RIDA®QUICK Norovirus Control

REF NP1404

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1. Intended use

For *in vitro* diagnostic use.
RIDA®QUICK Norovirus Control is designed for use in the RIDA®QUICK Norovirus rapid test (N1402) and in the RIDA®QUICK Rota/Adeno/Noro Combi rapid test (N1903).

2. Summary and explanation of the test

RIDA®QUICK Norovirus Control is sold as a separate accessory for RIDA®QUICK Norovirus (N1402) and RIDA®QUICK Rota/Adeno/Noro Combi (N1903). The control contains a recombinant norovirus genogroup I (GI) and genogroup II (GII) antigen.

3. Test principle

RIDA®QUICK Norovirus Control is ready for use and reacts specifically in the corresponding test cassettes N1402 and N1903 (norovirus strip). After the reaction stops, RIDA®QUICK Norovirus Control generates the specific reaction bands described under Section 10.

4. Reagents provided

Table 1: Reagents provided

Control +	1 x 1.8 ml	Vial with dissolved norovirus antigen material for up to nine (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 Norovirus Control is to be stored at 2 °C to 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 After the expiration date, the quality guarantee is no longer valid. 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
RIDA®QUICK Norovirus (N1402)
RIDA®QUICK Rota/Adeno/Noro Combi (N1903)

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 user instructions for carrying out this test. 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 completing the test. Do not smoke, eat, or drink in areas where samples are handled.
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.

RIDA®QUICK Norovirus Control contains a recombinant norovirus-specific antigen. The product should, however, be handled as 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

The positive control, the appropriate test-specific reagents, and the test cassettes must be brought to room temperature (20 °C to 25 °C) before use. The test cassettes should not be removed from their respective outer package until shortly before use. The test procedure must not be carried out in direct sunlight.

8.1. Preparation of the positive control and procedure (N1402)

RIDA®QUICK Norovirus Control is ready for use and is intended to be used along with a prepared stool specimen in the RIDA®QUICK Norovirus test cassettes (N1402). Dispense four (4) drops of RIDA®QUICK Norovirus Control into the 1+1 mixture of Reagent A and B and mix well. After a 5-minute incubation, pipette 150 µl of this mixture into the application field of the test cassette. Wait 15 minutes to read the test result.

8.2. Preparation of the positive control and procedure (N1903)

RIDA®QUICK Norovirus Control is ready for use and is to be applied directly to the RIDA®QUICK Rota/Adeno/Noro Combi test cassette (N1903).
Dispense four (4) drops of RIDA®QUICK Norovirus Control directly into the cassette opening for the specimen application of the norovirus strip. Read the test result after a 15-minute incubation.

9. Quality control – Indication of instability or deterioration of reagents

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

10. Evaluation and interpretation

10.1. Evaluation (N1402)

In addition to control band “C”, test band “T” will also be visible. All other constellations on the band patterns indicate an invalid test result.
If only the control band “C” is present, this indicates that the positive control has expired. If only test band “T” is visible or neither of the two bands appear, this could be the result of an incorrect test procedure or expiration of the kit reagents. Repeating the test using a new test cassette is recommended.

10.2 Evaluation (N1903)

The green control band “C” and the red test bands “GG1” and “GG2” must appear on the norovirus strips. The test is invalid if the control band “C” is not present. If only the control band “C” is present, this indicates that the positive control has expired. If only the “GG1” and/or “GG2” test bands are visible or neither of the three bands can be seen, this could be the result of an incorrect test procedure or expiration of the kit reagents. Repeating the test using a new test cassette is recommended.

11. Version history

Version number	Section and designation
2018-02-07	Previous version
2019-11-13	General revision
	1. Intended use 2. Summary and explanation of the test 3. Test principle 4. Reagents provided 6. Reagents required but not provided 7. Warnings and precautions for the users 8. Test procedure 10. Evaluation and interpretation 11. Version history 12. Explanation of symbols

12. Explanation of symbols

General symbols

IVD	For *in vitro* diagnostic use
LOT	Lot number
	Expiry
	Store at
REF	Article number
	Manufacturer

Test-specific symbols

Control | +	Positive control