

RIDASCREEN® Diluent 1

REF 3010P01-VK



1. Intended use

For *in vitro* diagnostic use. The RIDASCREEN® Diluent 1 (3010P01-VK) is a sample dilution buffer intended for use with the RIDASCREEN® Clostridium perfringens Enterotoxin (C0601), RIDASCREEN® Clostridium difficile GDH (C0701), RIDASCREEN® Clostridium difficile Toxin A/B (C0801), RIDASCREEN® Rotavirus (C0901), RIDASCREEN® Adenovirus (C1001), RIDASCREEN® Giardia (C1101), RIDASCREEN® Cryptosporidium (C1201), RIDASCREEN® Astrovirus (C1301), RIDASCREEN® Norovirus 3rd Generation (C1401), RIDASCREEN® Entamoeba (C1701), RIDASCREEN® Helicobacter (C2302), and RIDASCREEN® Campylobacter (C2401) test.

The product is intended for professional use.

2. Summary and explanation of the test

The RIDASCREEN® Diluent 1 is offered as an accessory for the RIDASCREEN® tests (see Section 1. Intended use).

3. Test principle

The RIDASCREEN® Diluent 1 is ready for use and must be used as described in the instructions for use for the RIDASCREEN® test (see Section 1. Intended use).

The RIDASCREEN® Diluent 1 is used to dilute stool samples before use in the RIDASCREEN® tests.

4. Reagents provided

 Table 1: Reagents provided for RIDASCREEN® Diluent 1

Kit components	Amount		Description
Diluent 1 Natural-colored lid	1 ×	100 mL	Sample dilution buffer 1, protein-buffered NaCl solution, ready for use, blue colored; contains Kathon CG

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date has passed or the recommended storage period of the opened product has elapsed, the quality guarantee is no longer valid.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	Maximum	Additional notes on
	temperature	storage time	storage
unopened	2 - 8 °C	Can be used until the printed expiration date	-
opened	2 - 8 °C	≤ 5 weeks	Immediately store any unneeded reagent refrigerated.

6. Reagents required but not provided

6.1 Reagents

Reagents

RIDASCREEN® test (see Section 1. Intended use)

6.2 Laboratory equipment

The laboratory equipment needed for the RIDASCREEN® test is required for performing the test (see Section 1. Intended use).

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. Adhere strictly to the operating manual when performing the RIDASCREEN® tests. 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/.

The sample dilution buffer 1 contains Kathon CG. Avoid contact with skin and mucous membranes.

Users are responsible for the proper disposal of the RIDASCREEN® Diluent 1 after use. For disposal, please adhere to national regulations.

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 RIDASCREEN® Diluent 1 to room temperature (20 - 25 °C). The RIDASCREEN® Diluent 1 must be used as described in the instructions for use for the RIDASCREEN® tests (see Section 1. Intended use).

9. Limitations of the method

- 1. The RIDASCREEN® Diluent 1 is only for use with said RIDASCREEN® tests (see Section 1. Intended use).
- 2. This product should be used in compliance with the regulation on good laboratory practice (GLP). When using the RIDASCREEN® Diluent 1, operators must precisely follow the manufacturer's instructions for the respective RIDASCREEN® test.

10. Version history

Version number	Section and designation
2021-12-29	Release version

11. Explanation of symbols

General symbols

For *in vitro* diagnostic use

Observe operating manual

LOT Batch number

REF Item number

Number of tests

Date of manufacture

Manufacturer

Test-specific symbols

Diluent 1 Sample dilution buffer 1