

IBDoc® Calprotectin Home Test

Setting New
Standards in IBD
Monitoring



IBDoc® fCAL Home Test – Technical Performance

Inflammatory Bowel Disease (IBD) is a chronic inflammation of the gut, which presents with periods of inflammatory activity (flares) and quiescent phases (remission) as can be seen in many chronic diseases. While treatment options have alleviated the disease burden for many patients in recent years, a large part still experiences more than one flare per year (IBD2020 Report, 2013).

In the CALM study more than 200 Crohn's Disease (CD) patients were included in an interventional adalimumab dose escalation protocol. The treat to target (T2T) interventional arm based on calprotectin and CRP was significantly superior in reaching mucosal healing after 48 weeks, as compared to conventional patient management based on Crohn's Disease Activity Index (CDAI) symptom score alone. Calprotectin especially was a decisive factor. 45.9% of patients with calprotectin based tight monitoring reached this primary endpoint as compared to 30% with conventional management (Figure 1). Steroid free remission was also achieved significantly more often in the calprotectin tight monitoring arm.

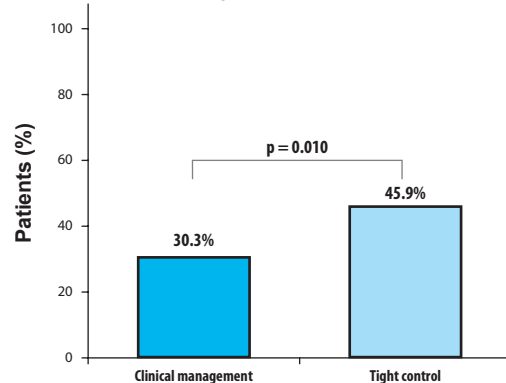
IBDoc® is the first CE-IVD certified fecal calprotectin home test that is fully designed for remote IBD disease monitoring. IBDoc® uses a reliable and easy to use smartphonebased remote care solution and is the next step to improve the Quality of Care and Quality of Life of IBD patients.

Key Benefits

1. Easy to use for all patients
2. High agreement with Laboratory based Methods
3. Excellent correlation with Endoscopic and Histologic scores
4. Independently clinically evaluated

- **Results performed by patients** using their own smartphone under the supervision of a trained professional **had an 88% agreement with the reference ELISA result from the trained professionals** (Figure 2).²
- In a real world situation where patients performed IBDoc® at home and sent in a stool sample to be measured via the reference **BÜHLMANN fCAL® ELISA**, **87% of the results (N=152) were in agreement at a cut-off of 100 µg/g**.³
- In a remote monitoring study setting, **66 UC patients were using IBDoc® over 6 months** at home. The correlation between **endoscopic and histologic scores and the patient's IBDoc® measurement** was excellent with a value of **r=0.88** (Figure 3).⁴

Primary endpoint at 48 weeks



adapted from Colombel et al., 2017¹

Figure 1 Mucosal Healing reached after 48 weeks, clinical management vs tight control including calprotectin

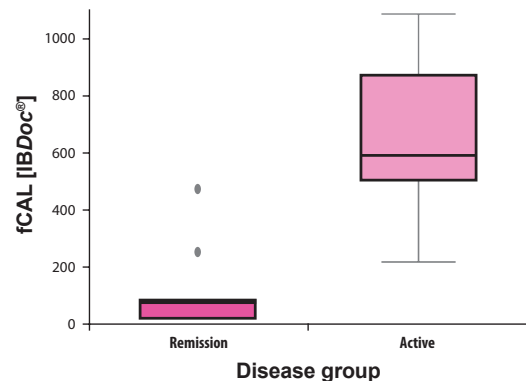
IBDoc® Result Patient

ELISA Reference	Normal ≤100	Moderate 101-299	High ≥300	TA/Total
Normal ≤100	19	2	0	19/21
Moderate 101-299	3	8	1	8/12
High ≥300	0	0	18	18/18
TA/Total	19/22	8/10	18/19	45/51

Total Target Agreement: 88 %

Moore A., et al., 2018²

Figure 2 Agreement between Patient performed Test and laboratory reference measurement



adapted from Walsh et al., 2018⁴

Figure 3 Correlation of IBDoc® calprotectin to active UC and to remission based on endoscopic and histologic indices

IBDoc® fCAL Home Test – Usability and Clinical Performance

Key Benefits for Patients

- **Easy to use:** Patients scored the overall usability of IBDoc® with **85 points out of 100** on a standardized usability questionnaire (Figure 4).⁵
- **Better disease management:** 83% of patients reported that IBDoc® **helps them to manage their disease better** (Figure 5).⁵
- **Preferred Method:** 85% of patients favored IBDoc® over traditional stool sample collections.⁶

“I think that IBDoc® is very useful in determining my Calprotectin value and it is incredibly easy to use. I think it is extremely convenient!”

Student & Crohn's Patient from Vienna

Key Benefits for Health Care Professionals

- **Remote IBD monitoring:** Patients can **stay away from clinics** for longer periods of time but are **still tightly monitored** via immediately shared IBDoc® results.

„There is **sufficient agreement** between IBDoc® home test and hospital-based ELISA in the lower ranges for calprotectin **to use this new test for disease monitoring**”³

- **Avoiding Hospital Visits:** Treating physicians can **keep track of their patients at home** and only need to contact them, when calprotectin values are high (Figure 6).

„An fCAL level below 187 µg/g is **not associated with active endoscopic disease** (UCEIS ≥4)”⁴

„Using these thresholds in clinical practice **may help to avoid endoscopic procedures** for those patients not having active endoscopic disease.”⁴



85 out of 100
System Usability Score Points

Figure 4 Usability Scores

Adapted from Bello et al., 2017⁵

Do you think this home test helped you manage your disease better?

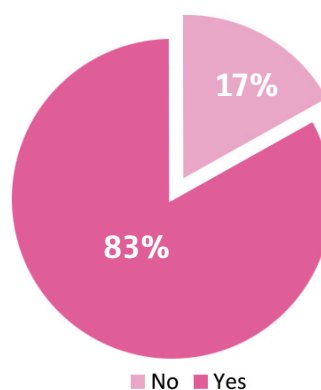


Figure 5 Disease Management

Adapted from Bello et al., 2017⁵

Clinical Performance for Detecting Endoscopic and Histologic Disease Activity with IBDoc®

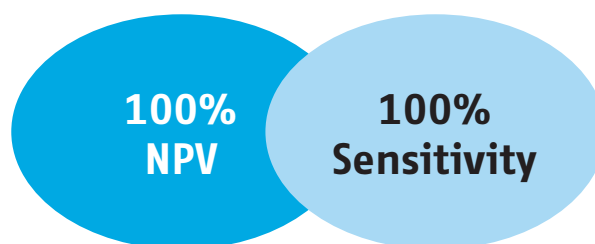


Figure 6 Clinical performance at the optimal fecal calprotectin threshold of 187 µg/g for detecting combined endoscopic and histologic disease activity

adapted from Walsh et al., 2018⁴

¹Colombel JF. et al., Effect of tight control management on Crohn's disease (CALM): a multicenter, randomised, controlled phase 3 trial, The Lancet, 2017.

²Moore AC. et al., IBDoc Canadian User Performance Evaluation, Inflammatory Bowel Diseases, 2018.

³Heida A. et al., Agreement Between Home-based Measurement of Stool Calprotectin and ELISA Results for Monitoring Inflammatory Bowel Disease Activity, Clin Gastroenterology and Hepatology, 2017.

⁴Walsh A., Defining Faecal Calprotectin Thresholds as a Surrogate for Endoscopic and Histological Disease Activity in Ulcerative Colitis - a Prospective Analysis, Journal of Crohn's and Colitis, 2018.

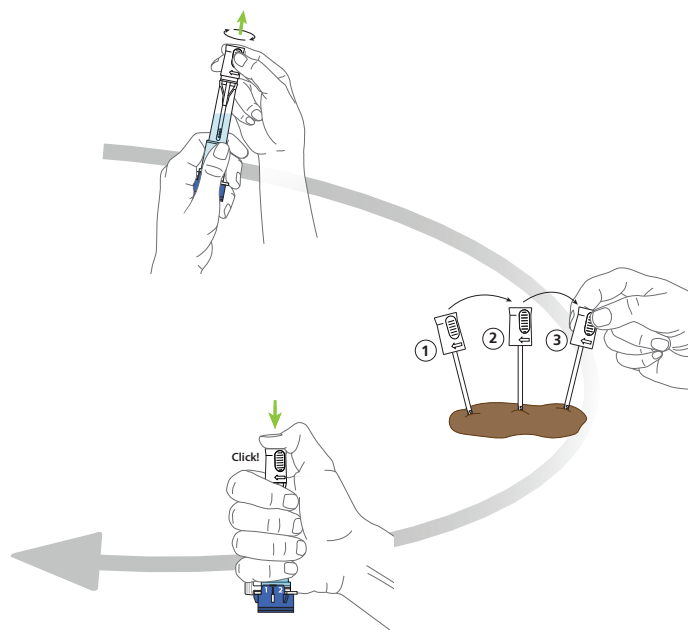
⁵Bello C. et al., Usability of a home-based test for the measurement of fecal calprotectin in asymptomatic IBD patients, Digestive and Liver Disease, 2017.

⁶Raker J., et al., P599 Home testing for faecal calprotectin: follow-up results from the first UK trial, ECCO 2017 Poster Abstract.

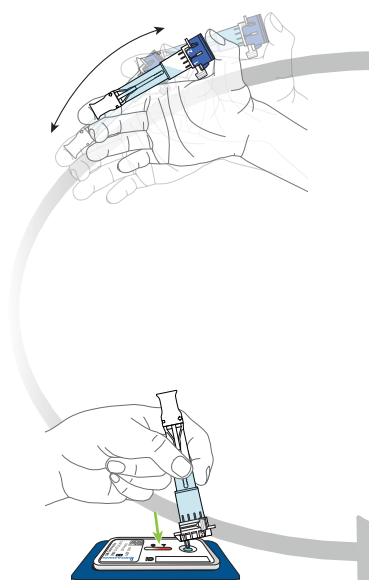
IBDoc®

Three easy steps to test calprotectin at home

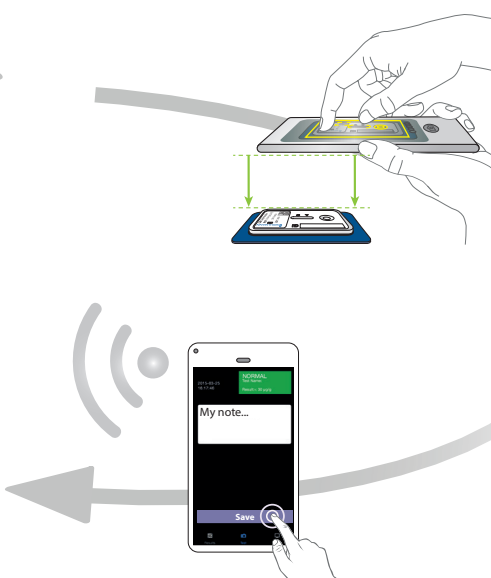
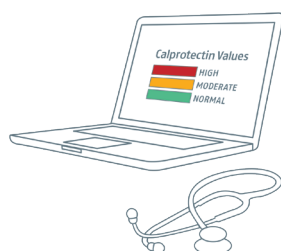
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visit us on www.ibdoc.net

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Health Canada Licence: 98903, Device class: 3

IBDoc® is not available for sale in the US.



BÜHLMANN Laboratories AG
Baselstrasse 55
4124 Schönenbuch
Switzerland

Phone +41 61 487 12 12
Fax orders +41 61 487 12 99
info@buhlmannlabs.ch
www.buhlmannlabs.ch

Ordering code:

BI-IBDOC
LF-IBDOC8

IBDoc Starter Kit
IBDoc Calprotectin Kit (8 tests)

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