RIDASCREEN® Control -

REF 3056C00-VK

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1. Intended use

For *in-vitro* diagnostic use. RIDASCREEN® Control | - (3056C00-VK) is a negative control intended for use with the following enzyme immunoassays:

- RIDASCREEN® C. perfringens Enterotoxin (C0601) test
- RIDASCREEN® Clostridium difficile GDH (C0701) test
- RIDASCREEN® Clostridium difficile Toxin A/B (C0801) test
- RIDASCREEN® Rotavirus (C0901) test
- RIDASCREEN® Adenovirus (C1001) test
- RIDASCREEN® Giardia (C1101) test
- RIDASCREEN® Cryptosporidium (C1201) test
- RIDASCREEN® Astrovirus (C1301) test
- RIDASCREEN® Norovirus 3rd Generation (C1401) test
- RIDASCREEN® Entamoeba (C1701) test
- RIDASCREEN® Verotoxin (C2201) test
- RIDASCREEN® Helicobacter (C2302) test
- RIDASCREEN® Campylobacter (C2401) test

The product is intended for professional use.

2. Summary and explanation of the test

RIDASCREEN® Control | - is sold as an accessory for the RIDASCREEN® tests listed above and must be used in compliance with the batch.

3. Test principle

RIDASCREEN® Control | - is ready for use and must be used as described in the operating manual for the respective RIDASCREEN® test.

RIDASCREEN® Control | - is used to check the test reagents and test performance of said RIDASCREEN® tests (Section 1 Intended use).

4. Reagents provided

Table 1: Reagents provided for RIDASCREEN® Control | -

Kit components	Amount		Description
Control | - *Natural-colored lid*	1 x	2 mL	Negative control; contains Kathon CG; ready for use; blue colored

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date has passed or the recommended storage period of the opened product has elapsed, the quality guarantee is no longer valid.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 - 8 °C	Can be used until the printed expiration date	-
opened	2 - 8 °C	≤ 5 weeks	Immediately store unneeded reagents refrigerated.

6. Reagents required but not provided

6.1 Reagents

RIDASCREEN® Control | - must be used with one of the RIDASCREEN® tests listed in Section 1 Intended use.

6.2 Laboratory equipment

The laboratory equipment needed for the respective RIDASCREEN® test is required for the test procedure.

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 using the RIDASCREEN® tests listed in Section 1 Intended use. 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/.

RIDASCREEN® Control | - contains Kathon CG. Avoid contact with skin and mucous membranes.

Users are responsible for the proper disposal of RIDASCREEN® Control | - 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 relevant national authorities.

8. Test procedure

Before use, bring RIDASCREEN® Control | - to room temperature (20 - 25 °C). RIDASCREEN® Control | - must be used as described in the operating manual for the respective RIDASCREEN® test.

9. Quality control - indication of instability or expiration of reagents

For quality control, the negative control Control | - of the enzyme immunoassay is to be run during every test procedure (see Section 1 Intended use) to ensure reagent stability and the correct test procedure. The negative control was run correctly if the extinction value (OD) at 450/620 nm is less than 0.160. A value greater than 0.160 for the negative control may indicate that there was insufficient washing. A deviation from the specified value can indicate expiration of reagents.

If the specified value is not met, check the following items before repeating the test:

- Expiration date of the reagents used
- Functionality of the equipment being used (e.g., calibration)
- Correct test procedure
- Visual inspection of the product for contamination or leaks

If the conditions are still not fulfilled after repeating the test, please consult the manufacturer or your local R-Biopharm distributor.

10. Evaluation and interpretation

At this time, there is no internationally recognized reference method or reference material for standardization. The control material can be metrologically traced to the internal R-Biopharm AG standard, based on a buffer.

For further information on metrological traceability, contact R-Biopharm AG.

The adjusted values and variations can be found in the enclosed Certificate of Analysis (CoA).

11. Limitations of the method

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

12. Version history

Version number	Section and designation
2021-09-14	Release version

13. Explanation of symbols

General symbols

IVD	For *in vitro* diagnostic use
	Observe operating manual
LOT	Batch number
	Use before
	Storage temperature
REF	Item number
	Number of tests
	Date of manufacture
	Manufacturer

Test-specific symbols

Control | -	Negative control