RIDA®TUBE Calprotectin

REF GZ3016

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1. Intended use

For in vitro diagnostic use. RIDA®TUBE Calprotectin is used for collecting and homogenizing human stool samples in the laboratory and is an accessory for RIDASCREEN® Calprotectin ELISA G09036.

2. Reagents provided

One package contains 50 buffer-filled stool collection tubes.

3. Description of the stool collection tube

A RIDA®TUBE Calprotectin consists of the following parts:
- Tube
- Measuring stick with measuring tip
- Funnel

4. Storage

The stool collection tubes must be stored at 2 – 8 °C.

5. Necessary equipment

Vortexer, inoculation loop or wooden stick

6.Precautions for users

For *in-vitro* diagnostic use only.

We do not recommend centrifuging RIDA®TUBE calprotectin.
Stool samples should be handled as potentially infectious material.

For further details, see the safety data sheets (SDS) at www.r-biopharm.com.

7. Collection and storage of samples

The stool samples should be transported chilled if possible and stored at 2 – 8 °C before testing. If the samples are not used immediately after receipt (within 3 days), we recommend storage at -20 °C or lower. Avoid freezing and thawing the sample repeatedly.

7.1. Liquid stool

If the stool sample is liquid, 10 µl of the stool sample can be taken using the pipette and pipetted 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, we therefore recommend – in addition to vortexing – tapping the tube lightly against a solid surface until the stool come loose from the grooves.

8. Sample preparation

Prior to extraction, stool samples should have reached room temperature (20 – 25 °C) and been homogenized, e.g., with an inoculation loop or a wooden stick. When transferring the sample into the stool tube, make sure that the grooves in the dosing tip are completely filled with stool. No stool should be on the stick of the measuring tip.
Before the start of the test, the tube is vortexed until the stool sample from the measuring tip is completely suspended in the extraction buffer.

9. Collecting samples with the stool collection tube – instructions

9.1. General information

1. Turn the measuring stick with the measuring tip (orange cap) counterclockwise.
2. Remove the stick with the measuring tip.
3. Dip the measuring tip into the stool sample at three different places.
4. Make sure that the grooves on the measuring tip are filled with stool.
5. Place the stick with the measuring tip back into the tube. Excess stool sample remains in the blue funnel. Close the tube by turning the cap clockwise. The measuring tip collects approx. 10 mg of stool. If the stool sample is liquid, 10 µl of the stool sample can be taken using the pipette and pipetted directly into the extraction buffer.

6. Before the start of the test, the tube is vortexed until the stool sample from the measuring tip is completely suspended in the extraction buffer. If the stool is very hard, we recommend tapping the tube lightly against a solid surface until the stool is removed from the grooves.
7. Allow the extracts to settle. RIDA®TUBE Calprotectin should not be centrifuged. The stool extracts should not be stored but must be used in the test immediately after dilution. Suspension shelf life (see 10. Storage of the extract).
8. To start the test, screw the tube onto the blue bayonet lock. Dilute 100 µl of the stool suspension in 900 µl RIDASCREEN® Sample Dilution Buffer (Diluent 3) (1:10). 100 µl of the final diluted stool sample can then be used in the test.

Note: 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.

10. Storage of the extract

The calprotectin concentrations in the extraction buffer of RIDA®TUBE Calprotectin (GZ3016) are not stable over a storage period of 7 days at 4 °C in all stool samples examined. We therefore recommend using the fresh extracts immediately in the test.

11. Precision data

11.1. Comparison of the sample extraction using a sample tube versus weighing

39 stool samples ranging in concentration from 19.50 to 800.00 mg/kg were measured using RIDASCREEN® Calprotectin. As described in the IFU, the stool volume was either weighed o sampled using the RIDASCREEN® Stool Tubes (GZ3006). The concentrations determined for both methods were compared, and a correlation coefficient (r^2) of $r^2 = 0.99$ was determined (see Fig. 1).

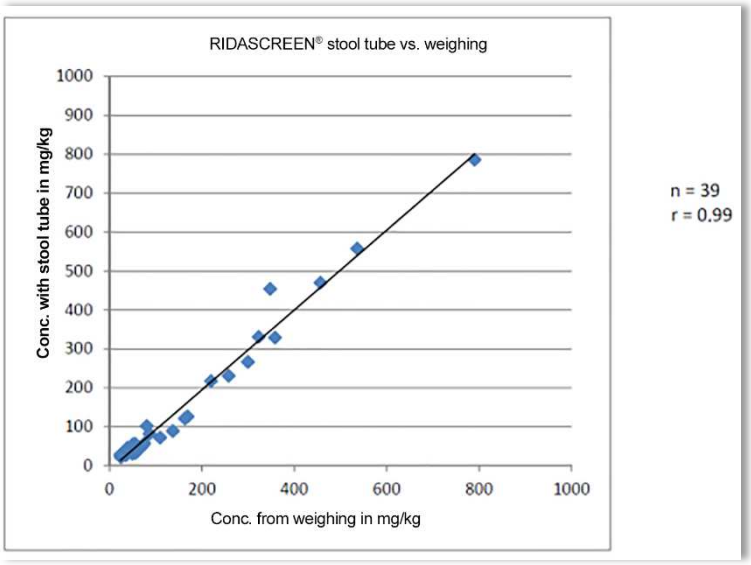

Fig. 1: Correlation of calprotectin concentrations after collection via the RIDASCREEN®Stool Tubes or weighing. The correlation coefficient is $r^2 = 0.99$.

The correlation coefficient of $r^{2=}$ 0.99 demonstrates the high agreement of the results of sampling using the RIDASCREEN® Stool Tubes and sampling by weight.

11.2. Equivalence between RIDASCREEN® Stool Tubes (GZ3006) and RIDA®TUBE Calprotectin (GZ3016)

40 stool samples ranging in concentration from 19.50 to 800.00 mg/kg were measured using RIDASCREEN® Calprotectin. As described in the IFU, the stool volume was collected using RIDA®TUBE Calprotectin (GZ3016) or the RIDASCREEN® Stool Tubes (GZ3006). The concentrations determined for both methods were compared, and a correlation coefficient (r) of $r^2 = 0.96$ was determined.
The correlation coefficient of $r^{2=}$ 0.96 demonstrates the high agreement of the results of sampling using the RIDASCREEN® Stool Tubes (GZ3006) and RIDA®TUBE Calprotectin (GZ3016).
The equivalence data clearly show the very high correlation between sampling by weighing and the RIDASCREEN® Stool Tubes, as well as between the RIDASCREEN® Stool Tubes and RIDA®TUBE Calprotectin.
This demonstrates that RIDA®TUBE Calprotectin is also suitable for sample preparation with RIDASCREEN® Calprotectin.

12. Version history

Version number	Chapter and designation
2019-07-01	General revision 14. Version history 15. Explanation of symbols

13. Explanation of symbols

General symbols

IVD	For in vitro diagnostic use
	Consult instructions for use
LOT	Lot number
	Expires
	Store at
REF	Article number
	Number of tests
	Date of manufacture
	Manufacturer