RIDA®TUBE Calprotectin

REF GZ3016

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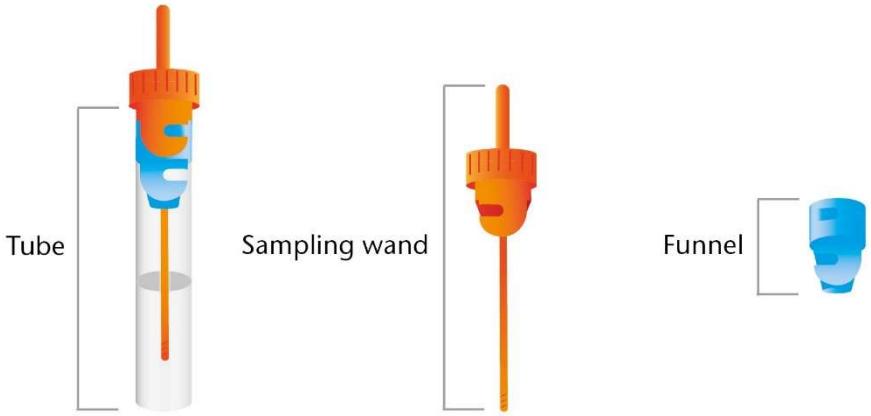
1. Intended use

For in vitro diagnostic use. RIDA®TUBE Calprotectin is intended for the collection, homogenization, and extraction of untreated human stool samples and is used as IVD equipment for the RIDASCREEN® Calprotectin ELISA G09036.
The product is intended for professional use.

2. Summary and explanation of the accessories

A RIDA®TUBE Calprotectin consists of the following parts:
- Tube
- Sampling wand with sampling tip
- Funnel

Components:



3. Reagents provided

One package contains 50 stool collection tubes, each filled with 2.5 mL buffer.

4. Storage instructions

Please follow the handling guidelines in Table 1 and store the kit directly after use according to the information specified. After the expiration date, the quality guarantee is no longer valid. Microbial contamination or mixing of the products with one another can render the products unusable.

Table 1: Storage conditions and information

	Storage temperature	Maximum storage time	Additional notes on storage
unopened	2°- 8 °C	Can be used until the printed expiration date	-
opened	-	-	Not applicable because the RIDA®TUBE Calprotectin should not be stored after opening.

5. Reagents required but not provided

5.1. Laboratory equipment

The following equipment is needed for preparing samples using the RIDA®TUBE Calprotectin tubes:

Equipment
Vortex mixer
Inoculation loop (optional)
Wooden applicator sticks

6. Warnings and precautions for the users

This test must be carried out only by qualified laboratory personnel.
The guidelines for working in medical laboratories (good laboratory practice) 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. Patient samples should be treated as potentially infectious. Do not smoke, eat, or drink in areas where samples are handled.
The extraction buffer contains guanidinium chloride and sodium azide. Avoid contact with skin or mucous membranes.

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/.

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

For users in the European Union: Report all serious adverse events associated with the product to R-Biopharm AG and the appropriate national authorities.

7. Collection and storage of samples

Collect stool samples in clean standard containers. Do not collect the stool samples in transport containers that contain transport media with preservatives or fixatives, animal sera, metal ions, oxidizing agents, or detergents since such substances can interfere with the RIDASCREEN® Calprotectin test.

Follow the sample storage instructions in Table 2. The stool samples should be transported chilled, if possible, and stored at 2 - 8 °C until the start of the test.

Table 2: Sample storage

Native stool sample		Note
23 °C (room temperature)	is not recommended	-
2 - 8 °C	1 - 2 days	-
-20 °C	is not recommended	Freezing the stool samples can cause neutrophils present in the stool sample to burst and release calprotectin. As a result, the determination of the concentration can produce different results in frozen samples compared with fresh samples. Avoid repeated freezing and thawing of the sample.
Sample in the RIDA®TUBE		**Note**
23 °C (room temperature)	is not recommended	-
2 - 8 °C	2 days	-
-20 °C	is not recommended	-

Particle-free supernatant from the RIDA®TUBE		Note
23 °C (room temperature)	2 days	-
2 - 8 °C	2 days	-
-20 °C	is not recommended	-

7.1. Liquid stool

If the stool sample is liquid, use the pipette to take 10 µL of the stool sample and pipette directly into the extraction buffer.

7.2. Very solid stool

Very solid stool should be thoroughly homogenized, e.g., using a wooden stick or an inoculation loop, prior to transfer into the stool collection tube.
Make sure the stool is fully removed from the grooves. If the stool is very hard, it is, therefore, recommended-in addition to vortexing-to tap the tube lightly against a solid surface until the stool comes loose from the grooves.

8. Test procedure

8.1. General information

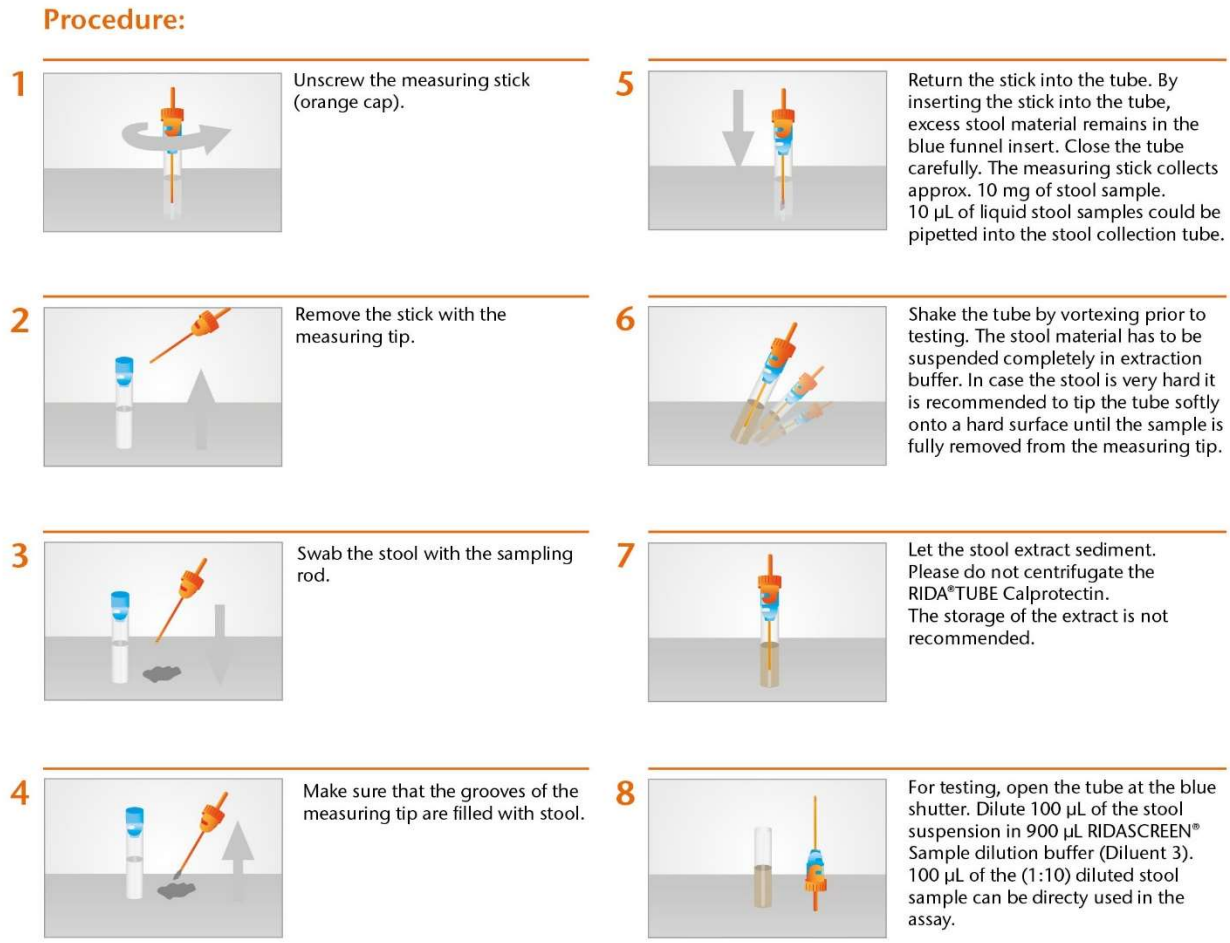
Prior to collection, stool samples should have reached room temperature (20 - 25 °C) and be homogenized, e.g., through stirring with an inoculation loop or a wooden stick.
When transferring the sample into the stool collection tube, make sure that the grooves in the sampling tip are completely filled with stool. No stool should be on the wand of the sampling tip.
Once used, the stool collection tubes must not be reused. Also, do not use stool collection tubes if the packaging is damaged or the vials are leaking. The test must not be carried out in direct sunlight.

8.2. Sample collection using stool collection tubes - procedure

1. Turn the sampling wand with the sampling tip (orange cap) counterclockwise.
2. Remove the stick with the measuring tip.
3. Dip the sampling tip into the stool sample at three different places.
4. Make sure that the grooves on the sampling tip are filled with stool.
5. Place the wand with the sampling tip back into the tube. Excess stool sample remains in the blue funnel. Close the tube by turning the cap clockwise. The sampling tip holds 10 mg stool sample. If the stool sample is liquid, use the pipette to take 10 µL of the stool sample and pipette directly into the extraction buffer.
6. Before the start of the test, vortex the tube until the stool sample from the sampling tip is completely suspended in the extraction buffer. If the stool is very hard, it is recommended to tap the tube lightly against a solid surface until the stool is removed from the grooves.
7. Allow the extracts to sediment for 30 min. Do not centrifuge the RIDA®TUBE Calprotectin. For the shelf life of the suspension, see Section 7. Collection and storage of samples.
8. To start the test, screw the tube onto the blue bayonet lock. Dilute 100 µL of the particle-free extraction buffer supernatant in 900 µL RIDASCREEN® sample dilution buffer (Diluent 3) (1:10). Then use 100 µL of the final diluted stool sample in the RIDASCREEN® Calprotectin test.

Note: The RIDA®TUBE Calprotectin can also be used on automated 4-plate ELISA systems, e.g., Dynex DSX. If foam forms after vortexing, allow to stand for 30 minutes to avoid any dispensing problems.

8.3. Quick guide



9. Performance characteristics

9.1 Analytical performance characteristics

9.1.1 Analytical sensitivity (LoB, LoD, and LoQ)

See G09036 RIDASCREEN® Calprotectin.

9.2.2 Analytical specificity

For information on cross-reactivity and interfering substances, see G09036 RIDASCREEN® Calprotectin.

9.3.1 Accuracy

Precision

Intra-extraction precision was determined using 4 native stool samples (1 stool sample around the cut-off and 3 stool samples above the cut-off). For each stool sample and tube lot, 20 extractions were performed, in which 1 new tube was used for each extraction. Each extract was tested with one replicate by 1 technician on the

same day using 2 RIDA®TUBE Calprotectin lots and 1 RIDASCREEN® Calprotectin lot. The kit controls were measured during every run to assess assay validity.

Reference Mean value / CV		Intra-extraction precision	
		Evaluation using the calibrator	Evaluation using the standard curve
	Tube lot 21310:		
1	Mean value [mg/kg]	51.62	48.34
	CV (%)	11.06	11.38
2	Mean value [mg/kg]	80.45	75.25
	CV (%)	7.19	7.77
3	Mean value [mg/kg]	209.49	201.34
	CV (%)	4.73	4.61
4	Mean value [mg/kg]	415.46	427.71
	CV (%)	4.19	4.46
	Tube lot 24421:		
1	Mean value [mg/kg]	53.04	49.71
	CV (%)	11.09	11.41
2	Mean value [mg/kg]	79.98	74.77
	CV (%)	6.02	6.50
3	Mean value [mg/kg]	212.63	204.28
	CV (%)	5.85	5.67
4	Mean value [mg/kg]	418.18	430.70
	CV (%)	4.20	4.47

For information on trueness and linearity, see G09036 RIDASCREEN® Calprotectin.

10. Version history

Version number	Section and designation
2019-07-01	Previous version
2022-04-08	General revision 1. Intended use 2. Summary and explanation of the accessories 3. Reagents provided 4. Storage instructions 5. Reagents required but not provided 6. Warnings and precautions for the users 7. Collection and storage of samples 8. Test procedure 9. Performance characteristics

11. 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


Do not reuse