

# IBDoc® Calprotectin Home Test

Health Canada Licence: 98903, Device class: 3

Not Available for Sale in the US.

Setting New  
Standards in IBD  
Monitoring



# IBDoc® fCAL Home Test – Technical Performance

Inflammatory Bowel Disease (IBD) is a chronic inflammatory disease 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 experience more than one flare per year (IBD2020 Report, 2013).

In the review article *"Improving quality of care in inflammatory bowel disease: what changes can be made today?"* Panes et al. conclude that one important element is to empower patients to actively participate in their disease management. A number of prospective studies show that calprotectin correlates well to mucosal healing and histologic inflammation with high sensitivity and specificity (Lobaton et al., 2013; Guardiola et al., 2012). Furthermore calprotectin assays also delivered valuable data on predicting coming relapses within the next 3 months in quiescent Crohn's Disease (Naismith et al., 2014).

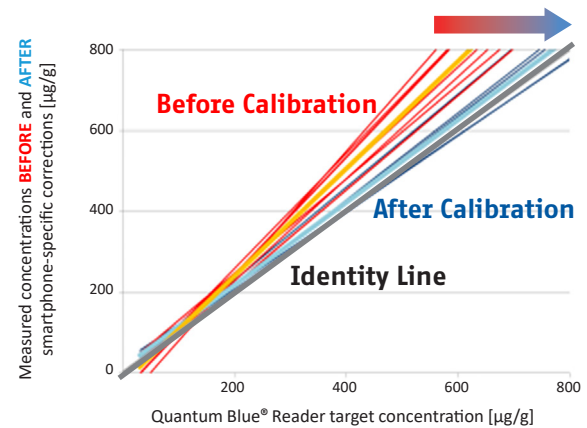
IBDoc® is the first CE-IVD certified fecal Calprotectin home test that is fully designed for remote IBD disease monitoring. IBDoc® uses a reliable and easy to use smartphone-based remote care solution and is the next step to improve the Quality of Care and Quality of Life of IBD patients.

## Key Benefits

1. **Easy to use** for all patients
2. **Excellent agreement** with Laboratory based Methods
3. **Reliable** Smartphone Validation process
4. **Independently clinically evaluated**

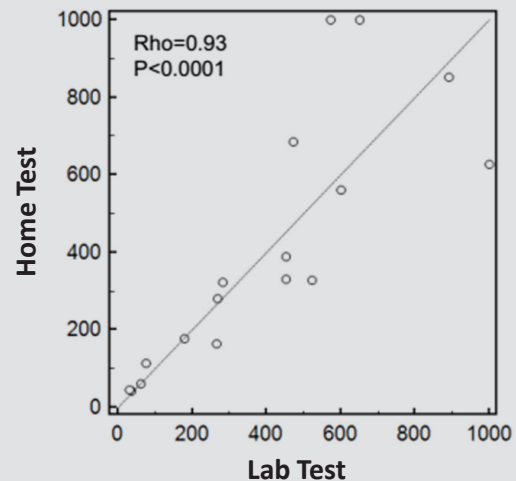
## Methods Comparison

- Due to a **robust and reliable validation procedure**, all validated smartphone models show improved correlation with the Point of Care **reference assay Quantum Blue® fCAL extended** (Figure 1).
- **Results performed by patient** under the supervision of a trained professional **correlate well to the reference result from the trained professional** (Figure 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** (Figure 3).



**Figure 1** Improved correlation with smartphone calibration

Adapted from Weber et al., 2015<sup>1</sup>



**Figure 2** Correlation between IBDoc® and Quantum Blue®

Adapted from Ungar et al., 2017<sup>2</sup>

		IBDoc® Result Patient		
		cut-off at 100 µg/g		TA/Total
ELISA Reference	<100 [Normal]	63	10	63/73
	>100 [Moderate-High]	10	69	69/79
	TA/Total	63/73	69/79	132/152
Total Agreement:				87%

**Figure 3** Agreement between Patient performed Test and laboratory reference measurement

Adapted from Heida et al., 2017<sup>3</sup>

# 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**<sup>4</sup> on a standardized usability questionnaire (Figure 4) and **were 100% satisfied** with the solution<sup>5</sup>
- **Better disease management:** 83% of patients reported that IBDoc® **helps them to manage their disease better** (Figure 5)<sup>4</sup>.
- **Preferred Method:** 85% favored IBDoc® over traditional stool sample collections<sup>6</sup>.

“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**”<sup>3</sup>
- **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). „IBDoc® has a **Negative Predictive Value (NPV)** of 88% to predict that patients with a value **below 100 µg/g (green)** stay in remission during the next 4 months”<sup>6</sup>



85 out of 100  
System Usability Score Points

Figure 4 Usability Scores

Adapted from Bello et al., 2017<sup>4</sup>

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

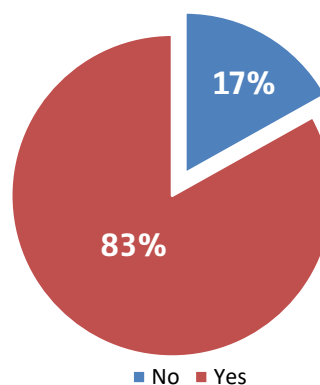


Figure 5 Disease Management

Adapted from Bello et al., 2017<sup>4</sup>

Clinical performance of IBDoc®  
to predict 4 months remission period

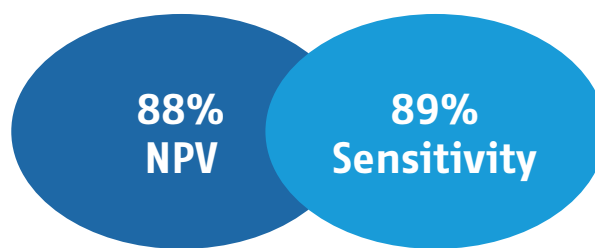


Figure 6 Comparison of IBDoc® and reference ELISA in regard of clinical performance at 100 µg/g cut-off

Adapted from Raker et al., 2017<sup>6</sup>

<sup>1</sup>Weber et al., Validation of a smartphone-based patient monitoring system measuring calprotectin, ECCO 2015 Poster

<sup>2</sup>Ungar B. et. al., P181 Home smart-phone based measurement of fecal calprotectin by IBD patients: correlation with laboratory assay and applicability as patient-friendly monitoring too, ECCO 2017 Poster

<sup>3</sup>Heida 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

<sup>4</sup>Bello C. et al., Usability of a home-based test for the measurement of fecal calprotectin in asymptomatic IBD patients, Digestive and Liver Disease, 2017.

<sup>5</sup>Fitzgerald D. et al., N804 An evaluation of patient satisfaction with IBDoc calprotectin home test system, ECCO 2017 Poster

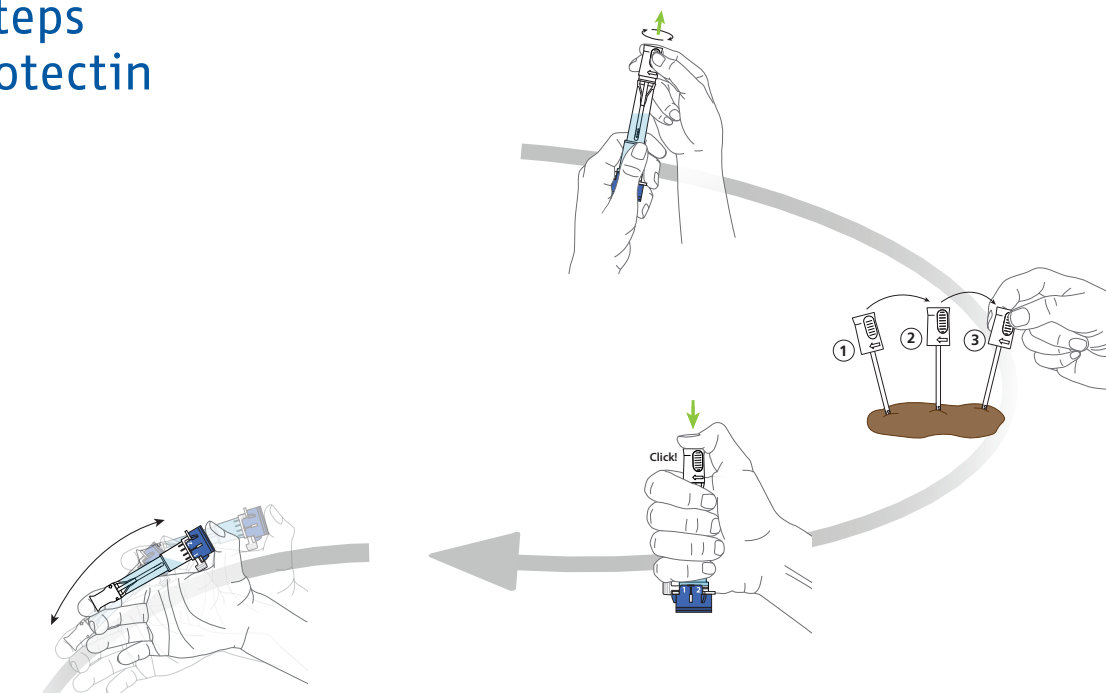
<sup>6</sup>Raker J., et al., P599 Home testing for faecal calprotectin: follow-up results from the first UK trial, ECCO 2017 Poster



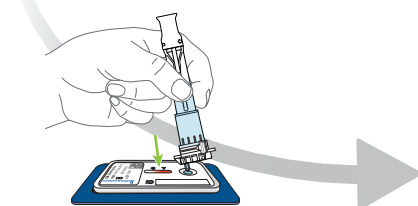
# IBDoc®

## Three easy steps to test calprotectin at home

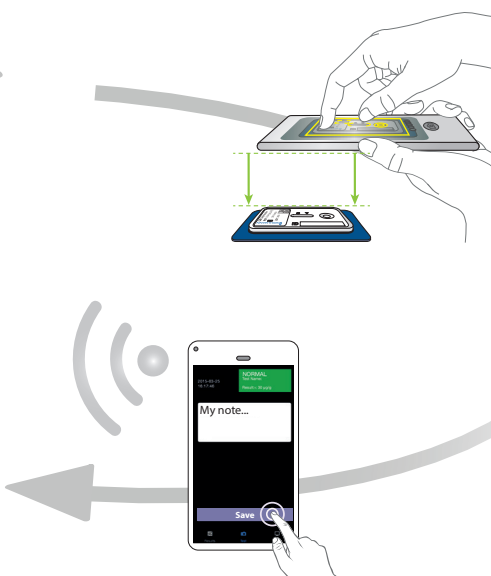
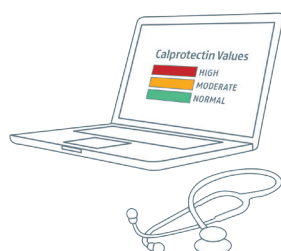
# 1



# 2



# 3



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BÜHLMANN Laboratories AG  
Switzerland  
[info@buhlmannlabs.ch](mailto:info@buhlmannlabs.ch)  
[www.buhlmannlabs.ch](http://www.buhlmannlabs.ch)  
Phone +41 61 487 12 12

BÜHLMANN Diagnostics Corp  
USA / Canada  
[info@buhlmannlabs.com](mailto:info@buhlmannlabs.com)  
[www.buhlmannlabs.com](http://www.buhlmannlabs.com)  
Phone 844 300 9799

#### Ordering code:

BI-IBDOC  
LF-IBDOC8

IBDoc Starter Kit  
IBDoc Calprotectin Kit (8 tests)

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