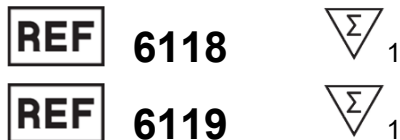


Calprotectin Rapid



Rapid immunochromatographic test for the determination of calprotectin in human stool samples



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1 Intended Purpose

The Calprotectin Rapid is a qualitative immunoassay for the determination of Calprotectin in human stool samples.

The Calprotectin Rapid intended as an aid in the diagnosis of inflammatory bowel disease in conjunction with other clinical and laboratory findings.

The immunoassay is designed for manual professional *in vitro* diagnostic use.

2 Diagnostic Relevance

Fecal calprotectin is a known marker of inflammatory bowel disease. Calprotectin is a heteromeric protein molecule comprised of the two subunits MAPS and MRP14. Calprotectin is predominantly located in cytoplasmic neutrophil granulocytes, comprising around 60% of the soluble proteins. The molecule is released following activation of neutrophils, and plays a central role in the immune response. Released calprotectin is found in the serum, bodily fluids and feces, and acts as a marker of inflammation. Fecal calprotectin is regarded as a surrogate marker of neutrophil entry into the intestinal lumen. Calprotectin thus allows a reliable differentiation between organically induced intestinal diseases and functional intestinal disorders (eg. Irritable bowel syndrome).

The measurement of fecal calprotectin can be used in the therapy and follow up control, as well as for prediction of relapse in patients with inflammatory bowel disease. Calprotectin can also be used as a positive predictive marker for the presence of invasive pathogens, and therefore as a screening parameter for infectious diarrhea (discrimination between organic and functional diarrhea). Likewise, increased concentrations of

calprotectin are found in the stool with colorectal neoplasia and adenomatous polyps.

3 Test Principle

Rapid immunochromatographic assays are widely used for the determination of specific antigens. If antigens are present in the patient's sample, they are recognized by to color-coded antigen-specific antibodies. The generated immune complex migrates through the test strips by capillarity. The test strips are coated with additional antigen-specific antibodies. If antigens are present in the patient's sample, the formed immune complex bind to the antibodies and colored bands become visible on the test strip. The signal intensity of the reaction product is proportional to the antigen concentration in the sample.

4 Test Components

Component 1 (10) Determination(s)	Description
Test cassette CASSETTE 1 (10) item(s)	Test cassette (ready-to-use), separately sealed; coated with mouse monoclonal antibodies against calprotectin and contains color-coded antibodies against calprotectin
Stool sample container BUF 1 (10) item(s)	Stool sample container incl. buffer solution (ready-to-use; contains sodium azide) and spiral rod
Instructions for Use 1 piece	-

5 Materials required but not provided

- Common laboratory equipment
- Timer

6 Storage and Stability

Upon receipt, all test components must be stored at 2 °C to 30 °C, preferably in the original kit box. If stored properly in their original containers, all components are stable until their expiry date indicate on the label. After opening all kit components are stable for at least 3 months, if stored properly.

7 General Information

This product is for *in vitro* diagnostic use only. The instructions for use must be carefully read before use. They are valid only for the present product with the given composition and must be strictly followed to ensure reliable test results. Deviations can lead to erroneous test results. Components must not be exchanged by test reagents of different lots or of other manufacturers.

8 Preparation

8.1 Preparation of Reagents

All components including the microtiter plate must be brought to room temperature (RT: 18 °C to 25 °C) before use for at least 30 min. All liquid components are ready-to-use.

8.2 Preparation of Samples

8.2.1 Sample Collection

The use of freshly collected stool samples is recommended.

Collect 1 to 2 g of stool sample (1 to 2 mL in case of liquid sample). Use a separate specimen collection vial for each sample. Unscrew the cap of the vial and introduce the stick three times

into the fecal specimen to pick up the sample. This vial with the sample can be stored at 2 °C to 8 °C for 5 days.

8.2.2 Sample Preparation

Allow frozen or refrigerated fecal samples to reach room temperature before use. Shake the test tube in order to assure good sample dispersion.

8.2.3 Sample Storage

Samples may be kept at 2 °C to 8 °C up to 7 days. Long-term storage, maximum 1 year, requires -20 °C. Repeated freezing and thawing should be avoided.

9 Test Performance

9.1 Procedure

All components including the test strips must be brought to room temperature (RT: 18 °C to 25 °C) before use for at least 30 min. The test cassette should be used immediately after the opening of the aluminum packaging. All liquid components must be mixed gently to ensure homogeneity.

Step

1. Carefully break off the tip of the stool sample container (avoid splashing) and add exactly 4 drops or 100 µL of the extracted sample to the specimen well (s) on the right side of the cassette.

2. Read the results after exactly 10 min.

It is possible that weak bands become visible after drying of the test window; in these cases results should be read again after additional 10 min.

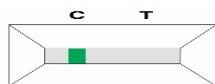
10 Test Evaluation

10.1 Metrological Traceability

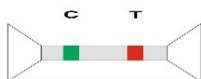
The immunoassay is calibrated using an internal reference sample.

10.2 Evaluation

A sample is evaluated negative, if only the green control line appears in the control region C of the test strip.



A sample is evaluated positive, if, in addition to the green control line, a distinguishable red line appears in the test region T of the strip.



A total absence of the control line, regardless of the appearance of any test line T, results in an invalid test run.



10.3 Criteria of Validity

Test runs are only valid if the following criteria of validity are fulfilled:

- The control line C must be clearly visible. A total absence of the control line, regardless of the appearance of any test line T, results in an invalid test run.

If these criteria are not met, the test is not valid and must be repeated.

10.4 Troubleshooting

In case of an invalid test run, the expiry dates and storage conditions, incubation times and temperatures, sample volume and test performance should be verified. If no reason for an invalid test run could be identified, please contact the supplier or manufacturer of the product.

10.5 Interpretation of Test Results

A positive test result indicates the presence of specific antigens. A negative result indicates the absence of specific antigens.

10.6 Limitations of the Method

The Calprotectin Rapid test allows a qualitative measurement of calprotectin in stool samples. A quantitative measurement, or detection of concentration changes, is not possible.

Samples containing particles can lead to false results (appearance of brown bands in the result window).

Although the test detects calprotectin with a high reliability, in some cases false results can occur. With inconclusive results, further clinical tests should be performed.

The interpretation of test results must always be considered in combination with the clinical picture of the patient. The diagnosis should not be based on the results of a sole diagnostic method. All clinical and laboratory findings should be evaluated to state a diagnosis. For confirmation, further investigations should be carried out.

11 Performance Characteristics

11.1 Analytical Performance Characteristics

11.1.1 Analytical Sensitivity and Specificity

The analytical sensitivity was assessed to 500 ng/mL calprotectin.

11.1.2 Precision

The precision of test results was assessed by the determination of the intra- and interassay variation by the analysis of multiple samples with different antibody activities. No differences in the qualitative evaluation have been detected.

11.2 Diagnostic Performance Characteristics

11.2.1 Diagnostic Sensitivity and Specificity

Sensitivity and specificity were assessed by the analysis of 64 clinical specimens from local hospital using a Calprotectin Elisa from a leading manufacturer as a reference test.

Diagnostic Performance	
Sensitivity	96.9 %
Specificity	85.4 %

12 Warnings and Precautions

The product is designed exclusively for *in vitro* diagnostic use by qualified, authorized and trained personnel. All test components and human samples should be handled with care as potentially hazardous. Good laboratory practices (GLP) and all relevant regulations should be adhered to.

In case the product is damaged or product information including labelling is wrong or incorrect, please contact the manufacturer or supplier.

This product contains preparations of human and / or animal origin. Any material derived from human body fluids or organs used for the preparation of components were tested and found negative for HBsAg (Hepatitis B-Virus-surface Antigen) and anti-HIV as well as anti-HCV antibodies. However, all components and all patient samples should be handled as potentially hazardous in accordance with national laws and appropriate guidelines on biological safety.

As the product contains potentially hazardous materials, the following precautions should be followed: Do not smoke, eat or drink while handling kit material or samples. Avoid direct contact

to kit material or samples by wearing protective gloves laboratory coat and safety glasses. Never pipette material by mouth. Wipe up spills promptly and wash the affected surface thoroughly with a decontaminant. Wash hands thoroughly after use.

Some of the reagents contain sodium azide (< 0.1 %) as a preservative and must not be swallowed or allowed to come into contact with skin or mucosa. The possible formation of heavy metal azides in the drainage has to be prevented by sufficient rinsing with water.

The information in the safety data sheet on possible hazards, first aid measures, measures in the event of the unintentional release of large quantities, handling and storage, personal protective equipment, information on disposal as well as information on toxicology must be observed.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the member state in which the user and/or the patient is established.

13 Disposal

For decontamination and disposal the recommendations of the CDC as well as the relevant local and national environmental guidelines and regulations should be adhered to. Samples, potentially contaminated materials and infectious waste must be decontaminated, e.g. by autoclaving for 20 min. at 121 °C.

14 References

- Striz I, Trebichavsky I: Calprotectin - a Pleiotropic Molecule in Acute and Chronic Inflammation. *Physiol. Res.* 2004, 53, 245 - 53.

- Tibble J, Sigthorsson G, Foster R, Sherwood R, Fagerhol M, Bjarnason I: Faecal calprotectin and faecal occult blood tests in the diagnosis of colorectal carcinoma and adenoma. *Gut* 2001, 49, 402 – 8.

- Schirmmacher S, Naumann M, Caspary WF, Stein J: Prospektive Validierung fäkaler Leukozytenmarker in der Differentialdiagnose der chronischen Diarrhoe. *Z Gastroenterol.* 2004, 42, P012.

15 Symbols

	Manufacturer
	CE marking of conformity
	Not for near patient testing
	<i>In vitro</i> diagnostic medical device
	Catalogue number
	Unique device identifier
	Batch code
	Temperature limit
	Use-by date
	Consult instructions for use
	Contains sufficient for <n> tests
	Do not re-use
	Caution
	Biological risk
	Keep away from sunlight
	Test cassette
	Extraction buffer

16 Changes

Changes in current Instructions for Use	
Current Version	003/01.2023
Summary of Changes	Editorial changes in all sections