Laboquick ROTA VIRUS ANTIGEN TEST

Rota Virus Antigen Test Instructions

Intended Use

Laboquick Rota Virus antigen cassette test is used as a diagnostic tool to detect qualitative immunochromatographic Rota virus antigen in stool.
One step, quick test to determine Rotavirus antigen in stool.
Product Code: LBRV.01

Introduction:

Rotaviruses are the main cause of acute gastroenteritis, especially in children under the age of two years. Rotaviruses have been identified in almost 50% of the feces of children with gastroenteritis. Rotavirus 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. Rotaviruses transferred via the fecal-oral route are eliminated in large quantities into the intestine, so that hospital-borne infections from rotaviruses are regarded very seriously, particularly in baby stations and paediatric clinics, and are difficult to control. Early and reliable detection so that rotaviruses can be recognized and further infections avoided is therefore very important.

Test Principle:

Rotavirus Rapid Test cassette contains a membrane Strip which employs red gold conjugated monoclonal antibodies against antigen VP6 of group A of rotavirus, and solid-phase specific rotavirus antibodies. 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 rotavirus antigens are passed through the test band space as well as the monoclonal antibodies specific to rotavirus passed through the front cover.
Rotavirus antibody takes part in the section of membrane contenting the golden resultant. In case the rotavirus 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 Rotavirus 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:

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

Storage Conditions:

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

Warnings and Measures:

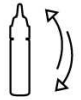
The following should be taken into consideration to get the correct results;
1-Before use, read the instructions carefully,
2-Only for In Vitro Diagnostic Use.
3-Never freeze the tests. If the test is stored in the refrigerator, The test should brought to the room temperature before use.The test should 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.

Instructions:

1. Unpackage the aluminum bag of test device by tearing as shown.

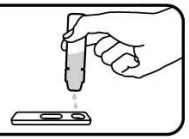
2. Check the sampling part.

3. Shake the sampling bottle throughly.



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 results display comfirms the NEGATIVE result.

7.

POSITIVE

Two indication lines taking part at the sections both marked with "C" and "T" comfirms 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: 98.4%

Specificity: 98.9%

Test Limits:

1-Only Laboquick Rotavirus Ag test cannot be used to diagnose the disease. This test can only be used to detect the presence of rotavirus 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 rotavirus 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:

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4. Dennehy PH (2000). "Transmission of rotavirus and other enteric pathogens in the home". Pediatr. Infect. Dis. J. 19 (10 Suppl): S103–5
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