



# INSTRUCTION MANUAL

REF 6119

June 23, 2014

## Calprotectin Rapid

10 determinations



IVD *In-vitro* diagnostic device

Immunochromatographic rapid test for the measurement of human calprotectin in stool samples

<b>REF</b>	Catalogue number	<b>LOT</b>	Batch code
	Consult accompanying documents		Manufactured by
	Temperature limitation		Use by
	Consult operating instruction		Biological risk



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### INTENDED USE

**Calprotectin Rapid is used for the qualitative determination of human calprotectin in stool samples.**

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.

This acute-phase protein demonstrates a high stability in the stool (up to 1 week at room temperature).

Striz I, Trebichavsky I: Calprotectin - a Pleiotropic Molecule in Acute and Chronic Inflammation. *Physiol Res* 2004, 53, 245-253  
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, 402-408  
Schirmacher S, Naumann M, Caspary WF, Stein J: Prospektive Validierung fäkaler Leukozytenmarker in der Differentialdiagnose der chronischen Diarrhoe. *Z Gastroenterol* 42, 2004, P012

### PRINCIPLE OF THE TEST

Calprotectin Rapid is a one-step immunochromatographic assay for the detection of human calprotectin in stool samples, based on latex conjugated monoclonal anti-calprotectin antibodies. A control band indicates the correct performance of the test.

### TEST COMPONENTS

The Calprotectin Rapid test kit contains the following components for the performance of a calprotectin measurement:

1. **Test cassette (in aluminium packaging)**
2. **Instruction manual**
3. **Stool sample container incl. Buffer solution and spiral rod**

### Materials required in addition

- Stop clock

### Storage and stability

The expiration date of the test is shown on the label. After this expiration date, the test must not be used.

Prior to use, the test cassette is to be stored at 4-30 °C. The reading time specified is based on performance of the test at 15 - 30 °C. If stored refrigerated, bring the test cassette to room temperature before use.

The test cassette is sensitive to humidity and high temperatures. Therefore the test should be protected from heat and used immediately after opening of the aluminum packaging.

## PATIENT SAMPLES

### Specimen collection

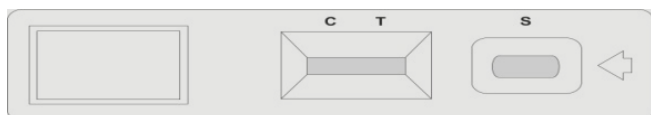
Collect sufficient quantity of faeces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-4°C/36-40°F) for 7 days prior to testing. For longer storage the specimen must be kept frozen at -20°C/-40°F. In this case, the sample will be totally thawed, and brought to room temperature before testing.

### Specimen preparation

1. 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. Close the vial with the buffer and stool sample. This vial with the sample can be stored during 5 days.
2. Shake the vial in order to assure good sample dispersion.
3. For liquid stool samples, aspirate the fecal specimen with a dropper and add approx. 10-20µL into the specimen collection vial with buffer.

## TEST PROCEDURE

4. Bring the test cassette to room temperature, remove it from the aluminum packaging and mark it with the name of the patient. The test cassette should be used immediately after the opening of the aluminum packaging.
5. If cooled, bring sample container with the patient sample to room temperature, shake again.
6. Carefully break off the tip of the stool sample container (avoid splashing) and add exactly **4 drops** or 100µl of the extracted sample to the specimen well (s) on the right side of the cassette.
7. Read the results after exactly **10 minutes**.  
It is possible that weak bands are only visible after drying of the test window; in these cases results should be read again after a further 10 minutes.



Test cassette

## INTERPRETATION OF RESULTS

### Interpretation of the test

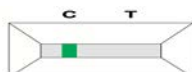
When the test has been processed correctly, the left hand side of the result window will show a green colored band as a control of test validity (C = control band). With a positive calprotectin concentration in the sample, a red band appears to the right of the control band (T = test band).

### Interpretation of the test results

After performing the test, the following statements can be made according to the colored bands visible:

1. Only the control line C is visible

#### Negative result- calprotectin not detectable



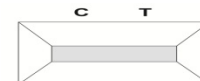
2. Only the test line (T) is visible

#### The test is invalid



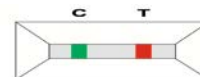
3. Neither test line T or control line C visible  
0

#### The test is invalid



4. Control line C and test line T visible

#### Positive result - calprotectin detectable (concentration >50 µg/g)



### 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.

A clinical diagnosis should not be made on the results of in vitro diagnostic methods alone. Doctors should consider all clinical and laboratory results possible to state a diagnosis.

## ASSAY CHARACTERISTICS

### Analytical Sensitivity

A sample containing calprotectin at concentration equal to or higher than 50µg/g faeces produces positive results when using Calprotectin Rapid.

### Diagnostic Specificity

This rapid test utilizes specific antibodies against human calprotectin. Cross reactivity with calprotectin of other origins does not occur.

### Comparison with Reference Methods

Upon comparison with another commercial rapid test, a relative sensitivity of 94% and a relative specificity of 93% was found.

## SAFETY PRECAUTIONS

- This kit is for in-vitro use only, and must be performed by trained laboratory personnel. The instruction manual is to be followed strictly.
- The test kit must only be used before the stated expiry date.
- Samples, test components and contaminated material must be treated as potentially infectious, and disposed of accordingly.
- When handling the components of this kit, as well as patient samples, observe all regulations relating to accident prevention with potentially infectious materials. The following rules in particular should be followed:
  - Do not eat, drink or smoke!
  - Never pipette by mouth!
  - Wear gloves to avoid contact with reagents and samples!