

RIDASCREEN® **Substrate**

REF 3019V01-VK



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1. Intended use

For *in vitro* diagnostic use. The RIDASCREEN® **Substrate** (3019V01-VK) is as substrate 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® Verotoxin (C2201), RIDASCREEN® Helicobacter (C2302), RIDASCREEN® Campylobacter (C2401), and RIDASCREEN® Legionella (C8001) test.

The product is intended for professional use.

2. Summary and explanation of the test

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

3. Test principle

The RIDASCREEN® **Substrate** 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® **Substrate** is used in the RIDASCREEN® tests, and, in the case of positive samples, is converted into a chromogenic compound by the bound peroxidase, resulting in a blue color reaction in the wells of the microtiter plate.

4. Reagents provided

Table 1: Reagents provided for RIDASCREEN® **Substrate**

| Kit components | Amount | | Description |
|-------------------------------------|--------|-------|--|
| Substrate <i>Blue lid</i> | 1 × | 13 mL | Hydrogen peroxide/TMB; contains 2-pyrrolidone; 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date has passed or the recommended storage period of the opened product has elapsed, the quality guarantee is no longer valid.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 - 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 colorless substrate must also be protected from direct light to prevent it from degradation or turning blue due to auto-oxidation. Once the substrate has turned blue, it must not be used.

The substrate contains 2-pyrrolidone. Avoid contact with skin and mucous membranes.

Users are responsible for the proper disposal of the RIDASCREEN® **Substrate** 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® **Substrate** to room temperature (20 - 25 °C). The RIDASCREEN® **Substrate** 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® **Substrate** 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® **Substrate**, operators must precisely follow the manufacturer's instructions for the RIDASCREEN® test.

10. Version history

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

11. Explanation of symbols

General symbols

| | |
|---|------------------------------------|
|  | For <i>in vitro</i> diagnostic use |
|  | Observe operating manual |
|  | Batch number |
|  | Use before |
|  | Storage temperature |
|  | Item number |
|  | Number of tests |
|  | Date of manufacture |
|  | Manufacturer |

Test-specific symbols

| | |
|---|-----------|
|  | Substrate |
|---|-----------|