

RIDA[®]QUICK Rotavirus/Adenovirus Sample diluent

REF ZN1004



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1. Intended use

For *in-vitro* diagnostic use. The RIDA[®]QUICK Rotavirus/Adenovirus Sample diluent is intended for the dilution of untreated human stool samples in people with symptoms of gastroenteritis who are tested with the RIDA[®]QUICK Rotavirus (N0903) or RIDA[®]QUICK Rotavirus/Adenovirus Combi (N1003) rapid test.

The product is intended for professional use.

2. Summary and explanation of the test

The RIDA[®]QUICK Rotavirus/Adenovirus Sample diluent is offered as an accessory for the RIDA[®]QUICK Tests (see Section 1. Intended use).

3. Test principle

The RIDA[®]QUICK Rotavirus/Adenovirus Sample diluent contains ready-for-use sample dilution buffer for the RIDA[®]QUICK Rotavirus (N0903) or the RIDA[®]QUICK Rotavirus/Adenovirus Combi (N1003) rapid tests.

The RIDA[®]QUICK Rotavirus/Adenovirus Sample diluent is used for diluting stool samples before use with the RIDA[®]QUICK Rotavirus (N0903) or the RIDA[®]QUICK Rotavirus/Adenovirus Combi (N1003) rapid test.

4. Reagents provided

One package contains 25 sample dilution buffer vials.

Table 1: Reagents provided

| Kit components | Amount | | Description |
|--------------------|--------|--------|---------------------------------------|
| Tube Yellow lid | 25 × | 1.5 mL | Sample dilution buffer; ready for use |

5. Storage instructions

Please follow the handling guidelines in Table 2 and store the product directly after use according to the information specified. After the expiration date has passed or the recommended storage period of the opened product has elapsed, the quality guarantee is no longer valid.

Table 2: Storage conditions and information

| | Storage temperature | Maximum storage time | Additional notes on storage |
|----------|------------------------|---|--|
| unopened | 2 - 30 °C | Can be used until the printed expiration date | - |
| opened | 2 - 30 °C | Can be used until the printed expiration date | Opened vials or vials whose lids have been unscrewed should not be stored and must be disposed of. |

6. Reagents required but not provided

6.1 Reagents

| Reagents | |
|--|--|
| RIDA [®] QUICK Rotavirus | |
| RIDA [®] QUICK Rotavirus/Adenovirus Combi | |
| | |

6.2 Laboratory equipment

The laboratory equipment needed for the RIDA[®]QUICK Rotavirus or the RIDA[®]QUICK Rotavirus/Adenovirus Combi rapid test is required for performing the test.

7. Warnings and precautions for the users

Only qualified laboratory personnel may use this product.

The guidelines for working in medical laboratories (good laboratory practice) must be followed. Strictly follow the instructions for use when using the RIDA[®]QUICK Rotavirus or the RIDA[®]QUICK Rotavirus/Adenovirus Combi rapid test. Do not pipette samples or reagents using your mouth. Avoid contact with broken skin and mucous membranes. Wear personal protective equipment (appropriate gloves, lab coat, safety glasses) when handling reagents and samples, and wash hands after finishing using the product. Do not smoke, eat, or drink in areas where samples are handled.

Hazardous materials are indicated according to labeling obligations. Further details on the Safety Data Sheet (SDS) can be found under the item number at https://clinical.r-biopharm.com/search/.

Users are responsible for the proper disposal of the RIDA[®]QUICK Rotavirus/Adenovirus Sample diluent after use. For disposal, please adhere to national regulations.

Make sure that the correct sample amount is used during sample dilution and that amount of sample extracted in the sample dilution buffer is correct during sample application.

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For users in the European Union: Report all serious adverse events associated with the product to R-Biopharm AG and the appropriate national authorities.

8. Test procedure

Before use, bring the RIDA[®]QUICK Rotavirus/Adenovirus Sample diluent to room temperature (20 - 25 °C).

For sample testing, prepare the test cassette as described in the instructions for use of the RIDA[®]QUICK Rotavirus or the RIDA[®]QUICK Rotavirus/Adenovirus Combi rapid test.

Do not use the RIDA[®]QUICK Rotavirus/Adenovirus Sample diluent if the vial containing the sample dilution buffer Tube is damaged or is not sealed prior to use. Avoid cross-contamination in general.

Do not reuse sample dilution buffer Tube vials that have been already used.

8.1 Sample dilution

Carefully unscrew the screw cap of the sample dilution buffer Tube.

Solid or semi-solid stool

If the stool is solid or semi-solid, use the grooved tip of the applicator stick attached to the screw cap to collect about 50 - 100 mg of the sample (Figure 1).

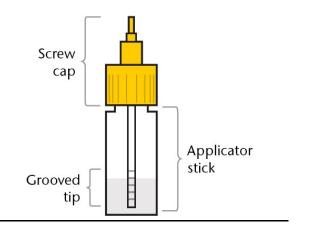


Figure 1: Design of the sample dilution buffer Tube

Note: Collect the sample from at least three different sample areas to obtain a sample that is as representative as possible.

Place the applicator stick with the sample into the sample dilution buffer Tube. Tightly close the screw cap and shake well to obtain a homogeneous suspension.

Liquid or semi-liquid stool

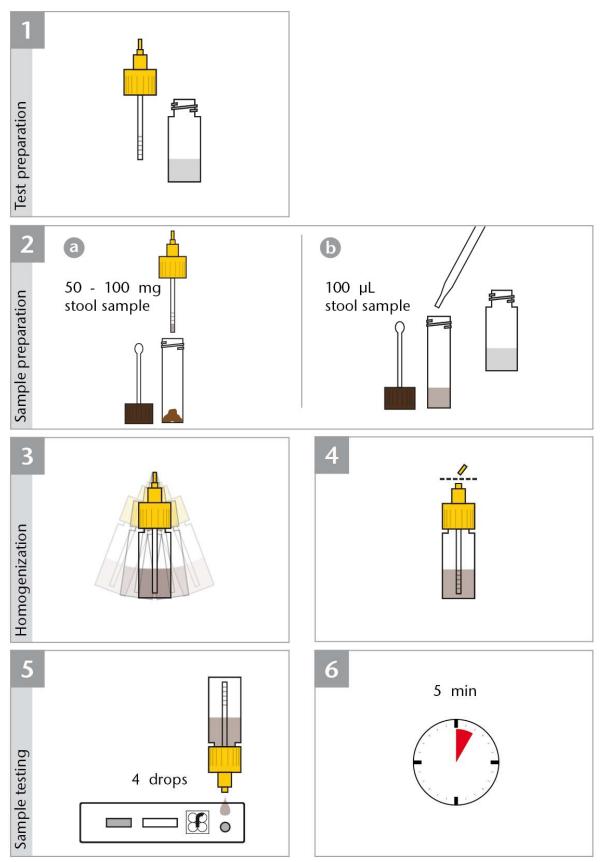
If the stool is liquid or semi-liquid, use a disposable pipette provided in the RIDA[®]QUICK Rotavirus or the RIDA[®]QUICK Rotavirus/Adenovirus Combi to collect 100 μ L of the sample (to just above the second bulge) and add to the sample dilution buffer Tube. Tightly close the screw cap and shake well to obtain a homogeneous suspension.

8.2 Sample testing

The homogeneous sample suspension can now be used according to the instructions for the RIDA[®]QUICK Rotavirus or the RIDA[®]QUICK Rotavirus/Adenovirus Combi rapid tests.

Break off the tip of the screw cap. Hold the sample dilution buffer Tube upright over the sample application field and apply 4 drops into the opening on the test cassette. Wait 5 minutes to read the test result. For the evaluation, please refer to the instructions for use of the RIDA[®]QUICK Rotavirus or the RIDA[®]QUICK Rotavirus/Adenovirus Combi rapid test.

8.3 Short protocol



- 1. Open the screw cap of the sample dilution buffer Tube.
- 2. Diluting the sample in the sample buffer:
 - a. **Solid stool sample:** Use the applicator stick to collect 50 100 mg stool sample.
 - b. **Liquid stool sample:** Use the disposable pipette of the RIDA[®]QUICK Rotavirus or the RIDA[®]QUICK Rotavirus/Adenovirus Combi to collect 100 μL liquid stool sample.
- 3. Tightly close the screw cap and mix well until a homogeneous suspension is obtained.
- 4. Break off the screw cap tip.
- 5. Dispense 4 drops into the sample application field of the RIDA[®]QUICK Rotavirus or the RIDA[®]QUICK Rotavirus/Adenovirus cassette.
- 6. Wait 5 minutes and then read the result.

9. Limitations of the method

- The RIDA[®]QUICK Rotavirus/Adenovirus Sample diluent is intended only for use with the RIDA[®]QUICK Rotavirus or the RIDA[®]QUICK Rotavirus/Adenovirus Combi rapid test.
- This product should be used in compliance with the regulation on good laboratory practice (GLP). When using the RIDA[®]QUICK Rotavirus/Adenovirus Sample diluent, operators must precisely follow the manufacturer's instructions for the RIDA[®]QUICK Rotavirus or the RIDA[®]QUICK Rotavirus/Adenovirus Combi rapid test.

10. Version history

| Version number | Section and designation | |
|----------------|--|--|
| 2011-08-11 | Previous version | |
| 2022-01-07 | General revision and introduction of section structure | |

11. Explanation of symbols

General symbols

| IVD | For in vitro diagnostic use |
|-----------|---------------------------------------|
| Ĩ | Observe operating manual |
| LOT | Batch number |
| Σ | Use before |
| X | Storage temperature |
| REF | Item number |
| Σ | Number of tests |
| ~ | Date of manufacture |
| | Manufacturer |
| | Product not for personal use |
| | Product not for point-of-care testing |
| \otimes | Do not reuse |

Test-specific symbols



Sample dilution buffer