

Laboquick

ADENOVIRUS ANTIGEN TEST

Adenovirus Antigen Test Instructions

Intended Use

Laboquick Adeno Virus antigen cassette test is used as a diagnostic tool to detect qualitative immunochromatographic Adeno virus antigen in stool.

One step, quick test to determine adeno virus antigen in stool.

Product Code: LBAV.01

Introduction:

Adenoviruses are the main cause of acute gastroenteritis, especially in children under the age of two years. Adenoviruses have been identified in almost 50% of the feces of children with gastroenteritis. Adenovirus infections occur frequently during the winter months. Gastroenteritis from enteric viruses can be mortal in risk populations such as children, the elderly or immunosuppressed individuals. Characteristic symptoms include vomiting, hydrodiarrhoea for between 3 and 8 days, high temperature and stomach pains. Adenoviruses transferred via the fecal-oral route are eliminated in large quantities into the intestine, so that hospital-borne infections from Adenoviruses are regarded very seriously, particularly in baby stations and paediatric clinics, and are difficult to control. Early and reliable detection so that Adenoviruses can be recognized and further infections avoided is therefore very important.

Test Principle:

Adenovirus Rapid Test cassette contains a membrane Strip which employs red gold conjugated monoclonal antibodies against antigen of Adenovirus. Test is based on the immunochromatographic principle. The test device has a sample hole made of the material enabling the reagent to proceed. The membrane that constitutes the test device has been formed ultimately once the Adenovirus antigens are passed through the test band space as well as the monoclonal antibodies specific to Adenovirus passed through the front cover.

Adenovirus antibody takes part in the section of membrane containing the golden resultant. In case the Adenovirus antigens are present in the patient's stool, it dissolves in the solution included in the sampling bottle then proceeds by using the mixture form of chromatographically antigen- antibody-antigen golden particles towards test space (T) in order to form a visible line. Thus, a visible line appearance in the T space confirms the positive result in the detection of Adenovirus antigen. Otherwise, this visible line shall not appear. Unless this visible line is seen in T space, the result is negative. However, there is a color line every time in the control space (C). This control line is a procedural indicator. It confirms that the sufficient sample solution is dropped, the sample expands in the test properly and reagent is under control.

Package content:

Adenovirus Ag test device, sampling device, silica gel bag.

Storage Conditions:



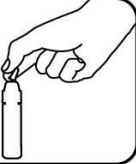

Adenovirus Ag test should be kept under 2 ... 30 C degree. The Test shouldn't be frozen. The product can be stored in stable condition until the date of expiry written on the product package unless it is open.

Warnings and Measures:

The following should be taken into consideration to get the correct results;

- 1-Before use, read the instructions carefully,
- 2-Only for In Vitro Diagnostic Use.
- 3-Never freeze the tests. If the test is stored in the refrigerator, The test should be brought to the room temperature before use. The test should definitely be done under room temperature (between 5.....30 C degree)
- 4-Expired products shouldn't be used.
- 5- The number of drops to be added should be observed carefully. Only 3-4 drops should be added in the test.
- 6-The test device should be used immediately after unpackaged.
- 7-If the package of the test is damaged or torn, the test device shouldn't be used.
- 8- During the test, any cosmetics should not be used; any food or beverage should not be consumed and smoking should be avoided.
- 9-The possibility of any leaping of samples or producing the steam during the test should be avoided.
- 10-It should be remembered that the best results can only be obtained depending on the proper conformance to the instructions.
- 11-Once the test procedure starts, every step should be taken uninterruptedly.

Test Cihazının Kullanımı:

- 1 Unpackage the aluminum bag of test device by tearing as shown. 
- 2 Check the sampling part.
- 3 Shake the sampling bottle thoroughly. 
- 4 Be sure that the sampling bottle is at the vertical direction in the manner that the top part is correctly positioned, then break off the plastic cover carefully. 
- 5 Put 3-4 drops from the sample solution into the dropping hole as shown in the picture. 
- 6 Read out the test results after 5-10 minutes. Do not take the results into consideration after 15 minutes.

Results Evaluation:



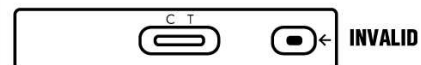
NEGATIVE

The indication line taking part at the section marked with "C" in the result display confirms the NEGATIVE result.



POSITIVE

Two indication lines taking part at the sections both marked with "C" and "T" confirms the POSITIVE result.



INVALID

If any line is not appeared in the result display until the end of the testing time, the test is invalid. The test should be repeated.

Sample taking:

Put the sample of stool into the sampling device in the package of the test. Loosen the top part of sampling device and take the test stick out and take the samples from three different parts of the stool. Then place the stick into the sampling bottle and fasten strictly. If the sample is not analyzed instantly, keep it under 4 C degree. At the time of the test to be done, the sample should be brought to the room temperature.

Sensitivity: 98.5%

Specificity: 99%

Test Limits:

1-Only Laboquick Adenovirus Ag test cannot be used to diagnose the disease. This test can only be used to detect the presence of Adenovirus antigen in the sample. The test results should definitely be supported by the supplement diagnosis and diagnostic methods with the expert comments.

2- In case the defects continue even if the test results are found negative, other various tests should be done by using the other clinical methods. Any result seen as negative does not remove the risk and possibility of Adenovirus antigen infection. The sole using purpose of the

3- Test device gives the best result under room temperature
4-.The most productive completion of the test is depending on full conformance to the instructions. Otherwise the results may lead to faults.

5- More than 4-5 drops is applied on the sample hole of the test device can lead to faulty results.

Resources:

1. Set-up of a new rapid immunochromatographic diagnostic test for a Adenovirus detection. D. Van Beers , M. DE Foor , R. Viehoff , D. Col , M.Venuti and T. Leclipteux.Progress in Clinical Virology III , Bologne , Septembre 1997.
2. Detection of adenovirus in faecal specimens with a monoclonal antibody enzyme-linked immunosorbent assay : comparison with polyclonal antibody enzyme-immunoassays and a latex agglutination test. Sneyers et al.Comp. Immun. Microbiol. Infect. Dis. , vol 12 , n°4 , pp 95-104 , 1989
3. Comparison of Three Rapid Immunoassays for the Detection of Adenovirus Antigen in Stool Samples I. Van der Donck et al. ESCV Winter Meeting 1999, Rotterdam, the Netherlands.
- 4.American Academy of Pediatrics. Adenovirus Infections. In: Peter G, ed. 1997 Red Book: Report of the Committee on Infectious Diseases. 24th ed. Elk Grove Village, IL: American Academy of Pediatrics; 1997: 131.
5. Horwitz MS. Adenoviruses. In: Fields BN, Knipe DM, Howley PM, eds. Fields Virology. 3rd ed. Philadelphia: Lippincott-Raven; 1995: 2149-71.
6. Foy HM. Adenoviruses. In: Evans A, Kaslow R, eds. Viral Infections in Humans: epidemiology and control. 4th ed. New York: Plenum; 1997:119-38

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