RIDA®QUICK Rotavirus

Article no: N0902

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1. Intended use

For *in vitro* diagnostic use. The RIDA®QUICK Rotavirus Test is a quick immunochromatographic test for the qualitative determination of rotaviruses in stool samples.

2. Summary and explanation of the test

Rotaviruses are the most important pathogens in non-bacterial gastroenteritis in children from 6 months to 3 years old. They have also been shown to be the cause of illness in older children and adults. In high-risk groups, i.e. children and old or immune-suppressed patients, they can lead to death. Rotavirus infections occur frequently during the winter months. Endemic diseases and epidemic diseases affecting some thousands of patients have also been described. In the case of hospitalised children with acute enteritis, up to 50 % of the samples examined are rotavirus positive. Rotaviruses transferred via the faecal-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 recognised and further infections avoided is therefore very important.

3. Test principle

This quick test is a single-step, immunochromatographic lateral-flow test where antibodies which are specifically directed against rotaviruses are attached to red latex particles. Other specific antibodies against the pathogen are firmly bound to the membrane. The stool sample is first suspended in the extraction buffer and then precipitated. The test strip is dipped in the clear supernatant of the sample. During this time, the sample containing the coloured latex particles, with the antigens attached if the test is positive, passes through the membrane and is bound to the specific bands.

4. Reagents provided

There are enough reagents in the pack for 25 determinations.

Strip	25 det.	Tube with 25 test strips
Diluent	26 ml	Extraction buffer, ready for use; contains 0.1 % sodium azide
Pipet	25 pieces	Bag with 25 disposable pipettes

5. Storage instructions

The pack can be stored at 2 – 30 ℃ and can be used until the printed expiry date. After the expiry date, the quality guarantee is no longer valid. The tube with the test strips contains a drying agent and, in order to prevent the strips from getting damp, must not be left open. It must be carefully closed again each time a test strip is removed.

6. Materials required but not provided

- Test tubes for stool suspension
- Tubes (optional: uncoated microwells) for the suspension supernatant
- Vortex mixer (optional)
- Micropipette (200 µl - 1000 µl)
- Waste container containing 0.5 % sodium hypochlorite solution

7. Precautions for users

For *in vitro* diagnostic use only. This test must only be carried out by trained laboratory personnel. The guidelines for working in medical laboratories must be followed and the instructions for carrying out the test must be strictly adhered to.

The sample dilution buffer contains sodium azide as a preservative. This substance must not be allowed to come into contact with the skin or mucous membrane.

Samples or reagents must not be pipetted by mouth and contact with injured skin or mucous membranes must be prevented. When handling the samples, wear disposable gloves and when the test is finished, wash your hands. Do not smoke, eat or drink in areas where samples or test reagents are being used.

All reagents and materials which come into contact with potentially infectious samples must be treated exactly like the samples themselves with suitable disinfectants (e.g. sodium hypochlorite) or autoclaved for at least one hour at 121 °C.

8. Specimen collection and storage

Stool samples must be collected in clean containers without any additives and stored at 2 – 8 °C before beginning the test. If stored for more than 3 days, the sample must be frozen at –20 °C. In this case, the sample must be completely thawed out and brought to room temperature before testing begins. Multiple freezing and thawing of the sample must be avoided.

If rectal swabs have to be used, make sure that sufficient stool material (approx. 50 mg) is collected to carry out the test.

9. Test procedure

9.1. General information

The extraction buffer and the test strips must be brought to room temperature (20 – 25 °C) before using the samples. The tube with the test strips must not be opened until it has reached room temperature and must be closed again after removing the necessary test strips. Once used, the test strips must not be used again. The test must not be carried out in direct sunlight.

Do not pour reagents back into vials as this may cause reagent contamination.

9.2. Preparing the samples

Place 1 ml Extraction Buffer Diluent in the test tubes indicated. With the **liquid** stool sample, pipette 100 µl of the sample with a disposable pipette Pipet (up to just above the second thickening) and suspend it in the buffer placed in the tube beforehand. With **solid** stool samples, suspend 50 mg of the sample in the buffer. The sample must then be well homogenised. This can be achieved either by repeated suction and ejection of the suspension using the disposable pipette Pipet or, alternatively, by mixing on a vortex mixer. After this, allow the homogenised suspension to precipitate for at least **3 minutes** until a clear supernatant is formed from which at least **200 µl** but at most **500 µl** is then transferred into another clean tube (or uncoated microwell).

9.3. Testing the sample

Remove the test strip Strip from the tube and immerse it in the prepared sample. The test strip must not be immersed any further than the line indicated by the arrow. The test result can be read off after **5 minutes**.

10. Quality control – indications of reagent expiry

The test must only be used for evaluation if the test strip is intact and no colour changes or bands can be seen on it **before** immersing it in the sample suspension which has been prepared. In addition to this, at least the control band must be visible after the test incubation. If this does not appear, the following must be checked before repeating the test:

- Expiry date of the test strips and the extraction buffer being used
- Correct test procedure
- Contamination of the extraction buffer

After this, if the control band is still not visible after repeating the test with a new test strip, please contact the manufacturer or your local R-Biopharm distributor.

11. Evaluation and interpretation

A maximum of two bands should appear, in the following order as seen from the sample-absorption site: one red test band and one blue control band. **If the blue control band is missing, the test is invalid and cannot be evaluated!**

The following interpretations are possible:

- **Rotavirus positive :** the **red** and **blue** bands are visible.
- **Rotavirus negative :** only the **blue** band is visible.
- **Not valid :** no visible band or a combination other than the one described above or other changes in band colour. Likewise, changes in band colour which only appear after 10 minutes or later are also without any diagnostic value and must not be used for evaluation.

12. Limitations of the method

The RIDA®QUICK Rotavirus Test determines rotavirus antigens in stool samples. The test cannot be used to derive a relationship between the intensity of the specific visible bands and the occurrence or severity of clinical symptoms. **The results obtained must always be interpreted in combination with the clinical picture.**

A **positive** result does not rule out the presence of another infectious pathogen.

A **negative** result does not necessarily rule out rotavirus infection. This can be caused by intermittent excretion of the pathogen or by the quantity of antigens in the sample being too small. If the patient is anaemic or is suspected as being infected by the pathogen being looked for, another stool sample should be tested after four weeks.

An excess of stool sample can cause brownish bands to appear instead of the specifically coloured bands. These brownish bands do not have any diagnostic value. In such cases, it will be necessary to repeat the test with a smaller stool quantity or dilute the suspension already prepared further (clear supernatant after sedimentation) in order to clarify whether the pathogen being looked for is in the sample and has been masked by too much stool matrix.

13. Performance characteristics

The sensitivity and specificity of this test were tested on the basis of clinical samples in comparison with a commercial Elisa. The results are listed in the following table.

Rotavirus		
	RIDA®QUICK	
Elisa	**+**	**-**
+	**105**	**0**
-	**1**	**95**

Sensitivity: **100 %**
Specificity: **99 %**
Pos. prognosis value : **99.1 %**
Neg. prognosis value : **100 %**

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