# RIDASCREEN® H. pylori Reference Controls

REF CRP2304

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## 1. Intended use

For *in vitro* diagnostic use. RIDASCREEN® H. pylori Reference Controls are external quality controls. They are intended for use in the corresponding RIDASCREEN® Helicobacter ELISA (C2302).

## 2. Summary and explanation of the test

RIDASCREEN® H. pylori Reference Controls are sold as separate items. As external controls, they are intended, in accordance with the statutory requirements, for internal laboratory quality controls and quality assurance for checking the respective commercial parameters.

## 3. Test principle

RIDASCREEN® H. pylori Reference Controls react specifically in the corresponding RIDASCREEN® Helicobacter ELISA (C2302). They are ready for use and are used in the same way as the pre-diluted patient samples. The measured OD value of the reference controls must meet the specifications described in Sect. 10.

## 4. Reagents provided

**Table 1:** Reagents provided

| | | |
|---|---|---|
| Control A | 1 x 2 ml | Reference control A; ready for use |
| Control B | 1 x 2 ml | Reference control B; ready for use |

Hazardous materials are indicated according to labeling obligations. For further details, see the safety data sheets (SDSs) at www.r-biopharm.com.

## 5. Storage instructions

RIDASCREEN® H. pylori Reference Controls are to be stored at 2°C to 8°C and used by the expiration date printed on the packaging. After the expiration date, the quality guarantee is no longer valid.
When stored correctly at 2°C to 8°C, the opened control can be used for 16 weeks.

## 6. Reagents required but not provided

### 6.1 Necessary reagents

The following reagents are required to perform the control reaction:

| Reagents |
| --- |
| RIDASCREEN® Helicobacter (C2302) |

### 6.2 Necessary laboratory equipment

The laboratory equipment needed for the RIDASCREEN® H. pylori ELISA kit (C2302) is required for the test procedure.

## 7. Warnings and precautions for the users

For *in vitro* diagnostic use only.

This test must be carried out only by trained laboratory personnel. The guidelines for working in medical laboratories must be followed. Always adhere strictly to the instructions for use when carrying out this test. Specimens or reagents must not be pipetted by mouth, and contact with injured skin or mucous membranes must be prevented. Wear personal protective equipment (appropriate gloves, lab coat, safety glasses) when handling reagents and specimens, and wash hands after completing the test. Do not smoke, eat, or drink in areas where specimens or test reagents are being used.
For further details, see the safety data sheets (SDSs) at www.r-biopharm.com.

Users are responsible for proper disposal of all reagents and materials after use. For disposal, please adhere to national regulations.

RIDASCREEN® H. pylori Reference Controls contain inactivated H. pylori antigen. However, they should be handled as if potentially infectious, pursuant to the national safety requirements.

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

## 8. Test procedure

RIDASCREEN® H. pylori Reference Controls are ready for use and can be used undiluted. Bring RIDASCREEN® H. pylori Reference Controls to room temperature prior to use. For the measurement, use 100 µl of reference control A Control A and 100 µl of reference control B Control B in RIDASCREEN® Helicobacter (C2302).

It is recommended to pipette 0.5 ml each of the two reference materials into their own separate, clean test tube for testing on fully automated equipment, such as DSX or Agility, and to test them in the same way as patient samples. Once the test is complete, the rest of the reference controls are to be disposed of. Residual materials may not be poured back into the original vials.

## 9. Quality control – Indication of instability or expiration of reagents

Please read the quality control information in the instructions for use for RIDASCREEN® Helicobacter.

## 10. Evaluation and interpretation

Reference control A must be measured after the test is complete through bichromatic measurement at 450/620 nm with a clear, positive extinction value of greater than 0.5.

Reference control B must be assessed as negative through bichromatic measurement at 450/620 nm using the determined cut-off value. If these specifications are not met, an internal error analysis must ensure that the target values are reached on retesting. All measurements must be documented pursuant to internal lab quality assurance measures.

## 11. Version history

| Version number | Section and designation |
|---|---|
| 2016-08-16 | Previous version |
| 2020-08-28 | General revision<br>1. Intended use<br>3. Test principle<br>4. Reagents provided<br>5. Storage instructions<br>6. Additionally necessary reagents<br>7. Warnings and precautions for the users<br>8. Test procedure |

## 12. Explanation of symbols

General symbols

| | |
|---|---|
| IVD | For in vitro diagnostic use |
|  | Consult instructions for use |
| LOT | Batch number |
|  | Use before |
|  | Store at |
| REF | Item number |
|  | Number of tests |
|  | Date of manufacture |
|  | Manufacturer |

Test-specific symbols

| | |
|---|---|
| Control \| A | Reference control A |
| Control \| B | Reference control B |