RIDA®UNITY Internal Control Kit

REF UN0010

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1. Intended use

For *in vitro* diagnostic use. The RIDA®UNITY Internal Control Kit is intended for control of automated isolation and purification, amplification, and detection of nucleic acids in connection with the RIDA®UNITY Universal Extraction Kit and the RIDA®UNITY PCR kits on the RIDA®UNITY System. The product is intended for professional use.

2. Summary and explanation of the test

The RIDA®UNITY Internal Control Kit works as a universal process control for the entire workflow. All the steps from extraction to amplification are monitored. During the test, the control performs as an extraction and amplification control. The test cannot differentiate between a potential purification loss during extraction and the potential inhibition of amplification in a sample. The RIDA®UNITY Internal Control Kit contains a defined number of copies of RNA (MS2 phage) and DNA (synthetic DNA amplicon).

3. Test principle

These instructions for use are intended for the use of the RIDA®UNITY Internal Control Kit in combination with the RIDA®UNITY Universal Extraction Kit and the RIDA®UNITY PCR kits on the RIDA®UNITY System.

The Internal Control (IC) of the RIDA®UNITY Internal Control Kit is placed on the RIDA®UNITY System, added automatically to each sample at the start of nucleic acid extraction, and purified using the RIDA®UNITY Universal Extraction Kit. Following the automated setup of the RIDA®UNITY (RT-) PCR test reactions, the system then performs amplification and detection of the specific target nucleic acids and IC nucleic acids.

4. Reagents provided

Table 1: Reagents provided (The reagents provided in the kit are sufficient for 576 determinations; 2 reagent vials are sufficient for 96 determinations each.*)

Reagent	Amount		Note
Internal Control	12 ×	1400 µL	Lid color green, ready for use

*In multiple smaller series, the number of reactions may be less.

5. Storage instructions

- The handling guidelines are listed in Table 2.
- All reagents (IC) must be stored away from light at -16 °C to -28 °C and, if unopened, can be used until the expiration date printed on the label. After the expiration date, the quality guarantee is no longer valid and the kit may no longer be used.
- All reagents should be carefully thawed prior to use (e.g., in a refrigerator at 2 °C - 8 °C).

Table 2: Storage conditions and information

	Storage temperature	Maximum storage time
unopened	-16 °C to -28 °C	Can be used until the printed expiration date
opened	-16 °C to -28 °C	The reagents may be used a maximum of 4 times and must be used within 4 weeks after opening.

6. Reagents required but not provided

The RIDA®UNITY Internal Control Kit is intended exclusively for use with the RIDA®UNITY System. The following products are absolutely required for correct use:

6.1 Reagents

The following reagents are needed for using the RIDA®UNITY Internal Control Kit:

Reagents	Item number
RIDA®UNITY Universal Extraction Kit (R-Biopharm AG)	UN0001
RIDA®UNITY real-time PCR kits (R-Biopharm AG)	UNxxxx

6.2 Laboratory equipment

The following equipment is needed for using the RIDA®UNITY Internal Control Kit:

Equipment
RIDA®UNITY (R-Biopharm AG)
RIDA®UNITY consumables (tips, plates, reaction vials, films) → See the instructions for use for the RIDA®UNITY System, ordering information for consumables.
Vortexer
Tabletop centrifuge
Powder-free disposable gloves

Should you have any questions regarding use, please contact R-Biopharm AG at pcr@r-biopharm.de or your local R-Biopharm distributor.

7. Warnings and precautions for the users

For *in vitro* diagnostic use only.
This test must be carried out only by qualified laboratory personnel.
The guidelines for working in medical laboratories must be followed. Always adhere strictly to the operating manual when 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.
Avoid contaminating the samples and components of the kit with microbes, nucleic acids, and nucleases (DNase/RNase).
Clinical samples must be viewed as potentially infectious and must be disposed of appropriately, like all reagents and materials that come into contact with potentially infectious samples.
Do not reuse used plastic materials.
Do not exchange or mix the Internal Control components of one kit lot with the components of another lot.
Do not use the test kit after the expiration date.

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

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/.

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. Collection and storage of samples

The RIDA®UNITY Internal Control Kit is to be used with the RIDA®UNITY Universal Extraction Kit. Additional information on the sample types, including their collection, handling, and storage, can be found in the instructions for use for the particular RIDA®UNITY PCR kits (Section: Collection and storage of samples).

9. Test procedure

Perform the following steps for preparation:

1. For an extraction run with up to 96 samples, you will need 2 IC vials from the kit. All reagents should be carefully thawed prior to use (e.g., in a refrigerator at 2 °C - 8 °C).
2. Next, vortex the IC vials for 5 seconds before centrifuging in a tabletop centrifuge. Remove the lid of the IC vials and place the vials on the respective carrier according to the loading instructions on the RIDA®UNITY System.
   Note: Make sure that the IC vials are positioned so as to allow the barcodes to be read (through the window). Set the lids down in a clean place. If fewer than 96 reactions are prepared, the IC remaining in the vial can be stored and reused as indicated on the label.
3. Automated processing is described in the RIDA®UNITY System instructions for use (Section: Performing a run).

9.1 Detection channel setting

The detection channel setting is specified in the instructions for use for the particular RIDA®UNITY PCR kits (Section: Detection channel settings).

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

The RIDA®UNITY PCR kits contain a positive and negative control. The instructions for use of the RIDA®UNITY PCR kits list the specifications of these controls for fulfilling a valid PCR run.

If the specified values are not met, check the following items before repeating the test:

- Expiration date of the reagents used
- Functionality of the equipment being used
- Correct test procedure

If the conditions are still not fulfilled after repeating the test, please consult R-Biopharm AG at pcr@r-biopharm.de or your local R-Biopharm distributor.

11. Evaluation and interpretation

Sample evaluation and interpretation are done using the RIDA®UNITY System analytical software, RIDA®SEEK.

12. Limitations of the method

1. This kit is intended only for use on the RIDA®UNITY System.
2. This kit should be used in compliance with the regulation on good laboratory practice (GLP). Users must precisely follow the manufacturer's instructions when performing the test.
3. The results obtained must always be interpreted in combination with the complete clinical symptoms.

13. Performance characteristics

The DNA and RNA target sequences in the RIDA®UNITY Internal Control Kit do not have homology to the RIDA®UNITY assay detection systems.
The performance of the RIDA®UNITY Internal Control Kit was verified along with the RIDA®UNITY Universal Extraction Kit and the RIDA®UNITY assays.

14. Version history

Version number	Section and designation
2022-04-20	Release version

15. Explanation of symbols

General symbols

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

Test-specific symbols

Internal Control	Internal control

16. References

Not applicable.