# Instruction For Use: CalproSmart Office

Package Insert

# LIST OF CONTENT

# CalproSmart Office™ -
# Rapid fecal Calprotectin test for clinic and laboratory use

## 1   INTENDED USE

CalproSmart office™ is a rapid test intended as a diagnostic tool at laboratories, clinics, and doctors' offices for the determination of Calprotectin in human stool samples in combination with the dedicated Calprosmart™ smartphone application to:

1.  Differentiate between inflammatory bowel diseases (IBD) and Irritable Bowel Syndrome (IBS)
2.  A tool to predict relapse, identify effect of treatment of IBD-patients, and/or identify non-responders

**The test is for *in vitro* use. Each test is for single use**

## 2   BACKGROUND

Various types of organic diseases in the gastrointestinal tract may cause damage to the intestinal epithelial lining (mucosa layer). Such damage may vary from increased permeability of the mucosa to inflammation and ulcerations. The bowel content is rich in bacteria and other microorganisms releasing substances which may be toxic or chemotactic, i.e. they stimulate leukocytes, in particular polymorphnuclear neutrophilic granulocytes (PMN), to migrate into the gut lumen where they release their contents including antimicrobial substances like Calprotectin. This protein constitutes about 60% of total proteins in the cytoplasm of PMNs [2] and can be reliably estimated in faecal samples stored for up to seven days at ambient temperature [3].

Calprotectin is a 36 kilodalton calcium and zinc-binding protein [4], produced by PMNs, monocytes and squamous epithelial cells (except those in normal skin) [5,6]. After binding of calcium, it can resist degradation by leukocytic and microbial enzymes [3,7]. By competing with different enzymes for limited, local amounts of zinc, Calprotectin can inhibit many zinc-dependent enzymes [8] and thereby kill microorganisms or animal and human cells in culture [9,10]. Different types of disease, for instance bacterial infections, rheumatoid arthritis and cancer, lead to activation of PMNs and increased levels of Calprotectin in plasma, cerebrospinal fluid, synovial fluid, crevicular fluid, urine or other human materials [1].

It is of special importance that the concentration of Calprotectin in faeces is correlated with the number of PMNs migrating into the gut lumen [11], and that it can be detected reliably even in small (less than one gram) random stool samples [3,12]. Furthermore, organic diseases of the bowel give a strong Calprotectin signal, i.e. elevations are regularly five to several thousand times the upper reference in healthy individuals [3,13,14,15], indicating intestinal inflammation.

Mucosal healing is the optimal goal for IBD treatment, and a test for faecal Calprotectin can tell when this has been achieved. Many IBD patients in clinical remission with normal C-reactive protein (CRP) levels still have on-going inflammation [16], reflected by increased faecal Calprotectin. Such patients have increased risk of relapse within a few months [17]. If mucosal healing can be achieved, the risk of relapse and need for expensive medical treatment and/or major abdominal surgery will be reduced [18,19]. Normalisation of Calprotectin levels means that mucosal healing has been achieved [20]. The risk and severity of side effects to treatment should be balanced against the risk of continued inflammation, severe clinical relapse and complications.

The importance of achieving mucosal healing has been focused in many scientific reviews [21-29] and articles [30-35].

# 3 PRINCIPLE OF THE TEST

The **CalproSmart™ Office** is based on lateral flow immunoassay. Samples are prepared using our patented Fecal Extraction buffer, which is then applied to the test cassette. The test cassette contains two types of α-Calprotectin antibodies: Gold-conjugated Ab (free and in excess), and capture Ab (immobilized to form test line). In addition, there is also α-gold-conjugated Ab antibodies (immobilized to form control line). Upon application of sample to the test cassette, Calprotectin binds to the gold-conjugated Ab, and the complex will travel along the membrane until the Calprotectin is captured by the immobilized antibodies and a test line is formed propotional to the amount or complex bound. Unbound gold-conjugated Ab travel further and is immobilized to form control line. Gold-conjugation help in making the lines visible. Using CalproSmart™ smartphone app uses the color intensity to calculate Calprotectin concentration in the sample.

The test is calibrated using faecal extracts with known concentrations, using the CalproLab™ ELISA (Calpro AS, prod. No. CALP0170).

# 4 MATERIALS

## 4.1 Reagents and components supplied with the kit

A) **Extraction device:** Faecal extraction device, prefilled with 5 ml Calpro Faecal Extraction buffer. The device is designed to collect 10 mg of faecal sample and give a 1:500 extract. The device is for single use only.

B) **Rapid test cassettes:** Tests individually sealed in aluminium foil with desiccant bag. The device is for single use only.

C) **Support frames**: Reference frame for the smartphone application with an opening for placement of the rapid test cartridge.

## 4.2 Materials and equipment required but not supplied

- Paper tissue
- Container to collect stool sample

## 4.3 IT components

- CalproSmart™ app: For reading the test cassette
- CalproSmart web portal: For registration of clinics, users and patients. For storage of patient results, located at www.calprosmart.com

# 5 TRANSPORT, STABILITY AND STORAGE

It is safe to transport the kits at ambient temperature for several weeks, but any long-term storage should be at 2 – 8°C.

For maximum shelf-life, avoid exposure to high temperature and direct sunlight.

# 6 USING CALPROSMART™ WEB PORTAL

Before using the CalproSmart™ Office, the clinic, staff and patients using the system must be registered in www.calprosmart.com.

## 6.1 Setting up new CalproSmart™ web portal

To use the CalproSmart™ Web Portal and allowing staff to use the CalproSmart™ mobile phone application for CalproSmart™ rapid test, you need to create a virtual clinic.

- Go to www.calprosmart.com
- Click the "Register new clinic" and fill out the form that appears with all relevant information. You will be required to fill in information on "contact person for the clinic" in first list and provide clinic information in second. The contact person and their details provided in the first list will automatically become first admin of the virtual clinic that will be created. Admin can later be changed.
- When you click "next" after □, you will see a summary list of all data you have entered. Please check all data is correct, before submitting the request to the Calpro Team by clicking the "Finish" button. You will also need to tick off the CAPTCHA box to be able to send in the request.
- Your virtual clinic request will be checked by the Calpro Team, and if all data is typed in correctly, the clinic will be activated within 24 hrs. The contact person will receive an email with directions for setting password and accessing the secured area for your virtual clinic.

Keep in mind that the person registered will be made the clinic admin, and you can easily give this person other roles according to your needs, as well as create new clinic admins in the portal.

## 6.2 User rights

For CalproSmart™ web portal users there are in total 4 rights, that can be selected in any combination. The only limitation is that a clinic cannot be without an admin.

Following rights are possible to assign to any user:

| | User types in CalproSmart™web portal | | | |
|---|---|---|---|---|
| **Rights and permissions:** | Clinic Admin | Clinic lab | Clinic User | Clinic User Full Insight |
| Register/ edit Staff (including new Admin) | X | | | |
| Register/edit Patients | X | X | X | X |
| Access patient results | | X | X | X* |
| Receive e-mail with patient's test results | | | X | X* |
| Approve/reject test results in portal | | X | | |
| Perform test on CalproSmart™ app | | X | | |

\* Clinic User Full Insight will be able to see results and be notified of both own and others' patients who are registered in the clinic.

## 6.3 Logging in

Once your virtual clinic is created at CalproSmart™ portal and registered you as a staff member in the clinic (For rights of various users, please go 6.2 User Rights), you can log in by following the steps below:

- Go to www.calprosmart.com.
- Click the "log in" button, and type in your email address and password you registered with. If you do not remember your password or do not have it, you can click the "forgot your password?" link to create a new email with reset password link. This is valid for 2 hrs at a time.
- Type in Multi Factor Authentication (MFA) pin from Google Authenticator. When logging in for the first time, you will be asked to set up the Google Authenticator. For installation of Google Authenticator, see "6.4 Installing Multi Factor Authenticator".
- Type in your 6-digit code from MFA to continue
- The first time you log in, you will be required to read and accept Data Protection Agreement, Privacy Policy and End User Lisence Agreement. Tick off "I agree" box at the end and click accept.

## 6.4 Installing Multi Factor Authentication

- Go to AppStore or Play Market and download "Google Authenticator" from Google LLC
- Install & Open
- Click on + symbol followed by the "Scan QR-code"
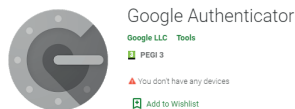
  scan the QR code displayed on the screen (www.Calprosmart.com)

- After scanning, a 6-digit code will be displayed in Google Authenticator App. Code is valid for the duration it is visible. New code is automatically generated
- Enter the code in the portal to log in



Google Authenticator
**Google LLC   Tools**
PEGI 3
You don't have any devices
Add to Wishlist

## 6.5 Create and edit Staff Users

From the web portal, you can create, edit or inactivate staff users. This is permission only given to the admins of the clinic. You can find out more about rights and permissions in the following chapter.

- To create or edit staff members, select the "Staff Users" button on left bar. To create a new user, click the "Create Staff User" button in top right corner. To edit an existing staff user, locate the name in the list, and click "Details" in right column.
- In the form that appears, enter the details required. Necessary fields are shown with asteriks.
- In order to allow a staff user to enter the virtual clinic, this must be set to be active user by ticking off the box for "is active". Conversely, if a staff should for any reasons not be allowed access to the portal, their account can be blocked be un-ticking the "is active" box.
- Select a role for the user by ticking off relevant box or boxes. One user might have different roles. One clinic can have any number of users with any combination of roles. Roles are explained in next chapter.
- Once information is put in or edited as desired, click the "create"/"save" button in the bottom right corner to save the information.

NOTE: for some screens you need to scroll down to see the entire form.

### 6.6 Create or edit patient account

- Click the "Manage Patients" button from the left menu
- If you are creating a new patient, click the "create patient" button in top left corner. If you like to edit an existing patient, identify and patient in the list and click "details"
- Make sure to fill out the required fields, and ensure to scroll down to see any remaining fields
- Select if the patient is a lab patient or home patient. The former is patient that will bring in stool sample for analysis, while the latter is the one who will perform a self-test at home. The home patient is required to put in an email address in order to gain access to the mobile phone application

### 6.7 Results

To view results for the patients in your clinic or those assigned to you, you will need to access the "results" area in the portal.

- Click the "Results" button from left side menu.
- You can also filter and sort basted on Patient ID, date and severity/color-code
- You can get more details on a patients result by clicking "details" button from the list

### 6.8 Pending results

CalproSmart™ measurements performed in the clinic or lab, will not directly get inserted into the relevant patients account. They will first end up in the "pending results" field to allow for double-checking the results and the patient they are linked to. To handle results in the pending field, please follow these steps:

- Navigate to the pending results page.
- From the list of tests, identify the test you would like to review and click "details".
- Ensure that the test is assigned to correct patient. If not, reassign to correct patient using the edit (pencil) button.
- If the test is okay to store in patient results, you can click "accept". If it is to be rejected for any reason, such as incorrect performance, duplicate test or other reasons, click "reject"

## 7 PERFORMING THE TEST

### 7.1 Preparations

- The test cassette and extraction device should be stored at 2-8°C to have maximum shelf-life until the expiry date as mentioned on the test cassette aluminium pouch.
- It is not necessary to bring the test cassette and extraction device (and stool samples) to room temperature before performing the test.
- Make sure to register the patient in the portal before starting the test procedure
- You will also need Lab_User rights to perform the test
- For this test you will need following additional equipment not provided:
  - o Android or iOS operating smartphone with latest CalproSmart™ application installed.
  - o Timer.
  - o Tissue paper
  - o 10µL pipette in case of liquid samples not collectable with the extraction device
- Make sure to always use protective equipment suitable for the assay

## 7.2 Collecting sample and extracting

- Start off with unpacking the test cassette from the pouch. Make sure to note the expiry date. If the date has passed, the test will not work.
- Remove the white cap from the extraction device and collect the stool sample by filling the two grooves in the sampling rod with stool. Ensure to collect sample from different spots (either by placing the tip into various spots or by "stirring" around with the sampling rod. Avoid solids, fibers, seeds, etc. If sample is too fluid to be collected, then use a pipette to transfer 10 µL into the extraction tube instead.
- Place the sampling rod back into the extraction device through the blue cap. Any access stool will be scraped off.
- Vigorously shake the tube for 3 minutes to dissolve the stool sample into the extraction buffer. You can shake the sample by hand or a vortex
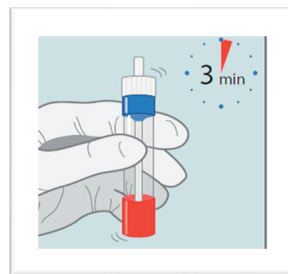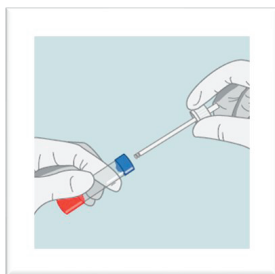


## 7.3 Applying the sample to the test cassette

Once sample has been shaken vigorously for 3 minutes, the sample needs be applied to the test cassette. The extract cannot be stored for later use.

- Holding the tube with the red cap point up; twist and pull the red cap from the tube.
- Flip back to upright position and discard the first 2-3 drops by gently squeezing the sides of the tube.
- Thoroughly wipe the tip of the device. Ensure it is completely dry before proceeding to next step.
  Place the test cassette into the blue reference frame and apply two drops into the application well of the test cassette. Hold the extraction device upright above the well. Holding it tilted will changed drop size/volume applied. Start timer once second drop is applied and allow to incubate for 15 minutes
  - o Once two drops are applied, you will see the flow in the window within 15 seconds. If no flow is observed, add another drop. If still no flow is observed, the test cassette must be discarded.
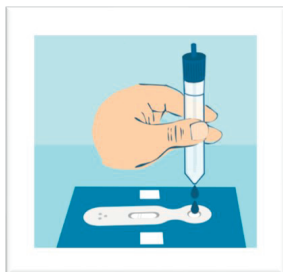
## 7.4 Measuring the Calprotectin levels

- After 15 minutes of incubation, you will have two minutes to perform the Calprotectin reading. Log in to the CalproSmart™ app and click "read cassette now to perform the reading
- Align the outline on your screen with the test cassette and the blue reference frame. The app will capture image automatically when it detects all checkpoints.
- Once the cassette has been read, the results will be shown on the screen. You will need to put in patient ID and run number, for the data to be registered in the patient test journal at www.calprosmart.com.
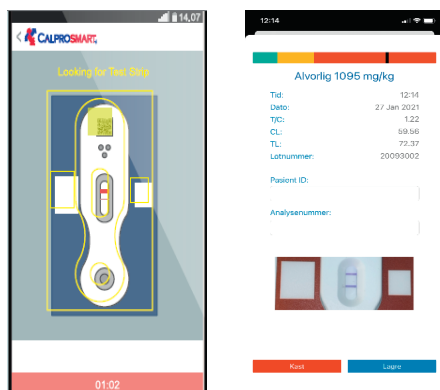


## 7.5 Notes and tips to when performing the test

- Collect sample from various spots. It is better to stir the stool sample to collect the sample.
- If the stool sample is too hard, use the sampling rod to scrape into the stool sample at various spots.
- Make sure to vigorously shake for 3 minutes to ensure good extraction.
- When measuring the test cassette after 15 minutes of incubation time, make sure to do so within 2 minutes. Our test has been validated for this. Measuring test cassette older than this can give you inaccurateresults.
- When scanning the cassette:
  - Do not hold the phone static. By slightly moving it up and down, and tilting it slightly in all directions, you will allow the app to get in right position to capture the image. This is done automatically.
  - Do not place the test cassette on shiny and white surfaces. Many cameras adjust their lens and this makes it difficult for the app to take picture.
  - If the app cannot read the cassette, move it move it to a different surface and retry.
  - If the barcode is damaged, the cassette will not be detected by the software. The message "looking for barcode" will be visible on the screen.
  - The Control and Test lines should be clear and well defined. If the lines are missing, or the quality of the lines is not acceptable, the app will not be able to

recognize the control line and "looking for test line" will be visible on top of the screen.

## 7.6 Approving the results in the CalproSmart™ Web Portal

All results performed as PoC or in the laboratory using the CalproSmart Office™ test kit, are required to be processed in the Web Portal before they are inserted into the given patient's area.

### 7.6.1 Review, approve or reject

Once a test is performed the results will be transferred to a temporary list in the web portal under "pending results". By logging in to the portal and navigating to the list from the left-side menu, it will appear as below:



Here it is possible to look at the details of a specific test, as well as to accept or reject the results. By clicking "accept", the results will directly be inserted into the list of the patient mentioned. By clicking "reject", the results will be deleted from the system. Rejected results cannot be retrieved later.

You can edit patient ID and get more information about the test by clicking "details". The screen below will appear:
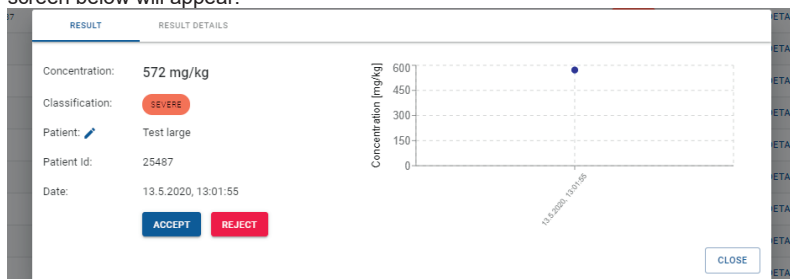


Here you will be given more information about the test, and you can also edit the patient by clicking the pencil button. If you have typed in incorrect ID, or an ID that does not exist, you will see the typed ID under patient, and in some cases, you will find it under "notes" under the "Result details" flap. You can search for correct patient by ID or patient name. If patient does not exist, leave the screen to register the patient and come back to correct the patient ID.

If the result is to be stored, then once it is accepted, it will be found under the allocated patient's list along with any previous and future results.

# 8 INTERPRETATION OF RESULTS

CalproSmart Office™ have a measuring range of 77-1500 mg/kg Calprotectin in stool sample and is validated against CalproLab™ ELISA.

## 8.1 Differential diagnosis

The analysis provides a contribution together with other clinical signs to differentiate between inflammatory bowel disease (IBD) an irritable bowel syndrome (IBS). The table below shows the default interpretation of the results given as quantitative calprotectin concentrations in mg/kg:

| Reported results (mg/kg) | Clinical interpretation |
|---|---|
| < 77 mg/kg | negative test, no active IBD condition likely |
| 77-100 mg/kg | Grey zone. Repeat test at a later time point for conclusive result |
| > 100 mg/kg | Positive test, IBD cannot be ruled out, further investigations advisable |

## 8.2 Follow-up of patients with IBD diagnosis

Calprotectin is a very useful tool when treating patients with established IBD, along with other relevant tests and patient's symptoms. The color-coded results in the app and the portal will mainly reflect this group of patients, while for the differential diagnosis, it is more relevant to look at the values presented.

Table below shows the default interpretation of the results:

| Degree of disease activity | Traffic light colour | Calprotectin concentration |
|---|---|---|
| Mild disease activity/ Remission | Green | < 200 mg/kg |
| Moderate disease activity | Yellow | 200-500 mg/kg |
| Severe disease activity | Red | > 500 mg/kg |

Keep in mind that Calprotectin is not a standalone marker for inflammation, and the results should be seen as a part of more complete workup of the patient with other biomarkers and/other clinical symptoms.

# 9 LIMITATIONS OF PROCEDURE

To get correct readout, it is important the procedure for this test is followed as outlined in this document. Any changes made to the amount of sample collected, extract applied, incubation time, and reading of test cassettes beyond what is stated in this document, can eventually lead to higher or lower results than what is correct.

The assay is performed as a rapid test and aligned with CalproLab™ ELISA. The numeric values from the test can differ from tests performed with kits from other suppliers and the values are therefore not interchangeable. CalproSmart™ results need to be assessed based on CalproSmart™ calibrations and cut-offs. "Conversion" to other suppliers' Calprotectin results can be done using the color-codes for indication of the level of inflammation.

## 10  PRECAUTIONS AND WARNINGS

In compliance with article 1 paragraph 2b European directive 98/79/EC the use of the *in vitro* diagnostic medical devices is intended by the manufacturer to secure suitability, performances and safety of the product. Therefore, the test procedure, the information, the precautions and warnings in the instructions for use have to be strictly followed. The use of the test kits with analysers and similar equipment has to be validated. Any change in design, composition and test procedure as well as for any use in combination with other products not approved by the manufacturer is not authorized; the user himself is responsible for such changes. The manufacturer is not liable for false results and incidents for these reasons. The manufacturer is not liable for any results by visual analysis of the patient samples.

- *Only for in vitro diagnostic use.*
- Read the Instructions for Use carefully before performing the test.
- Ensure that the extraction device is held vertically over the application well, when the 2 drops of extract are put onto the rapid test. Tilting the extraction device may cause wrong volume of the drops.
- Do NOT read the same test cassette several times. If the time limit for measuring the test is exceeded, the test must be performed from the start with a new extraction device and a new rapid test cassette.
- Ensure that both grooves in the stick of the extraction device always are completely filled. For very liquid samples, insert the rod deep into the sample to ensure the grooves are completely filled.
- Avoid carrying out the test in a dark room.
- Do not interchange reagents of different production lots.
- Do not use reagents from other manufacturers with reagents of this test kit.
- Do not use reagents after expiry date stated on the label
- The extraction buffer contains sodium azide at less than 0.1% (w/v).

## 11  DISPOSAL CONSIDERATIONS

Fecal extracts are potential contagious and should be treated as hazardous waste. Be sure that the extraction device is completely closed after use, to prevent leakage/spillage to the surroundings. All used component (except from the EasySampler) should be placed in the empty plastic bag of the sampler, before closed securely and disposed.

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# 13 ORDERING INFORMATION

Product code:   CAL220

CalproSmart Office™ kit for measurement of calprotectin levels in faecal samples.

| Symbols Key/ Symbolschlüssel/ Explication des symboles / Legenda / Símbolos | |
| --- | --- |
| **IVD** | *In Vitro* Diagnostic Medical Device/ *In Vitro* Diagnosticum/ Dispositif médical de diagnostic *in vitro*/ Diganostico *in vitro*/ Producto para diagnóstico In vitro |
| **LOT** | Lot Number/ Chargenbezeichnung/ Numéro de lot/ Lotto/ Número de lote |
| ⧖ | Expiration Date/ Verfallsdatum/ Date de péremption/ Scadenza/ Fecha de caducidad |
| ⌓ | Storage Temperature/ Lagertemperatur/ Température de conservation/ Temperatura di conservazione / Temperatura de almacenamiento |
| CE | CE Mark/ CE-Zeichen/ Marquage CE / Marchio CE / MarcaCE |
| [REF] | Catalogue Number/ Katalog Nummer/ Référence du catalogue/ Numero di codice/ Número de Catálogo |
| $\sum_n$ | Contains sufficient for "n" tests/ Ausreichend für "n" Tests/ Contenu suffisant pour "n" tests/ Contenuto sufficiente per "n" saggi/ Contenido suficiente para "n" tests |
| ⊗ | Do not reuse/nicht wiederverwenden/ ne pas réutiliser/ non riutilizzare/ no reutilizar |
| 📖 | Consult instructions for use/Gebrauchsanweisung konsultieren/consulter les instructions d'utilisation/consultare le istruzioni per l'uso/consultar instrucciones de uso |
| ↑↑ | This side up/Diese Seite oben/ce côté vers le haut/questo lato in su/Este lado hacia arriba |
| ⬛ | Manufacturer/Fabricant / Fabricante / Hersteller / Fabbricante |