RIDA®QUICK Verotoxin/O157 Combi Control

REF NP2204

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1. Intended use

For *in vitro* diagnostic use.
The RIDA®QUICK Verotoxin/O157 Combi Control is suited for use in conjunction with the RIDA®QUICK Verotoxin/O157 Combi rapid test (N2203) to detect the verotoxin and the O157 test band.

2. Summary and explanation of the test

The RIDA®QUICK Verotoxin/O157 Combi Control is sold as a separate accessory for the RIDA®QUICK Verotoxin/O157 Combi rapid test. The positive control and the test-specific reagents (extraction buffer, test cassettes or test strips) must be brought to room temperature (20 - 25 °C) before use. The test cassettes and test strips must be taken out of their package shortly before use. Do not carry out the test procedure in direct sunlight.

3. Test principle

The RIDA®QUICK Verotoxin/O157 Combi Control specifically reacts with the corresponding test strips and at the end of the reaction yields specifically colored test bands as described in the instructions for use.

4. Reagents provided

Table 1: Reagents provided

Kit components	Amount	Description
Control +	1 x 1.8 ml	Vial with dissolved verotoxin and O157 antigen material for up 9 control reactions

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

RIDA®QUICK Verotoxin/O157 Combi Control should be stored at 2 - 8 °C and can be used until the expiration date printed on the packaging. After the expiration date, the quality guarantee is no longer valid.

6. Additional necessary reagents - required equipment

6.1 Necessary reagents

The following reagents are required to perform the control reaction:

Reagents
RIDA®QUICK Verotoxin/O157 Combi (N2203)

6.2 Necessary laboratory equipment

The following equipment is required to perform the control reaction:

Equipment
Vortex mixer (optional)
Stopwatch/timer
Waste container containing 0.5 % hypochlorite solution (optional)

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.

The RIDA®QUICK Verotoxin/O157 Combi Control contains antigen material from an inactivated culture. The control should be handled as if potentially infectious, pursuant to the national safety requirements.
For further details, see the safety data sheets (SDSs) at www.r-biopharm.com.

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.

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

8. Test procedure

8.1 Preparing the positive control

Before its use in the test, the RIDA®QUICK Verotoxin/O157 Combi Control must be mixed in a 1+1 proportion with the extraction buffer from N2203. Add (pipette) 4 drops (200 µl) of RIDA®QUICK Verotoxin/O157 Combi Control and 4 drops (200 µl) of extraction buffer to a clean test tube and mix thoroughly.

8.2 Execution

Add 4 drops (200 µl) of the positive control as prepared in 8.1 into the round opening of the test cassette and incubate the cassette for 15 minutes at room temperature. Then read the result.

9. Quality control - indication of expiration of reagents

Non-specifically stained or additional bands indicate possible expiration of the reagents.

10. Evaluation and interpretation

Both test bands, red for verotoxin and green for O157, must appear next to the blue control band.

The test is invalid if one of the three bands is missing. An invalid test may be caused by performing the test incorrectly or using an expired control or test cassette.

11. Version history

Version number	Section and designation
2018-11-19	Previous version
2021-08-06	7. Warnings and precautions for the users

12. Explanation of symbols

General symbols

IVD	For *in vitro* diagnostic use
LOT	Lot number
	Use before
	Storage temperature
REF	Item number
	Manufacturer

Test-specific symbols

Control +	Positive control