Additional information

- Manual
- Medical information
- Literature
**PreventID® CalScreen® (KST11004)**

The PreventID® CalScreen® is an immunological rapid test for the detection of calprotectin in faeces. The determination of calprotectin in stool allows the differentiation between organic intestinal diseases (e.g. chronic inflammatory diseases, infectious diseases, polyps, colon cancer) and functional intestinal diseases (e.g. irritable bowel syndrome). The determination of calprotectin is also ideal for monitoring disease activity (e.g. of M. Crohn or after polyp resection), early detection of relapse and for therapy monitoring.

**The use of this test with a cut-off at 50 µg/g calprotectin enables the rapid screening of patients with chronic intestinal problems and the differentiation in inflammatory (≥50 µg/g) and non-inflammatory (<50 µg/g) diseases.**

Calprotectin (MRP 8/14) is present in the cytoplasm of neutrophils and plays a central role in immune defense. Upon neutrophil activation or endothelial adhesion of monocytes, calprotectin is released and may be detected in serum, body fluids or stool as a potentially useful clinical inflammatory marker. The acute phase protein shows a high stability in faeces (stable for one week at room temperature) and has been established as a faecal marker of inflammatory bowel diseases (IBD). It allows a reliable differentiation between organic intestinal diseases (e.g. chronic inflammatory diseases, infectious diseases, polyps, colon cancer) and functional intestinal diseases (e.g. irritable bowel syndrome).

Calprotectin is ideal for monitoring disease activity (e.g. of M. Crohn or after polyp resection) and early detection of relapse. Furthermore, calprotectin can discriminate between an organic diarrhoea and a functional diarrhoea.

**Principle**

The test device is composed of a sample well and a result window. In the result window one or two colored lines can be seen after the test has been performed.

**Materials Provided**

One PreventID® CalScreen® test kit contains the following items to perform the test:

1. PreventID® CalScreen® test device (with drying agent, not required for test)
2. Sample collection device with extraction buffer solution and sample collection stick
3. Paper faecal sample collection strip
4. Instruction sheet for sample collection

**Materials required but not provided**

Timer or stop watch

**Reagent Storage**

Store all reagents at 4 – 30°C. Beware: The interpretation time is based on reading the test results at room temperature (15 – 30°C). If the test device or the extraction buffer were stored at lower temperatures make sure they are at room temperature before starting the test. All reagents are provided ready to use.

**Precautions**

1. For in vitro diagnostic use only.
2. Do not use beyond the expiration date.

3. Do not open the aluminium-laminated wrapper until you are ready to perform the test.
4. Do not use test device if the aluminium pouch is torn or if the membrane of the rapid test device is visibly damaged.
5. Used test devices, sample diluent, and sample collection device should be disposed of according to appropriate guidelines of biohazardous waste.
6. If you have questions please contact the manufacturer.

**Specimen collection**

1. The faecal sample is directly collected in flat-pan toilets or in the case of funnelled toilets according to the printed instructions on the paper sample collection strips.
2. Unscrew the cap of the sample collection device and stick the attached sample collection stick in one go at three different sites into the faeces. Only the amount of stool that sticks to the grooves of the sample collection stick should be transferred to the sample collection device.
3. Now retract the sample collection stick with the adhering faecal sample and insert it only once into the sample collection device containing an extraction buffer solution.

Please note: A repeated transfer of stool into the sample collection device compromises the test performance!
4. Screw cap on firmly and shake well. This defined stool sample solution is now ready to use for the test.
5. If PreventID® CalScreen® rapid test is not run within one day of sample collection, the sample collection device should be stored at 2 – 8°C, but not longer than 7 days.

**Test procedure**

1. Remove the test device from the pouch and place it on a flat dry surface. The round sample opening at the one end of the test device should be at the right side (Fig. 1). Label the device with patient name or identification number. Use test device immediately.
2. If necessary, bring sample collection device to room temperature after sample collection and shake again.
3. After the sample collection procedure has been completed, break off the tip of the sample collection device carefully (avoid dripping). Squeeze 3 drops of the extracted sample into the sample opening on the right side of the test device (by gently pressing the sample tube of the middle).
4. In a properly working test, a violet band will pass through the square result window in the middle of the test device.
5. The result should be interpreted **10 minutes** after the last drop has been placed.

**Fig. 1: PreventID® CalScreen® Test Device**
Interpretation of the test result

A solitary red control band (C) in the result window indicates that the test has run correctly. Depending on the Calprotectin concentration, a test band (T) will appear to the right of the control band (s. Fig. 2a-c).

Positive:
Calprotectin-concentration ≥50 µg/g: Control band (C) and test band (T) are visible (s. Fig. 2a). An intestinal inflammation has been detected.

Negative:
Only the red control band (C) appears (s. Fig. 2b). The test has run correctly, no intestinal inflammation has been detected.

Invalid:
The test is invalid if no control band (C) appears, even if a test band (T) is visible (s. Fig. 2c).

Limitations of the Test

Although the PreventID® CalScreen™ is very accurate in detecting calprotectin, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

References:

Short Instruction for the handling of the PreventID® CalScreen®

1. Collect the faecal samples with the aid of the sample collection device and the sample collection stick as described in the instruction.
2. Shake the solution in the sample collection device very thoroughly. Unpack the test unit.
3. Break off the tip of the sample collection device carefully.
4. Squeeze 3 drops of the extracted sample into the round sample opening.
5. Read the findings of the test after 10 minutes.

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Irritable Bowel Syndrome or Inflammatory Bowel Disease?

PreventID® CalScreen®
Rapid test for the determination of calprotectin in faeces*

PreventID® CalScreen is a qualitative immunochromatographic test for the determination of faecal calprotectin. Calprotectin is an established faecal marker of inflammatory bowel diseases (IBD). The parameter enables the differentiation between organic and functional intestinal diseases. The rapid test with only one cut-off at 50 µg/g is ideal for first-line screening of patients with chronic intestinal problems in primary care.

Calprotectin (MRP 8/14) is present in the cytoplasm of neutrophils and expressed by the membranes of monocytes. It constitutes nearly 60% of the soluble cytosol proteins in neutrophils and plays a central role in neutrophil defense. Upon neutrophil activation or endothelial adhesion of monocytes, calprotectin is released and may be detected in serum, body fluids or stool as a valuable inflammatory marker. Faecal calprotectin indicates neutrophil invasion in the intestinal lumen. The determination of this acute phase protein has been established as a marker of intestinal bowel diseases (IBD). Calprotectin allows a reliable differentiation between organic intestinal diseases (e.g. chronic inflammatory diseases, infectious diseases, polyps, colon cancer) and functional intestinal diseases (e.g. irritable bowel syndrome, IBS). In addition, calprotectin serves as a positive predictive marker for invasive pathogens and therefore as a screening parameter for infectious diarrhea.

The cut-off at 50 µg/g enables a reliable classification of patients with chronic diarrhea in inflammatory (≥ 50 µg/g) and non-inflammatory (< 50 µg/g) diseases. This discrimination serves as a swift decision aid for further diagnostic procedures in first-line screening of patients with intestinal problems.

Differentiation between organic and functional intestinal disease

The discrimination between IBS and IBD is often difficult and leads to many unnecessary colonoscopies. Faecal calprotectin is elevated in gastrointestinal diseases of infectious or neoplastic origin, but not in IBS. The parameter is therefore ideal for the differentiation of organic and functional intestinal diseases (Tibble et al. 2000, Tibble et al. 2002). The PreventID® CalScreen® enables the quick identification of inflammatory diseases (caused e.g. by IBD, infections, polyps or colon carcinoma).

Indications for the determination of Calprotectin:
- Differentiation between organic intestinal diseases (e.g. IBD) and functional intestinal diseases (IBS)
- Differentiation between organic diarrhoea and functional diarrhoea
- In patients with IBD symptoms but normal CRP
- In children with suspected IBD, when a colonoscopy is deliberated

* Not for export and sale in the USA
Discrimination between organic and functional diarrhea

Calprotectin is also a discriminating parameter between organic and functional diarrhea as well as a positive predictive marker for infectious diarrhea. Increased calprotectin concentrations may indicate invasive pathogens as causative of diarrhea.

Easy test application of the PreventID® CalScreen®

A faecal sample needs to be collected in the stool sample tube prior to the test application. The dissolved sample is dropped onto the sample window. After a few minutes, the band(s) in the result window can be interpreted.

Interpretation of test results

Positive:

Calprotectin concentration ≥50 µg/g:
An intestinal inflammation has been detected. Elevated levels are indicative of e.g. Crohn’s disease, ulcerative colitis or infectious diarrhea. Further examinations for clarification of the cause are required.

Negative:

Calprotectin concentration <50 µg/g:
An intestinal inflammation has not been detected. Possible disease causes include IBS or food intolerances.

Literature

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