

IBDoc[®] Calprotectin Home Test

Enabling
Remote 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 protocol¹. 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 smartphone based remote care solution and is essential 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

- **No significant difference** was found between the BÜHLMANN methods used to measure fecal calprotectin. All assays are highly comparable and have an **excellent clinical performance** (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

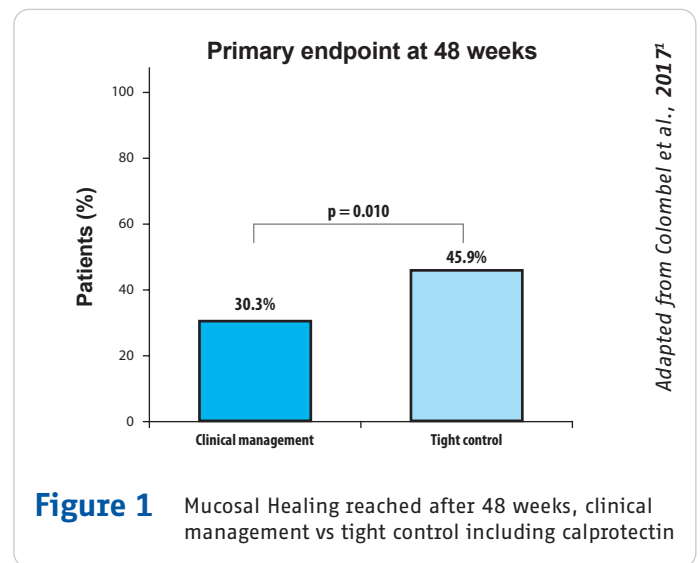


Figure 1 Mucosal Healing reached after 48 weeks, clinical management vs tight control including calprotectin

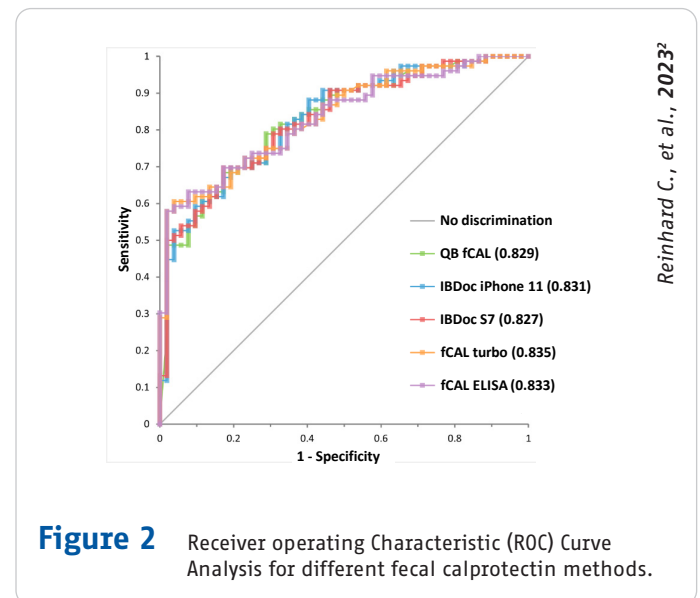


Figure 2 Receiver operating Characteristic (ROC) Curve Analysis for different fecal calprotectin methods.

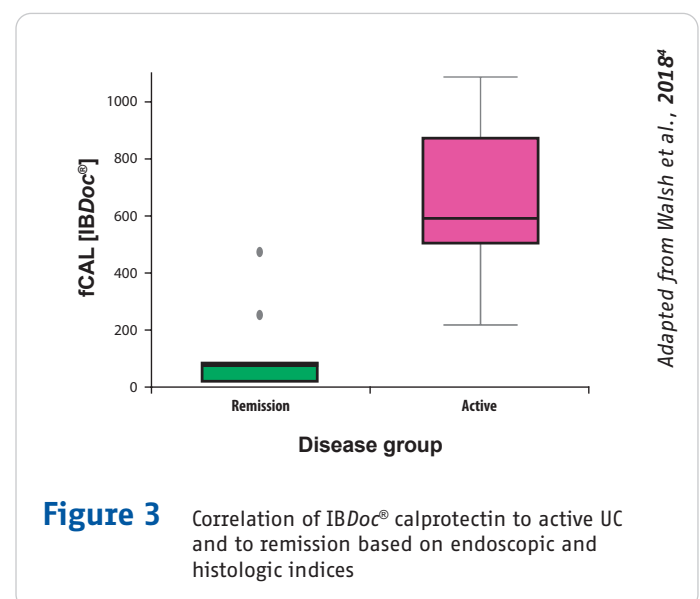


Figure 3 Correlation of IBDoc® calprotectin to active UC and to remission based on endoscopic and histologic indices

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.⁵
- **User-friendly:** The IBDoc® app outperformed its competitors in terms of error-friendliness and general system usability. Overall, IBDoc® was deemed less cumbersome to use (Figure 5).⁷
- **Better disease management:** 83% of patients reported that IBDoc® helps them to manage their disease better.⁵
- **Increased comfort:** patients felt that they were more comfortable and less anxious when doing the test at home.⁸
- **Preferred Method:** 85% of patients favored IBDoc® over traditional stool sample collections.⁶
- **Increased compliance:** IBDoc® improved compliance to fCAL testing from 52 to 70% as compared to a regular lab test (Figure 4).¹⁰

“Brilliant, efficient and a lot easier and less stress waiting on hospital tests.”

Patient’s feedback on IBDoc®, Jere et al., 2021⁸

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).

- **Increased Patient Compliance:** „Patients’ compliance with performing the FC home test was more than satisfactory reaching **90%**.”⁹

„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

„Offer benefits as part of routine paediatric IBD monitoring to **reduce unnecessary hospital attendances**”⁸

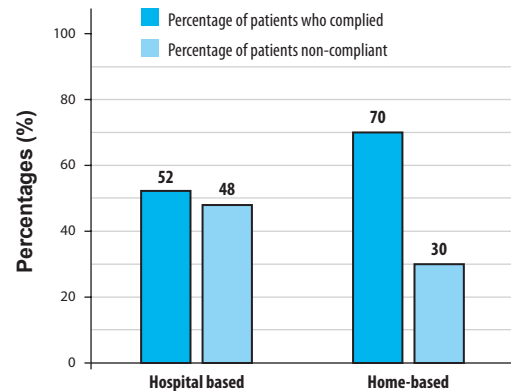


Figure 4 Compliance with lab tests versus IBDoc®

Adapted from Edwards et al., 2021¹⁰

Head-to-head comparison of three stool calprotectin tests for home use

	Concordance	RER	SUS
IBDoc®	😊	😊	😊
Competitor A	😐	😐	😞
Competitor B	😐	😐	😐

Concordance: Agreement between home test and its ELISA; RER: Reading Error Rate; SUS: System Usability Score

Figure 5 Comparison between calprotectin home tests

Adapted from Haisma et al., 2019⁷

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

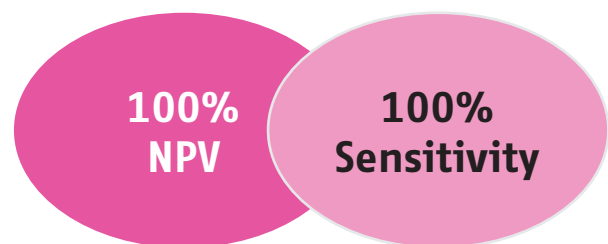


Figure 6 Clinical performance at the optimal fecal calprotectin threshold of 187 µg/g for detecting combined endoscopic and histologic disease activity

Adapted from Walsh et al., 2018⁴

IBDoc® fCAL Home Test – Connected Remote Care

Application Programming Interface

- Offers an easy solution for the IBD patients to get **everything in one app** making IBDoc® part of a complete remote monitoring patient pathway (Figure 8).
- **IBD Smart:** „IBDsmart and IBDoc have been demonstrated to be acceptable, usable, and noninferior”, compared to the Standard of Care.¹²
- **IBD Home:** In Sweden, the IBDoc® system is fully integrated in a nation-wide program called IBD Home.
 - Capio St Goran Hospital: IBD Home provides **increased flexibility and security** to patients.¹²
 - Vastra Götaland region: BD Home allows a **shift in hospital resources**, tailored to the patients needs (Figure 7).¹³

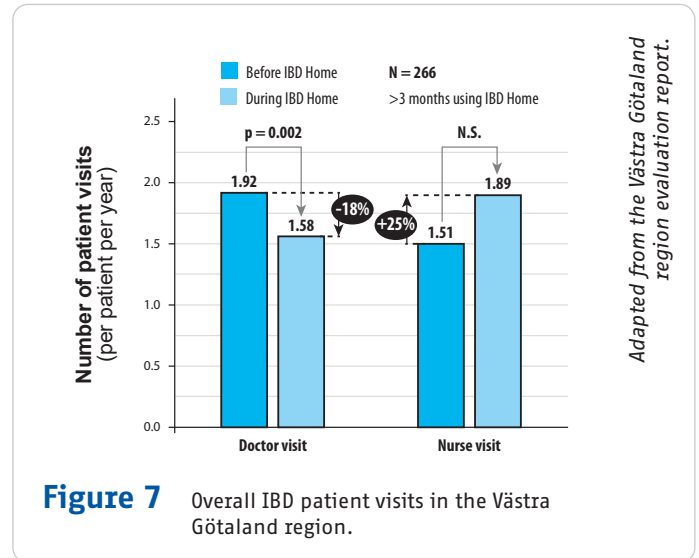


Figure 7 Overall IBD patient visits in the Västra Götaland region.

“We are happy that we have established a modern way of working that we can now shift up. Our patients can leave active life like most people when their illness is under control.”

Chief Physician Charlotte Söderman, Capio St. Goran hospital, Stockholm

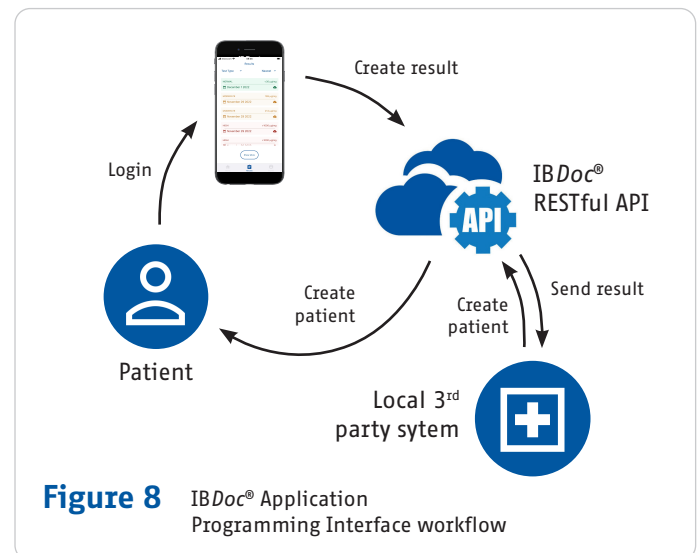


Figure 8 IBDoc® Application Programming Interface workflow

Literature list

- ¹Colombel JF. et al., Effect of tight control management on Crohn's disease (CALM): a multicenter, randomised, controlled phase 3 trial, The Lancet, 2017.
- ²Reinhard C. et al., Clinical performance of four fecal calprotectin assays from smartphone-based home test to high throughput central lab methods, UEGW 2023 Poster, 2023.
- 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.
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- ⁶Raker J., et al., P599 Home testing for faecal calprotectin: follow-up results from the first UK trial, ECCO 2017 Poster Abstract.
- ⁷Haisma et al., Head-to-head comparison of three stool calprotectin tests for home use, PLOS One, 2019.
- ⁸Jere et al., Point-of-care faecal calprotectin testing in patients with paediatric inflammatory bowel disease during the COVID-19 pandemic; BMJ Open Gastroenterology, 2021
- ⁹Orfanoudaki E. et al., Real-life utility and diagnostic accuracy of a home-performed fecal calprotectin test to predict endoscopic activity in patients with inflammatory bowel disease under maintenance treatment with adalimumab, European Journal of Gastroenterology & Hepatology, 2021.
- ¹⁰Edwards D. et al., P518 Compliance with Faecal calprotectin home testing as standard during COVID-19 pandemic compared to laboratory based testing pre-COVID, ECCO 2021 Poster Abstract.
- ¹¹McCombie et al., A Noninferiority Randomized Clinical Trial of the Use of the Smartphone-Based Health Applications IBDsmart and IBDoc in the Care of Inflammatory Bowel Disease Patients, Inflammatory Bowel Disease, 2019
- ^{12,13}IBD Home evaluation from the Capio St Goran Hospital and Vastra Gotaland Region. www.ibdoc.net/news

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Health Canada licence: 98903, Device class: 3
IBDoc® is not available for sale in the US.

Parts of the kit are patent protected by EP2617362(B1); EP2833795(B1); EP2947459(B1); US9752967(B2); US10620216(B2); AU2013210989(B2); AU2016203121(B2); AU2015261919(B2); BR112014017755-4; CA2861386(C); CA2997598(C); JP6043365(B2); JP6307132(B2); JP6467436(B2); KR10-1716740(B1); KR10-1875862(B1); ZL 201380009198.3



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Ordering code:

BI-IBDOC IBDoc Starter Kit
LF-IBDOC8 IBDoc Calprotectin Kit (8 tests)

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