IBDoc® Calprotectin Test
Instructions for Use
Patients and Lay Users

Version 2.0: 25-03-2015
INTENDED USE

IBDoc® is a diagnostic device for the quantitative determination of calprotectin levels in stool samples for self-testing. Calprotectin level determination supports therapy monitoring of inflammatory bowel disease (IBD) and is combined with patient status evaluation by his or her treating physician.

INTENDED USER

IBDoc® can be used by professional users in the laboratory or at the Point-of-Care or by trained lay users at their home (i.e. IBD patients at a minimum age of 12 years).

Disclaimer: The screenshots in this Instruction for Use are based on the iOS version of CalApp®. The Android version might differ in layout but not in functionality.
PRINCIPLE OF THE ASSAY

IBDoc® is a home test to measure the inflammatory biomarker calprotectin in stool samples. The patient uses the CALEX® Valve extraction tube to collect a precise amount of stool sample. Inside the CALEX® Valve, calprotectin present in the stool sample is transferred to the extraction solution. The extract is then applied to the Test Cassette, where calprotectin is visualized by red gold particles. Calprotectin flows with the extract through the Test Cassette and is caught on the test line. The test and control lines are measured by a smartphone app (CalApp®). The result is calculated by CalApp® and sent to a secure server for the treating physician to review. The test has a range of 30 - 1000 μg calprotectin/ g stool.

MATERIALS AND ACCESSORIES

MATERIALS AND ACCESSORIES PROVIDED IN ONE IBDOC® TEST KIT (B-IBDOC):
Before running the test, please ensure that all components are in the kit.

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>CALEX® Valve Device filled with extraction solution (5 ml)</td>
</tr>
<tr>
<td>1</td>
<td>Test Cassette</td>
</tr>
<tr>
<td>2</td>
<td>Stool Collection Papers</td>
</tr>
<tr>
<td>1</td>
<td>Camera Test Card</td>
</tr>
<tr>
<td>1</td>
<td>Quick Guide</td>
</tr>
</tbody>
</table>

THE IBDOC® KIT MUST BE STORED IN THE REFRIGERATOR (2-8°C).

MATERIALS AND ACCESSORIES REQUIRED, BUT NOT PROVIDED WITH THE TEST KIT.

• iOS or Android smartphone validated by BÜHLMANN for the use with IBDoc®.
• You can find a complete list of validated smartphones on www.ibdoc.net. An internet connection on your smartphone (see also important information).
• The smartphone App „CalApp®“: Available from the iTunes App Store or Google Play Store.
• Examination gloves, if necessary available from your doctor.
Please read the Instruction for Use carefully before starting the test procedure. Pages 5 to 7 contain an overview of all kit components. The step by step procedure walkthrough starts on page 7. For experienced users there is a quick guide on page 15.

Take your time to perform the test at your home and make sure you are not distracted.

Do not adapt your treatment without first consulting your physician.

Keep your smartphone away from water to avoid damage.

Additional costs for your internet connection may arise depending on your carrier.

You can perform the IBDoc® test under different lighting conditions, but you must prevent direct sunlight, strong sideward-light or casting a shadow onto the test cassette while reading the Test Cassette in Test Procedure - Step 6.

Your smartphone must have at least 20% of battery charge left.

The CALEX® Valve and the Test Cassette must not be used after the expiry date printed on the labels. The Test Cassette is stable at Room Temperature for 4 hours after opening the pouch.

The CALEX® Valve and the Test Cassette must not be reused.

None of the components are poisonous or otherwise hazardous.

A link to set your password will be sent to your IBDoc® email (username), which you provided to your doctor. If you fail to receive this message then check your spam folder.

If either the pouch holding the Test Cassette is damaged or the CALEX® Valve is leaking after opening the original packaging, do not use the test kit.

IMPORTANT INFORMATION

Many stool samples require up to 2 hours to fully detach from the grooves (Step 4, p.11). It may be easiest to prepare and extract your stool sample (as described in Test Procedure - Step 3 and 4) in the morning and continue with the next steps in the evening. Do not leave the processing of the extract for more than 24 hours. In this way, the stool sample has enough time to completely detach from the grooves and you are not under any time pressure for the rest of the test procedure.

Stool that does not stick to the grooves can be sampled as follows: place the stool sample on a spoon. Press the Dosing Tip (Fig. 2, p.5) flat against the surface of the spoon and rotate the Sampling Pin until the grooves are completely filled with stool.

Liquid stool samples cannot be collected. Please perform the test on a day with a solid stool.
COMPONENTS OF THE IBDoc® TEST KIT

CALEX® Valve Device

Figure 1:
CALEX® Valve

Figure 2:
Sampling Pin

Figure 3:
CALEX® Valve Body

Funnel

Dosing Tip with grooves

Throttle

Outlet

Protection Cap
**Figure 4:** Test Cassette

- Bar Code
- Reading Window
- Sample Loading Port

**Figure 5:** Camera Test Card

- Front side
- Camera Test Pattern

**IBDoc®**

Camera Test Card

Code: B-IBD-CTC
Lot: 0302

BÜHLMANN

Reverse side
**Figure 6: CalApp® Navigation Menu**

- **First Tutorial Screen**: Navigation through tutorial screens
- **Secondary Menu (tap to open)**: Tutorial Video & Contact Information, Logout
- **Primary Menu**: Result List, Navigation through tutorial screens
- **Result List**
  - NORMAL
    - Test Name: Calprotectin
    - Result: 30 µg/g
  - MODERATE
    - Test Name: Calprotectin
    - Result: 143.2 µg/g
  - HIGH
    - Test Name: Calprotectin
    - Result: 485.6 µg/g
  - HIGH
    - Test Name: Calprotectin
    - Result: 511.6 µg/g
  - MODERATE
    - Test Name: Calprotectin
    - Result: 130.4 µg/g
  - NORMAL
    - Test Name: Calprotectin
    - Result: 35.9 µg/g

- **Mobile IBDoc® Portal**
  - Results for Sarah Tester
  - Value vs. Time graph
  - Options: All test results
1.1 Search for „CalApp“ or „IBDoc“ (A) on the iTunes App store or Google Play store.

1.2 Download and install CalApp® onto your smartphone.

1.3 Make sure that you have a stable internet connection.

   NOTE: Please be aware that you need an internet connection to log into CalApp® at first startup.

1.4 Tap on the CalApp® icon and start the login process.

   NOTE: At the first start up you will have to agree that CalApp® is allowed to send you push notifications. A push notification will send you a reminder one day before the next test is due.

   You need to have at least 20% battery charge left on your smartphone to perform the test.

   On iOS you will have to agree that CalApp® is allowed to use the camera.

1.5 Enter your IBDoc® account email address (username) and password (B).

   NOTE: If you forgot your password you can reset it by tapping on the „Forgot Password“ button (B). Once you entered your IBDoc® account email address (username), a link to reset your password will be sent to your email address.

1.6 Read and accept the End User Licence Agreement (EULA).

   NOTE: Due to data protection and security reasons your session expires after 7 days and you will need to log in again.
STEP 2: PREPARATIONS FOR THE TEST PROCEDURE

2.1 Take the IBDoc® Test Kit out of the fridge and keep the single components in a dry and shady place until needed in the Test Procedure.

   NOTE: Keep the Test Cassette in the pouch until you are ready to load the Test Cassette in Step 5.

2.2 Open the IBDoc® Test Kit and take out the Camera Test Card (Fig. 5, p.6).

2.3 Perform a Camera Test by aligning the Test Pattern of the Camera Test Card with the yellow frame in the camera view of CalApp® (C).

2.4 Tap the “OK” button when the Camera Test has passed.

   NOTE: The Camera Test is valid for 30 days. Within this 30 days-time period Steps 2.3 - 2.4 are not necessary and after the login you can directly start with Step 2.5. After 30 days the Camera Test needs repeating.

2.5 You can freely navigate between the tutorial screens and get additional text information by tapping the circled “i” button (D). If you are an experienced user you may skip these instructions (by tapping the “Skip intro” button) and start with the Test Procedure right away (see Step 3).

   NOTE: You can consult the tutorial video in the Help Menu (Fig. 6, p.7) at any time.

2.6 Now you have completed the smartphone preparations. Put it aside but keep it in reach for later steps. Start with the Test Procedure (Step 3).
STEP 3: STOOL COLLECTION

The subsequent Steps 3 and 4 must be performed continuously without interruption

3.1 Please empty your bladder first if necessary, since urine can affect the test.

3.2 Unfold the Stool Collection Paper by holding the open ends and gently pulling outwards (E).

3.3 Place the Stool Collection Paper on top of the toilet seat near the back (F).
   CAUTION: The paper must not touch the toilet water.

3.4 Make sure that the Stool Collection Paper is correctly fixed on the toilet seat.

3.5 Make sure that your stool sample is caught on the collection paper (G).
   NOTE: In case your stool collection fails the first time, you have a second Stool Collection Paper provided with the Test Kit.
   If needed put your examination gloves on and proceed to Step 4 of the Test Procedure.
4.1 Hold the CALEX® Valve Device with the white cap at the top and remove the white Sampling Pin by simultaneously turning clockwise and pulling it upwards (H).

4.2 Dip the Dosing Tip with the grooves into the stool, and twist before removing. Repeat the procedure at 3 to 5 different positions of the stool sample in order to fill the grooves of the Dosing Tip (Fig. 2, p.5) completely (I).

   CAUTION: Make sure that all grooves are completely filled with stool. It does not matter if the Dosing Tip of the Sampling Pin is fully covered with stool, since excess stool will be stripped off at the next step.

4.3 Place the Sampling Pin back into the Funnel of the CALEX® Valve Body (Fig 3, p.5) and push it into the final locking position. You feel and hear a “click” (J).

   NOTE: After the stool sample is collected, you can flush the remaining stool down the toilet together with the stool collection paper.

4.4 Shake the CALEX® Valve vigorously for 10 seconds (K) and let it stand for 2 hours.

   NOTE: Since many stool samples require up to 2 hours to fully detach from the grooves you have to wait at least 2 hours before proceeding with the next step. Continue with the procedure at a convenient time point within the next 24 hours.

   Keep the CALEX® Valve device in a dry and shady place during the waiting period.
CAUTION: Make sure you have your smartphone ready and are logged into CalApp®.

5.1 Unpack the Test Cassette and place it onto the blue reverse side of the Camera Test Card (Fig 5, p.6) so that the white area is fully covered by the Test Cassette (L, 1).

5.2 Shake CALEX® Valve again vigorously for 10 seconds. Check that the grooves of the Dosing Tip are free from any residual stool. Holding the CALEX® Valve upright, flick the bottom of the CALEX® Valve to remove any airbubbles trapped in the outlet.

CAUTION: In order to get a correct test result, it is mandatory that the grooves of the Dosing Tip are free from any stool residue before continuing with the next step.

5.3 Remove the Protection Cap (L, 2) and place the Outlet of the CALEX® Valve onto the circular Sample Loading Port (Fig. 4, p.6) of the Test Cassette (L, 3). Turn the Throttle (Fig. 3, p.5) from position 1 to position 2 counterclockwise (M) and make sure that the Outlet remains in close contact with the Sample Loading Port.

5.4 As the liquid is loaded a reddish colour appears in the Reading Window. Allow the reddish colour to reach the middle of the Reading Window of the Test Cassette (N, arrow). This will take 20 to 30 seconds.

5.5 Start the timer in CalApp® immediately (O, 1)

CAUTION: Open the Throttle of the CALEX® Valve only once. The test is designed to work with the first drop released.

5.6 Remove the CALEX® Valve from the Sample Loading Port of the Test Cassette and put the Protection Cap back on (O, 2).

NOTE: The CALEX® Valve must be used only once.

5.7 Leave the Test Cassette for 12 minutes until the timer starts to “beep”. Then proceed immediately to Step 6 of the Test Procedure.

NOTE: Make sure that your phone is not on mute, so you can hear the timer ring.
NOTE: Make sure that the Test Cassette is positioned on the blue reverse side of the Camera Test Card. The bar code has to be in the top right corner (P).

6.1 Once the timer has run out, proceed immediately to take an image of the Test Cassette by pressing the "Scan" button.

CAUTION: A time out message will appear 90 seconds after pressing the "Scan" button. The camera view will close and CalApp® will return to the start screen.

6.2 Align the yellow frame in the camera view with the edges of the Test Cassette (R). Touch the screen to focus, if necessary.

NOTE: Hold your smartphone horizontally to the Test Cassette and not at an angle (Q).

Move smartphone slowly up and down to get proper alignment with the Test Cassette. Touch the screen to focus, if the scanning takes too long. Make sure that the Test Cassette is lying correctly on the reverse side of the Camera Test Card, so that any white part of the Camera Test Card is covered by the Test Cassette.

6.3 Once the CalApp® has found a good image to analyse, five green dots appear and the screen displays "Analyzing test".
7.1 As soon as the Test Cassette has been read, CalApp® takes you to the result view (S).

**NOTE:** If you do not have an internet connection while performing the test, the result may appear as „Pending“ in a blue box until an internet connection is established at the next login. Your test result is not lost in any case.

7.2 By tapping into the „Notes“ box you can leave a comment for yourself or for your healthcare professional.

**NOTE:** Only full stops and commas are allowed as punctuation marks.

7.3 Once you have typed your note, tap the „Save“ button (S) to save the test result.

**NOTE:** Test results are sent automatically to the IBDoc® Portal and your doctor is notified via email. If CalApp® does not have an internet connection at the time the Test Cassette is measured, the test result is automatically sent the next time an internet connection is established.

7.4 After the test result is saved, dispose of the CALEX® Valve Device and the test cassette (T).

7.5 You have reached the end of the Test Procedure. CalApp® will return to the start screen of the Navigation Menu.

**CAUTION:** Do not read the same Test Cassette again.

**NOTE:** You can review your test result history at any time by accessing the Test Result List or the Mobile Portal (Fig. 6, p.7).
QUICK GUIDE

Stool sample extraction: 15 minutes plus 2 hours of waiting:

1. Collect stool sample with the Stool Collection Paper.
2. Insert Sampling Pin into stool at 3 to 5 different positions and twist.
4. Continue with the next step within 24 hours.

Loading and reading test cassette: 15 minutes

5. Shake vigorously for 10 seconds.
6. Hold the CALEX® Valve on the Sample Loading Port until the reddish colour reaches the middle of the Reading Window.
7. Start CalApp® timer and wait 12 minutes.
8. Make sure that the Test Cassette is lying on the blue reverse side of the Camera Test Card.
   - Ensure all stool is removed from grooves before proceeding.
   - Scan Test Cassette.

Stool sample extraction: 15 minutes plus 2 hours of waiting:

Loading and reading test cassette: 15 minutes
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<th>Explanation</th>
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<td>Consult Instruction for Use</td>
</tr>
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<tr>
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</tbody>
</table>

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