

RIDA® UNITY Universal Extraction Kit

REF UN0001



1. Intended use

For *in vitro* diagnostic use. The RIDA®UNITY Universal Extraction Kit is intended for the automated isolation and purification of nucleic acids from defined human biological samples and is carried out on the RIDA®UNITY System. The product is intended for professional use.

2. Summary and explanation of the test

The RIDA®UNITY Universal Extraction Kits contain reagents for the automated isolation and purification of nucleic acids from stool and cultures on the RIDA®UNITY System.

The RIDA®UNITY System automatically performs the following steps of the isolation and purification protocol: The samples are lysed through the addition of a lysis buffer during shaking. After the bonding conditions are set, the nucleic acids are bound to magnetic beads, washed, and eluted after the magnetic beads are dried. The isolated nucleic acids from the samples are then transferred to a separate eluate plate, thus making them accessible for further processing using the RIDA®UNITY PCR Kits.

The use of magnetic beads allows for purification of the nucleic acids with high purity and a short time requirement.

3. Test principle

Extraction is based on the proven and efficient magnetic beads-based purification technology. The reagents of the RIDA®UNITY Universal Extraction Kit can be placed directly on the RIDA®UNITY System.

The nucleic acids are isolated and purified on the RIDA®UNITY System in four simple steps:

- 1. Lysis:** The system transfers the lysis buffer, samples, and Internal Control (IC) (of the RIDA®UNITY Internal Control Kit) one after another into a deep well plate. The nucleic acids are released by means of chemical and mechanical lysis under chaotropic conditions.
- 2. Binding:** The system pipettes magnetic beads and binding buffer into the lysate. Nucleic acids are selectively bound to the magnetic beads under the conditions created by the binding buffer. Through magnetic separation, the nucleic acid-free supernatant can be discarded.
- 3. Washing:** The nucleic acids bound to the magnetic beads are washed in two wash steps followed by repeated magnetic separation.
- 4. Elution:** The nucleic acids isolated from the sample are stripped from the magnetic beads through the addition of the elution buffer. After repeated magnetic separation, the supernatant (= eluate) is transferred to the eluate plate and is ready for the PCR setup and subsequent amplification on the RIDA®UNITY System.

4. Reagents provided

Table 1: Reagents provided (The reagents provided in the kit are sufficient for 96 purifications.*)

Reagent	Amount		Note
RIDA®UNITY Cartridge	1 ×	Lysis buffer: 40 mL	Ready for use
		Binding buffer: 40 mL	
		Wash buffer 1: 60 mL	
		Wash buffer 2: 60 mL	
		Elution buffer: 20 mL	
RIDA®UNITY Magnetic Beads	2 ×	1750 µL	Lid color black, ready for use
Re-Sealing Foil	4 ×	-	Ready for use

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

The RIDA®UNITY Cartridge contains materials subject to mandatory labeling; see Section: Warnings and precautions for the users.

5. Storage instructions

- The handling guidelines are listed in Table 2.
- The cartridge (RIDA®UNITY Cartridge) must be stored away from light at 15 °C - 25 °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. Precipitates can form if the storage temperature is below the temperature printed on the label (< 15 °C). They can be dissolved through incubation at 25 °C under occasional gentle shaking.
- Prior to use, the magnetic bead vials (RIDA®UNITY Magnetic Beads) must be thoroughly vortexed for at least 60 seconds until fully homogenized.
- The cartridge can be used to process a total of 96 samples. For reuse, adhere the resealing film (provided in the kit) to the cartridge immediately after the extraction run to prevent evaporation. Store the cartridge at 2 °C - 8 °C.
- For reuse, seal the magnetic bead vials and store at 2 °C - 8 °C.

Table 2: Storage conditions and information

	Storage temperature	Maximum storage time	Additional notes on storage
unopened cartridge	Room temperature 15 °C - 25 °C	Can be used until the printed expiration date	Store the cartridge upright
unopened magnetic bead vials	Room temperature 15 °C - 25 °C	Can be used until the printed expiration date	-
Cartridge opened	2 °C - 8 °C	The reagents may be used a maximum of 4 times and must be used within 4 weeks after opening.	Store the cartridge upright (avoid inverting it)
opened magnetic bead vials	2 °C - 8 °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 Universal Extraction 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 Universal Extraction Kit:

Reagents	Item number
RIDA®UNITY Internal Control Kit (R-Biopharm AG)	UN0010
RIDA®UNITY real-time PCR Kits (R-Biopharm AG)	UNxxxx

6.2 Laboratory equipment

The following equipment is needed for using the RIDA®UNITY Universal Extraction 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
Powder-free disposable gloves
The following equipment is needed for stool preparation: <ul style="list-style-type: none">- Test tubes, 2-mL screw-cap micro tubes (Sarstedt, mat. no. 72.694)- PBS (R-Biopharm AG, item no. RBRRP202)- Disposable pipette, 1-mL graduated transfer pipette (Sarstedt, item no. 86.1170)- Disposable inoculation loop, flexible capacity, 10 µL (VWR, mat. no. 612-9357)- Centrifuge- Pipette 1000 µL

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.

Only qualified laboratory personnel may use this product.

The guidelines for working in medical laboratories must be followed. Always adhere strictly to the operating manual when using this product. Do not pipette samples or reagents using your mouth. Avoid contact with skin and mucous membranes. Wear personal protective equipment (appropriate gloves, lab coat, safety glasses) when handling reagents and samples, and wash and disinfect hands after using the product. 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 and/or mix components of one kit lot (cartridge, magnetic beads) with components of another lot.

Do not use the product after the expiration date.

Some buffer solutions in the extraction cartridges contain guanidine salts that can form highly reactive compounds when combined with chlorine bleach (sodium hypochlorite, NaOCl). If these buffer solutions are spilled, clean the affected surfaces with an appropriate laboratory detergent and water.

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










Note: Ensure that chlorine bleach and acidic solutions are not added directly into the RIDA®UNITY System's liquid waste created during sample preparation. The liquid waste contains flammable components.

Hazardous materials identification in accordance with labeling requirements (see Table 3).

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.

Table 3: Hazard information

Component designation	GHS symbol	Hazard information	Product identifier
RIDA®UNITY Cartridge: Lysis Buffer	 GHS05  GHS07	Causes severe chemical burns on the skin and severe eye injury. Harmful to health if swallowed or inhaled. Can cause allergic skin reactions.	Guanidine thiocyanate, maleic acid
RIDA®UNITY Cartridge: Binding Buffer	 GHS02  GHS05  GHS07	Flammable liquid and vapor. Causes severe chemical burns on the skin and severe eye injury. Can cause allergic skin reactions. Can cause sleepiness and dizziness.	Guanidine thiocyanate, propan-2-ol, maleic acid
RIDA®UNITY Cartridge: Wash Buffer 1	 GHS02  GHS07	Flammable liquid and vapor. Harmful to health if swallowed. Causes skin irritation. Causes severe eye irritation.	Ethanol, guanidinium chloride
RIDA®UNITY Cartridge: Wash Buffer 2	 GHS02  GHS07	Highly flammable liquid and vapor. Causes severe eye irritation.	Ethanol

8. Collection and storage of samples

Frozen specimens should be thawed immediately prior to extraction to prevent degradation of the nucleic acid. 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).

8.1 Nucleic acid preparation from stool samples

Transfer 900 μ L PBS into a labeled 2-mL screw-cap micro tube.

For liquid stool, use a graduated transfer pipette (e.g., Sarstedt, item no. 86.1170) to pipette 100 μ L stool and suspend it in the respective PBS. For solid stool, remove approximately 30 - 50 mg stool as illustrated in Figures 1 - 4, using a disposable inoculation loop (e.g., VWR, mat. no. 612-9357) (Fig. 1 and 2a), and suspend (Fig. 3). Homogenize the stool suspension by thoroughly mixing with a vortex mixer (Fig. 4). Next, centrifuge the stool samples at 1000 g for 90 seconds to clarify them. Ensure the centrifuge is set correctly: g force instead of speed in rpm.

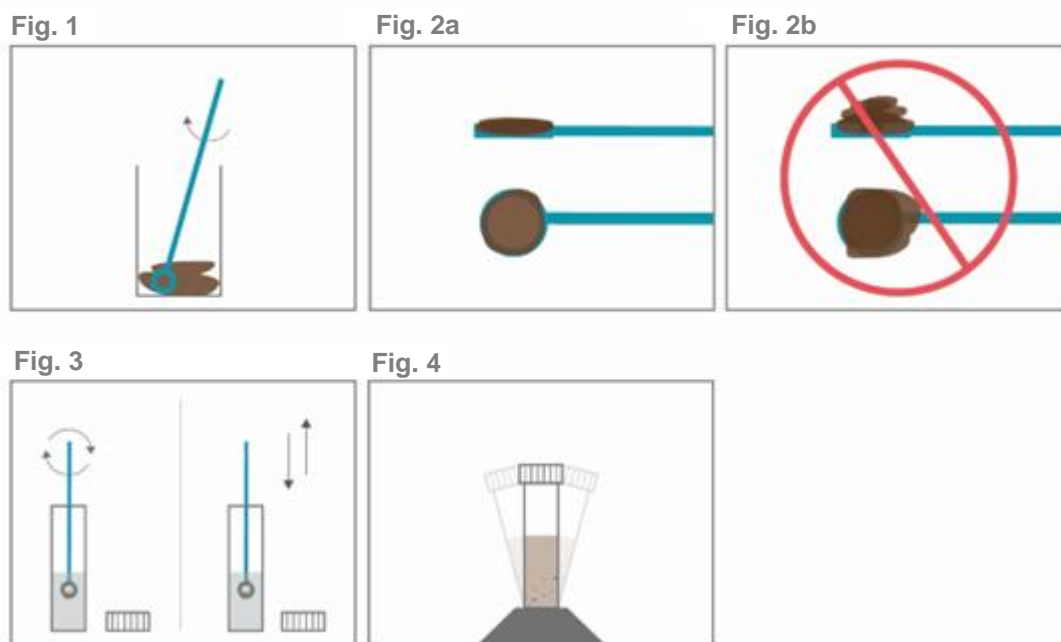


Fig. 1 - 4: Schematic diagram of stool sample preparation of solid stool.

8.2 Nucleic acid preparation from culture samples

Transfer 500 µL PBS or demineralized water into a labeled 2-mL screw-cap micro tube. For each sample, pick a bacterial colony with an inoculation loop and wash it out in PBS/demineralized water. The samples can be used on the system after they are thoroughly mixed (vortexed) and briefly centrifuged (3 seconds).

8.3 Storage of eluates

Store eluates at -20 °C. The length of eluate storage is specific to the analyte and is listed in the instructions for use of the respective RIDA®UNITY PCR Kits.

9. Test procedure

Perform the following steps for preparation:

1. For an extraction run with up to 96 samples to be extracted, the following items are needed:
 - 1 x cartridge from RIDA®UNITY Universal Extraction Kit. Ensure that the cartridge has no precipitates. They can be dissolved through incubation at 25 °C under occasional gentle shaking.
 - 2 x magnetic bead vials from RIDA®UNITY Universal Extraction Kit. Vortex the vials for 60 seconds until there are no longer any bead pellets in the bottom of the vial. Transfer bead/liquid residue in the lid back into the vial (do not centrifuge).
 - 2 x IC vials from the RIDA®UNITY Internal Control Kit. All reagents should be carefully thawed prior to use (e.g., in a refrigerator at 2 °C - 8 °C). Next, vortex the IC vials for 5 seconds before centrifuging in a tabletop centrifuge for 3 seconds.
2. Carefully remove the film after loading the cartridge in the appropriate carrier.
Note: For reuse, adhere the resealing film (provided in the kit) to the cartridge immediately after the extraction run to prevent evaporation. Store the cartridge at 2 °C - 8 °C.
3. Remove the lid of the magnetic bead and IC vials, and place vials on the respective carrier according to the loading instructions on the RIDA®UNITY System.
Make sure that the magnetic bead and IC vials are positioned so as to allow the barcodes to be read (through the window).
Note: Set the lids down in a clean place. If fewer than 96 reactions are being prepared, the IC and magnetic beads remaining in the vial can be stored at -16 °C to -28 °C (IC) and 2 °C - 8 °C (magnetic beads) and reused.
4. Automated processing is described in the RIDA®UNITY System instructions for use (Section: Performing a run).

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.

If you have any questions regarding additional run controls, please contact R-Biopharm AG at pcr@r-biopharm.de or your local R-Biopharm distributor.

11. Evaluation and interpretation

The evaluation and interpretation of the samples and controls are done using the RIDA®UNITY System analytical software, RIDA®SEEK.

12. Limitations of the method

1. This product is intended only for use on the RIDA®UNITY System.
2. This product is verified only for stool and cultures.
3. Stool samples should be collected only in transport containers without transport media.
4. The RIDA®UNITY Universal Extraction Kit should be used in compliance with regulations on good laboratory practice (GLP). Users must precisely follow the manufacturer's instructions when using this product.
5. Precipitates can form if the storage temperature is below the temperature printed on the label (< 15 °C). They can be dissolved through incubation at 25 °C under occasional gentle shaking.
6. The results obtained must always be interpreted in combination with the complete clinical symptoms.

13. Performance characteristics










The performance of the RIDA®UNITY Universal Extraction Kit was verified through purification of stool and culture samples and with RIDA®UNITY PCR Kits.

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

RIDA®UNITY Cartridge	Cartridge
RIDA®UNITY Magnetic Beads	Magnetic beads
Re-Sealing Foil	Re-sealing film

16. References

Not applicable

17. Troubleshooting

Possible problems:

1. Purity of nucleic acids and low yield

Possible causes	Solution
<ul style="list-style-type: none">Incomplete lysis	<ul style="list-style-type: none">Precipitates can form if the storage temperature is below the temperature printed on the label (< 15 °C). They can be dissolved through incubation at 25 °C under occasional gentle shaking.For reuse, adhere the resealing film (provided in the kit) to the cartridge immediately after the extraction run to prevent evaporation.After the expiration date, the quality guarantee is no longer valid and the kit may no longer be used.
<ul style="list-style-type: none">Incomplete homogenization of magnetic beads	<ul style="list-style-type: none">Prior to use, the magnetic bead vials (RIDA®UNITY Magnetic Beads) must be thoroughly vortexed for at least 60 seconds until fully homogenized.
<ul style="list-style-type: none">Improper sample preparation	<ul style="list-style-type: none">Prepare samples according to Section: Collection and storage of samples.
<ul style="list-style-type: none">Frozen samples were not thawed or mixed	<ul style="list-style-type: none">Completely thaw frozen samples and then mix.
<ul style="list-style-type: none">Improper storage and/or improper resealing of reagents	<ul style="list-style-type: none">Dispose of the reagents (see Section: Warnings and precautions for the users).Store the reagents according to Section: Storage instructions. For reuse, adhere the resealing film (provided in the kit) to the cartridge immediately after the extraction run.

2. Precipitates in the reagents of the cartridge

Possible causes	Solution
<ul style="list-style-type: none"> Store cartridge at < 15 °C. 	<ul style="list-style-type: none"> Precipitates can form if the storage temperature is below the temperature printed on the label (< 15 °C). They can be dissolved through incubation at 25 °C under occasional gentle shaking. For reuse, adhere the resealing film (provided in the kit) to the cartridge immediately after the extraction run to prevent evaporation. After the expiration date, the quality guarantee is no longer valid and the kit may no longer be used.
<ul style="list-style-type: none"> Heavy evaporation due to improper use and/or improper resealing can alter the concentrations in the reagents. 	<ul style="list-style-type: none"> Dispose of the reagents (see Section: Warnings and precautions for the users). For reuse, adhere the resealing film (provided in the kit) to the cartridge immediately after the extraction run to prevent evaporation.

3. Samples commonly rejected by the RIDA®UNITY System

Possible causes	Solution
<ul style="list-style-type: none"> Solids in the sample or high sample viscosity 	<ul style="list-style-type: none"> Prepare samples according to Section: Collection and storage of samples.
<ul style="list-style-type: none"> Insufficient sample volume 	<ul style="list-style-type: none"> Prepare samples according to Section: Collection and storage of samples to prevent insufficient sample volume.