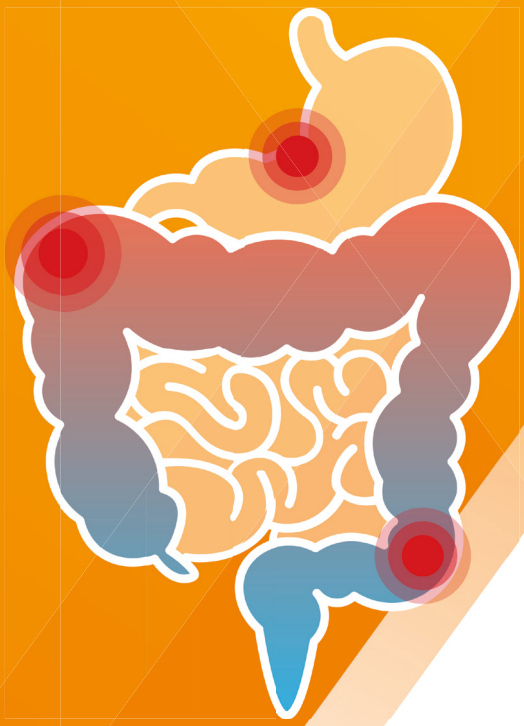
PREVENTIS *SmarTest*®

Calprotectin Home

Manual

Rapid, single-use self-test for the quantitative determination of calprotectin in stool



PREVENTIS QuantOn® Technology

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If you have any questions, please contact our customer service at +49 6251 70711-0 or info@preventis.com

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Intended use

SmarTest Calprotectin Home is a rapid test, which is performed manually. It includes a smartphone app developed for the quantitative detection of inflammation marker, Calprotectin, in human stool.

This test is an in vitro diagnostic medical device for single use only and suitable for self-testing by non-professionals from 18 years old. It serves as an aid in follow up and therapy monitoring of inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis). The test is single-use-only.

Introduction

Calprotectin is a calcium-binding protein that is produced in large quantities by specific immune cells, the neutrophilic granulocytes (neutrophils), and is released when inflammation occurs. In inflammatory bowel disease, neutrophils migrate into the intestinal lumen and release calprotectin there, which can then be detected in the stool.

Based on the clinical symptoms, however, it is often difficult to distinguish patients with chronic inflammatory bowel diseases (IBD) such as Crohn's disease and ulcerative colitis from patients who suffer from irritable bowel syndrome. With the determination of calprotectin in the stool, however, inflammation in the intestinal tract can be clinically diagnosed with certainty. An increased calprotectin concentration in the stool provides information about the presence of inflammation in the intestine. With the non-invasive determination of calprotectin, the doctor can often save patients with normal irritable bowel syndrome from an unnecessary invasive colonoscopy if the concentration is low.

Since scientific studies have shown that the concentration of calprotectin in stool correlates well with the histological and endoscopic findings of disease activity in patients with IBD, the calprotectin concentration in stool can also be used diagnostically to objectively evaluate the success of the therapy. Furthermore, one can monitor IBD patients who are apparently symptom-free in order to be able to detect and avert a relapse (a recurrence) at an early stage.

Test principle

SmarTest Calprotectin Home is an antibody based strip test for the detection of calprotectin in a stool samples (15 mg). The stool sample is added and dissolved in an extraction solution using a specific sample extraction system. Afterwards, 3 drops of the solution are placed on the sample application window of the rapid test. Existing calprotectin reacts in the test strip with calprotectin antibodies, which are marked with gold. If carried out correctly, a red test line becomes visible after no longer than 15 minutes. The appearance of the control line (C) indicated whether the test functioned correctly. Using the SmarTest Calprotectin app, the quantitative result is then evaluated based on the intensity of the color in the control and test lines.

Depending on the personal app settings, the result can then be transmitted directly to the treating medical specialist.

Interpretation of results

A test result of ≥ 250 µg calprotectin/g stool indicates an inflammatory process in the intestine. Healthy children under the age of 4 often also have elevated calprotectin values.

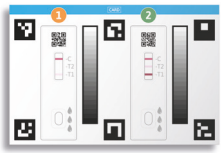
Since the calprotectin concentration depends on the patient, the individual base value should be discussed with the treating medical staff. Regardless of the outcome, medical professionals should always be contacted if symptoms persist or if the results are questionable.

Contents of the test kit

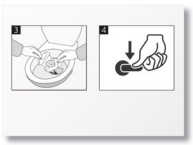
Materials provided

1 test cassette TEST, individually wrapped with desiccant bag*

1 camera test card CARD



1 paper stool catcher



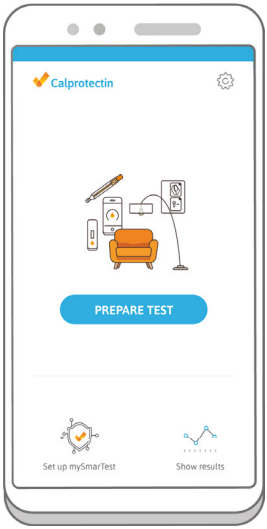
1 sample collection tube with buffer solution TUBE

*To prevent the test strip from absorbing moisture, the desiccant bag is included in the packaging. Dispose of desiccant bag after opening.

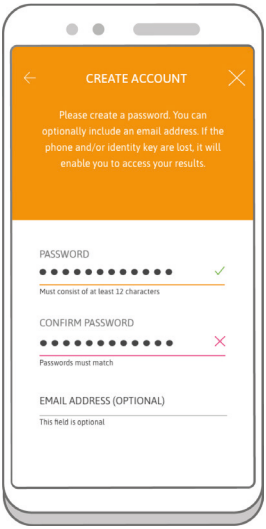
Additional materials required

Disposable gloves, a smartphone with the **SmarTest Calprotectin** app and an internet connection

mySmarTest

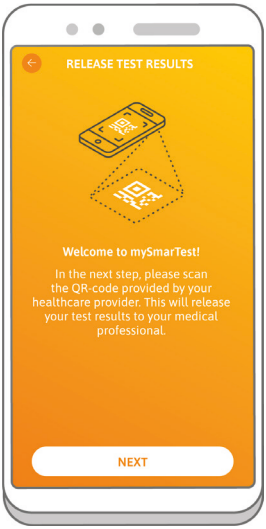


The **SmarTest Calprotectin** app offers – optionally – the possibility to create an account in the „**mySmarTest**“ patient portal. This enables the encrypted transmission of the test results to the treating medical specialist and allows the test history to be transferred to a new smartphone.



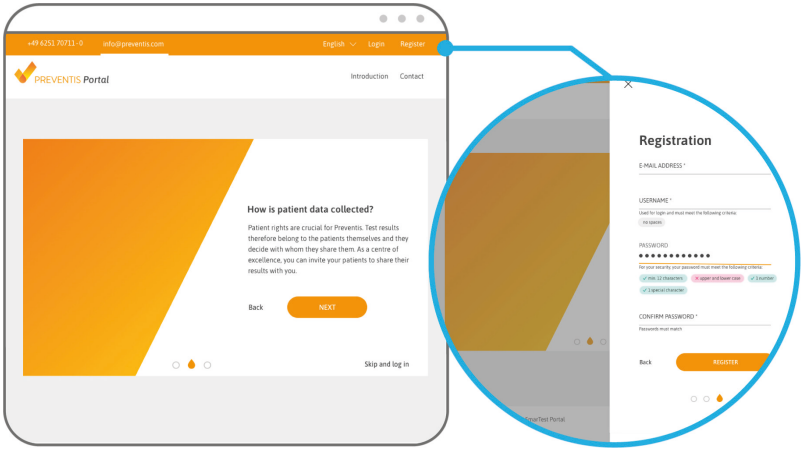
The patient portal **mySmarTest** can be used without providing personal data. An automatically generated ID and a personal password serve as access data. The option to add an e-mail address allows this to be used to log in and can be used to reset a lost password.

With regards to data security, no link can be established between the pseudonymised data and the e-mail address even if an e-mail address is provided.



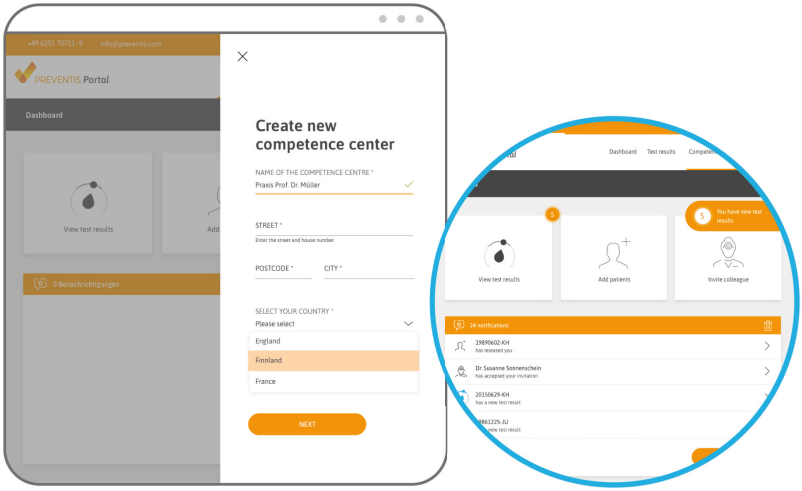
To release the test results to the treating medical staff a patient information sheet is generated. This contains a QR code that patients can use to link to the registered medical center. The data always remains in the possession of the patient and the release of the data can be changed or revoked at any time.
This function is managed in the settings “**Manage Sharing**”. If the deletion of all data is required, this can be requested at **info@preventis.com**.

Preventis Portal

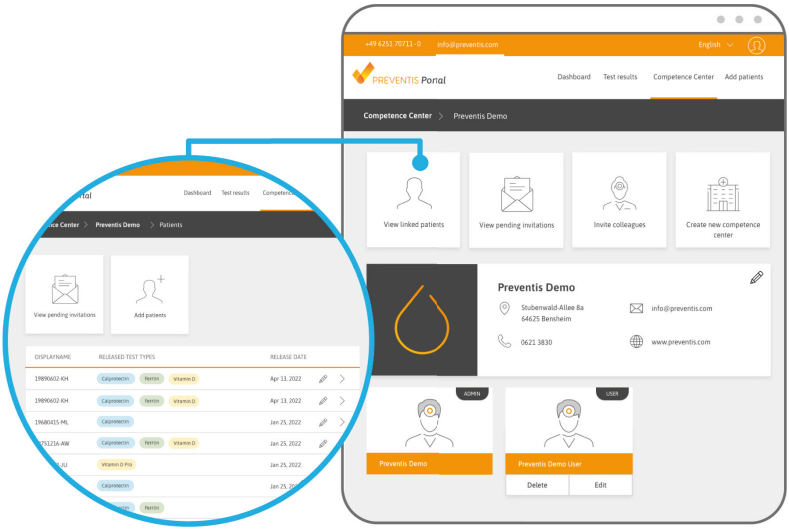


The "**Preventis Portal**" is available to treating medical specialists at **portal.preventis.com** enabling them to view the test results of patients.

Medical professionals can create an account via the „**Register**" field and log into the account via the „**Login**" field. Only your name, e-mail address and a personal password are required here.



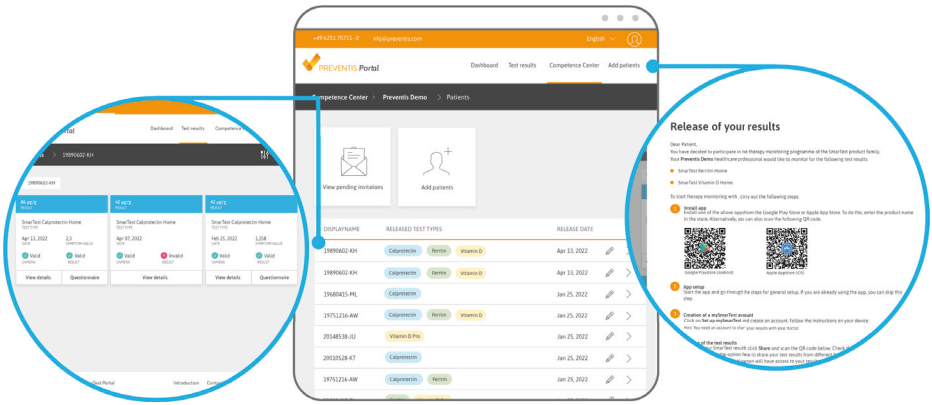
After successful registration, you can set up your own competence center, under which you can view the test results of the patients belonging to the competence center. You will then be taken directly to the start screen of the competence center. If you have been invited to join an existing competence center, you will be forwarded directly to the start screen of the inviting competence center after registration.



A competence center can have several users. So for example, a group practice can share a competence center or several employees of a practice can access patient data.

In principle, there are two different user groups for each competence center – administrators and users – who have different rights.

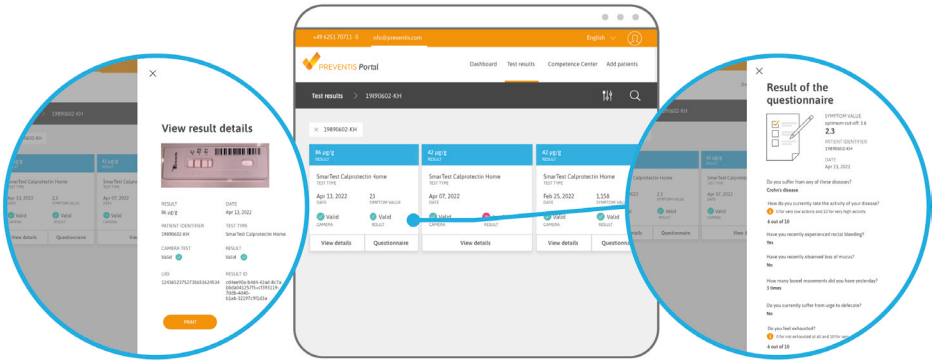
On the Competence Center's start page, you have the option of inviting new members, managing existing invitations and editing and personalising the general data of the Competence Center.



The „**Show linked patients**" function takes users to an overview of all patients belonging to the competence center. New patients can be added to the competence center using the "**Add patients**" function.

To do this, enter a pseudonymised patient code, e.g. the practice ID, required. Following this, a patient information sheet will be generated automatically which the patients can use to share their results with the treating medical staff.

Note: Each patient information sheet can only be used once.



For all patients, the user can display the history and thus the course of the last measurements.

You also have the option of choosing whether you want to be notified when new results arrive and you can set patients inactive if the **Preventis SmarTest® Calprotectin Home** product is not currently being used.

Test characteristics

Measuring range

The test has a measuring range of 31–4000 µg calprotectin/g stool.

Analytical sensitivity

Limit of Blank (LoB)	11.3 µg/g
Limit of Detection (LoD)	31 µg/g
Lower Limit of Quantitation (LLoQ)	31 µg/g
Upper Limit of Quantitation (ULoQ)	4000 µg/g

Analytical specificity

The analytical specificity was proven by determining the cross-reactivity with related substances. No cross-reactivity could be detected for the following substances:

Hemoglobin, Lysozyme, Lactoferrin, PMN Elastase, MPO

Cross-reactivities were found for the substances *bilirubin*, *S100A12* and *S100A8*. However, their influence was rated as not relevant.

Interference with medications and other substances that may be present in the blood have also been investigated. Again, no interference was found for the following substances:

Soybean Oil, Ethanol, Azathioprine, Pantoprazole, Mesalazine, Clartihromycin, Levofloxacin, Ferrosanol, Acetylsalicylic Acid, 25-OH Vitamin D_3, Gabapentin, Multivitamin Supplement, Ibuprofen.

Precision of measurement

The precision of the measurement was carried out according to the multisite approach of the CLSI Guideline EP05-A3. For this purpose, measurements were carried out in different laboratories under different light and environmental conditions.

A total of 4 samples with 2 different batches were measured on 5 different days with 6 different smartphone models (iPhone 6/iPhone 6s/iPhone 6 Plus/iPhone 7/Samsung Galaxy S6/Samsung Galaxy S7). 5 replicates were carried out for each measurement.

Overall, the following results were obtained:

	CV
Repeatability	16.0%–27.3%
Reproducibility	23.1%–33.5%
Lot-to-Lot Comparability	< 12.2%

Diagnostic accuracy

The **IDK® Calprotectin ELISA** from **Immundiagnostik AG** (K 6927) was used as the reference method.

n = 101 samples were measured in duplicate with 2 different smartphone models (iPhone 6s and Samsung Galaxy S7) and 2 batches. This resulted in the following relative sensitivity and specificity for the cut-offs of 50 µg/g, 200 µg/g and 600 µg/g:

	Cut-Off = 50 µg/g	Cut-Off = 200 µg/g	Cut-Off = 600 µg/g
Sensitivity	**93.8%** (91.7%–95.5%)	**92.1%** (89.2%–94.3%)	**89.3%** (84.4%–92.8%)
Specificity	**93.8%** (89.4%–96.4%)	**91.3%** (88.0%–93.7%)	**93.0%** (90.7%–94.8%)

Lay study

A usability study according to the IEC 62366-1:2015 standard was carried out as part of the approval for the self-application of **Preventis SmarTest® Calprotectin Home**.
For the lay study, a total of 15 subjects from different age groups and educational backgrounds tested the handling and comprehensibility and were observed by independent people.

Part of the testing was the comprehensibility of the test instructions for laypeople, the taking of samples and the execution of the test. In addition, the evaluation with the app, the entire handling of the app including verification and validation and the registration in the „**mySmarTest**“ patient portal were checked.

The results of the usability study have shown that the test could be carried out largely without critical errors. Application errors could not be traced back to a faulty design of the user interface of the test components. In all cases, the incorrectly performed actions were clearly described in the test instructions.

The feedback from the participants on the test was very positive. Everyone found it easy to carry out and could imagine using such a test. On a rating scale of 1 (very good) to 5 (poor), the test and handling received a rating of 1.5 from the test subjects of the usability study.

Glossary

Analytical specificity	Analytical specificity describes the extent to which the laboratory method measures only what it purports to measure *(Source: Bundesgesundheitsbl. 2008.)*.
Cut-off	Cut-off is/are the limit values of a measurement. They indicate from which value a result can be interpreted as negative or positive.
Intestinal lumen	The intestinal lumen refers to the inner cavity of the intestine.
Diagnostic accuracy	Describes how accurate a method is based on diagnostic sensitivity and specificity.
Diagnostic sensitivity	The diagnostic sensitivity describes the ability of the test method to detect as many patients as possible *(Source: Bundesgesundheitsbl. 2008)*.
Diagnostic specificity	The diagnostic specificity describes the ability of the test method to specifically record a clinical picture and thus to keep misclassifications to a minimum *(Source: Bundesgesundheitsbl. 2008)*.
Competence centre	Medical specialists can create a competence center in the **Preventis Portal** in order to be able to see the test results of the patients belonging to the competence center. A competence center can include several users whose access rights can be divided into administrators and users.

Cross reactivity	The cross-reactivity indicates whether the antibody used in the test reacts to antigens of other substances that are not intended to be measured with the test. If this is the case, there is a risk that the test carried out will display incorrectly high values under certain conditions.
Limit of Blank (LoB)	The Limit of Blank (LoB) describes the highest detectable analyte concentration that is expected when replicates of a blank containing no analyte are tested *(Source: Armbruster et al. Clin Biochem Rev. 2008)*. A sample without analyte always generates a signal during measurements, albeit a very small one, which can be described as a background signal.
Limit of Detection (LoD)	The limit of detection (LoD) or detection limit of a diagnostic measurement method describes the lowest analyte concentration that can be reliably distinguished from the LoB and at which detection is possible. The LoD is determined by using both the measured blank (see LoB) and test replicates of a sample known to contain a low concentration of the analyte *(Source: Armbruster et al. Clin Biochem Rev. 2008)*.
Lot	Lot is a synonym for the term batch and designates a production unit.
Lower Limit of Quantitation (LLoQ)	The lower limit of quantification (LLoQ) is the lowest analyte concentration that can be quantitatively detected with a specified accuracy and precision *(Source: Armbruster et al. Clin Biochem Rev. 2008)*. It is defined as the lowest calibration standard.
mySmarTest	**mySmarTest** is a portal integrated in the app for patients. It gives users an overview of the test results over time, enables them to be transmitted in encrypted form to the treating medical specialist and allows the test history to be transferred to a new smartphone.
Neutrophil Granulocyte (Neutrophil)	Neutrophils belong to the white blood cells. They are part of the innate immune system and their main task is to defend against pathogens.

Preventis Portal	Portal for treating medical specialists, through which the test results of the patients can be viewed. The prerequisite is the release of the values by the patient. Medical professionals can create a personal account via the „**Register**“ field and log into their personal account via the „**Login**“ field. Only your name, e-mail address and a personal password are required here.
QuantOn® Technology	The **QuantOn® Technology** enables the quantitative evaluation of a lateral flow rapid test. After an appropriate incubation period, the test is scanned using an app specially developed by **Preventis**. The app determines the quantitative measurement result based on the color intensity of the test bands. This is highly valid and comparable to parameter-specific gold standards.
Upper Limit of Quantitation (ULoQ)	The upper limit of quantification (ULoQ) is the highest calibration standard that can be quantified with a specified accuracy and precision.

WWW.PREVENTIS.COM

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