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PreventID® **CalDetect® 50/200**

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PreventID® CalDetect® 50 / 200 (KST11003)

The **PreventID®** ***CalDetect® 50 / 200*** is an immunological rapid test for the determination of calprotectin in faeces. The two cut-offs at 50 and 200 µg/g enable not only the differentiation between inflammatory (≥50 µg/g) and non-inflammatory (<50 µg/g) diseases but also the individual therapy control of patients with inflammatory bowel diseases (IBD). A faecal calprotectin concentration above 200 µg/g in drug-treated IBD patients indicates a relapse and can be utilized to adjust therapy accordingly. A periodic application of the **PreventID®** ***CalDetect® 50 / 200*** in IBD patients is therefore an effective tool for individual therapy control.

Calprotectin (MRP 8/14) is a heteromer of two calcium-binding proteins (MRP8 and MRP 14) present in the cytoplasm of neutrophils and expressed by the membranes of monocytes. It plays a central role in neutrophil defense, when it is released and may be detected in serum, body fluids or stool as inflammatory marker. Faecal calprotectin has been established as marker of inflammatory bowel diseases (IBD). It allows a reliable differentiation between IBD and functional intestinal diseases (e.g. irritable bowel syndrome). In addition, calprotectin is ideal for monitoring disease activity (e.g. of M. Crohn) and for early relapse detection.

Test principle

The test device is composed of a sample well and a result window. In the result window two colored lines enable the determination of calprotectin in the sample.

Materials provided

One **PreventID®** ***CalDetect® 50 / 200*** test kit contains the following items:

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

Materials required but not provided

Timer or stop watch

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. 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 are stored at lower temperatures bring to room temperature before starting the test.
6. Used test devices, sample diluent, and sample collection device should be disposed of according to appropriate guidelines of biohazardous waste.

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 strip.
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 the test is not run on the day of sample collection, the sample collection device should be stored at 2 - 8°C, but no 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 well 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. Break off the tip of the sample collection device carefully (avoid dripping). Squeeze **3 drops** of the extracted sample into the sample well on the right side of the test device (by gently pressing the sample tube in 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.

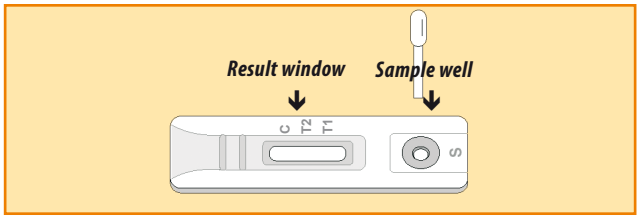

Fig. 1: **PreventID®** ***CalDetect® 50/200*** test device

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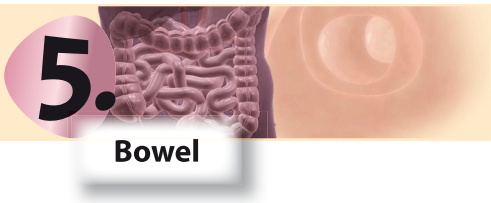
PreventID® *CalDetect® 50 / 200*

Manual (for professional use)



Test interpretation

A solitary red control line (C) in the result window indicates that the test has run correctly. Depending on the concentration of calprotectin in the sample, test bands (T1, T2) will appear to the right of C (Fig. 2).

Negative:
Only the red control band (C) is visible. The test has run correctly, an intestinal inflammation could not be detected.

Positive:
Calprotectin concentration ≥50 µg/g: The control band (C) and the test band T1 are visible. An inflammatory process has been detected.

Calprotectin concentration ≥ 200 µg/g: The control band (C) and both test bands T1 and T2 are visible. A high-grade inflammatory process has been detected.

Invalid:
The test result is invalid if the control band (C) does not appear (even if test bands are visible).

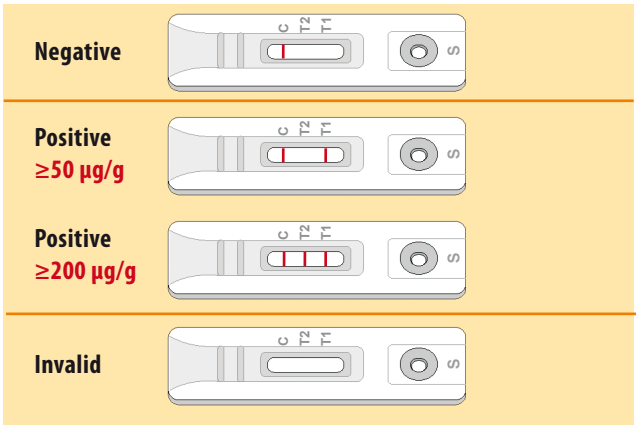


Fig. 2: PreventID® ***CalDetect® 50/200*** test results

Test limitations

Although the **PreventID® *CalDetect® 50 / 200*** is very accurate in detecting calprotectin a low incidence of false results may 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 a physician after all clinical andlaboratory findings have been evaluated.

Literature:

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Gaya DR et al. (2005), QJM 98: 435-441
Schirrmacher S et al. (2004), Z Gastroenterol 42: 785-944 (P013)
Tibble JA et al. (2002), Gastroenterology 123: 450-460
Tibble JA et al. (2000), Gut 47: 506-513

Short instructions for the PreventID® *CalDetect® 50/200*

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. Interpret the test **after 10 minutes**.

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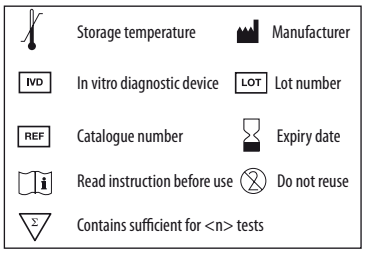

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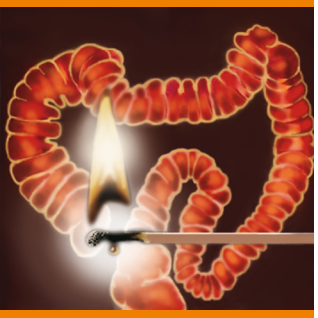

Diagnosis and therapy control of IBD

PreventID® CalDetect® 50 / 200

Rapid test for the determination of calprotectin in faeces*

PreventID® *CalDetect® 50 / 200* is an immunological rapid test for the determination of calprotectin in faeces. The two cut-offs at 50 and 200 µg/g enable not only the differentiation between inflammatory (≥50 µg/g) and non-inflammatory (<50 µg/g) diseases but also the individual therapy control of patients with inflammatory bowel diseases (IBD). A faecal calprotectin concentration above 200 µg/g in drug-treated IBD patients indicates a relapse and can be utilized to adjust therapy accordingly. A periodic application of the PreventID® *CalDetect® 50 / 200* in IBD patients is therefore an effective tool for individual therapy control.

Calprotectin (MRP 8/14) is a heterodimer of two calcium-binding proteins 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 potentially useful clinical inflammatory marker.

The acute phase protein correlates significantly with histologic and endoscopic assessment of disease activity in ulcerative colitis (UC), as well as with faecal α_1-antitrypsin levels and faecal excretion of ^{111}indium-labeled white blood cells in patients with Crohn's disease (Roseth et al. 1992, Tibble et al. 2000). **Calprotectin 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, IBS).

Faecal calprotectin has several characteristics of an ideal parameter for clinical routine: simple, non-invasive, and low cost. These features allow for serial monitoring of disease activity and treatment success.

Indications for the determination of calprotectin:

- Differentiation between organic intestinal diseases (e.g. IBD) and functional intestinal diseases (IBS)
- Ideal for monitoring disease activity in IBD patients
- Ideal for monitoring the early detection of relapse
- Differentiation between organic diarrhoea and functional diarrhoea

Prediction of IBD Relapse

Crohn's disease and ulcerative colitis are related conditions characterized by periods of remission marked by episodes of clinical relapse. The clinical implications of predicting which patients with IBD are likely to relapse are considerable. Such knowledge may allow targeted treatment at an earlier stage (with fewer side effects) to avert the relapse, as well as an assessment of new therapeutic strategies for maintaining symptomatic remission (Hodgson 1999, Tibble et al. 2000). Calprotectin is ideal for monitoring disease activity (e.g. of M. Crohn or after polyp resection) and early detection of the relapse.

* Not for export and sale in the USA

We will gladly send further information about this test and our other point-of-care diagnostics on request

Simple handling of the PreventID® *CalDetect® 50/200*

Before test run, a stool sample is collected comfortably and hygenically using the stool sample tube according to the manual. The dissolved stool sample is then applied to the sample window in the test cassette. Test results can be interpreted after 10 minutes.

Interpretation of test results

The **Prevent**ID® ***CalDetect® 50/200*** features two cut-offs:
The first calprotectin cut-off at 50 µg/g differentiates between inflammatory (≥ 50 µg/g) and non-inflammatory (< 50 µg/g) processes.
The second calprotectin cut-off at 200 µg/g is utilized for IBD therapy monitoring. A calprotectin concentration above 200 µg/g in drug-treated IBD patients indicates a disease relapse.

Literature

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