
|---|---|---|---|---|
| Adenovirus Cassette | Results | Positive | Negative | |
| | Positive | 197 | 6 | 203 |
| | Negative | 7 | 840 | 847 |
| Total Results | | 204 | 846 | 1050 |

Relative Sensitivity: 96.6 % Relative Specificity: 99.3 %
Accuracy: 98.8 %

**Cross Reactivity**
The DIAQUICK Adenovirus Cassette may cross-react with simian and porcine rotavirus antigen.

**Analytical Specificity**
The following organisms were tested and did not show any interference with the with the DIAQUICK Adenovirus Cassette:

| | |
|---|---|
| *Rotavirus Wa* | *Candida albicans* |
| *Campylobacter jejuni* | *Citrobacter freundii* |
| *Clostridium perfringens A* | *Escherichia coli* |
| *Enterococcus faecalis* | *Listeria monocytogenes* |

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| | |
|---|---|
| *Klebsiella pneumonia* | *Neisseria gonorrhoeae* |
| *Moraxella catarrhalis* | *Stapylococcus epidermidis* |
| *Pseudomonas aeruginosa* | *Shigella flexneri* |
| *Stapylococcus aureus* | *Streptococcus dysgalactiael* |
| *Shigella sonnel* | *Streptococcus pyogenes* |
| *Streptococcus agalactiae* | |

## TRACEABILITY

The sample correlation results show that the DIAQUICK Adenovirus Cassette has a high relative sensitivity, relative specificity and overall accuracy compared to reference Adenovirus Rapid Test.

## EXPECTED VALUES

The DIAQUICK Adenovirus Cassette detects the presence of adenovirus antigens in stool specimens. Expected values for any given population should be determined for each laboratory. The positivity rate of any given laboratory may vary depending on geographic location, season, and living environment.

## LIMITATIONS

- The test will only qualitatively indicate the presence of adenovirus antigen in human faecal samples. Neither the quantitative value nor the rate of increase in antigen concentration can be determined by this test.
- This test delivers preliminary results only. All results must be confirmed with alternative clinical tests and information available to the attending physician. A definitive clinical diagnosis should only be made by the physician after all clinical and laboratory finding have been evaluated.
- The test devices are for one-time use only. Use a separate cassette for each sample.

## WASTE MANAGEMENT

Dispose all used materials in appropriate container. Treat as potential biohazard.

## LITERATURE

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3. Al-Yousif YJ et al 2001. Evaluation of a latex agglutination kit (Virogen Rotatest) for detection of bovine rotavirus in fecal samples. Clin. Diagn. Lab. Immunol. 8:496-498
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8. Wood SR et al 1997. Rapid detection and serotyping of adenovirus by direct immunofluorescence. J. Med. Virol. 51: 198-201.

## USED SYMBOLS

| Symbol | Description |
|---|---|
| Cont. | Content |