

IBDoc® Key Literature - Calprotectin Home Testing

Health Canada Licence: 98903, Device class:3
Not Available for Sale in the US.

Calprotectin as a surrogate marker in IBD Monitoring:

- Colombel JF. et al., 2017, Effect of tight control management on Crohn's disease (CALM): a multicentre, randomised, controlled phase 3 trial, *The Lancet*.
"...CALM is the first study to show that timely escalation with an α TNF therapy on the basis of clinical symptoms combined with biomarkers in patients with early Crohn's disease results in better clinical and endoscopic outcomes than symptom-driven decisions alone."
- Turvill J. et al., 2017, Validation of a care pathway for use of faecal calprotectin in monitoring patients with Crohn's disease, *Frontline Gastroenterology*.
"...the PPV of 0.85 and a NPV of 0.97 of this clinical validation are compelling..."
- Ferreira-Iglesias R. et al., 2016, Accuracy of Consecutive Fecal Calprotectin Measurements to Predict Relapse in Inflammatory Bowel Disease Patients Under Maintenance With Anti-TNF Therapy, *J Clin Gastroenterol*.
"...time interval to the next FC measurement should be probably shorter than 4 months after a FC result of 130 to 300 mg/g..."
- Rosenfeld G. et al., 2016, Focus: Future of fecal calprotectin utility in inflammatory bowel disease, *World J Gastroenterol*.
"...FC is a simple, non-invasive test that is gaining widespread use in the diagnosis and management of IBD."
- Theede K. et al., 2016, Fecal Calprotectin Predicts Relapse and Histological Mucosal Healing in Ulcerative Colitis, *Inflamm Bowel Dis*.
"Two consecutive measurements of a 1-month interval with FC >300 mg/kg were most predictive of relapse."

Benefits of Remote Monitoring

- Heida A. et al., 2017, The efficacy of home telemonitoring versus conventional follow-up: a randomised controlled trial among teenagers with inflammatory bowel disease, *Journal of Crohn's and Colitis*.
"Follow-up of teenagers with IBD by home telemonitoring is as safe as conventional follow-up, reduces outpatient visits and societal costs..."
- Squires S. I. et al., 2015, The financial impact of a nurse-led telemedicine service for inflammatory bowel disease in a large district general, *Frontline Gastroenterology*.
"Moreover, the cost savings when specialist nurse time is compared with GPs, consultants or hospital facilities is striking."

IBDoc® Publications

- Haisma S., 2019, Head-to-head comparison of three stool calprotectin tests for home use, *PLOS ONE*.
"We conclude that the flow-based home-test and the companion ELISA method can be used interchangeably..."
- McCombie A., 2019, 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 Diseases*.
"Remote symptom and fecal calprotectin monitoring is effective and acceptable. It also reduces the need for face-to-face outpatient appointments. Patients with mild-to-moderate disease who are not new diagnoses are ideal for this system...."

- Røer MJ., 2019, Usability of IBDoc, a Novel Fecal Calprotectin Home-Based Rapid Test in Clinical Practice, Point of Care.

"Clearly, the majority of the IBD patients found the homebased test valuable..."

- Walsh A. et al., 2018, 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.

"FCal is a useful surrogate marker for detecting endoscopic or histological remission or disease activity in ulcerative colitis."

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

"This study also showed a good correlation between the FC measurements from the IBDoc® and the ELISA method, with no false positives or negatives..."

- Avery P. et al., 2018, IBDoc® Self-care/Point of care Calprotectin Test: Early Value in a District General Hospital Inflammatory Bowel Disease Service ECCO 2018 Poster.

"The BÜHLMANN IBDoc® adds value to patient care; it enhances the patient's journey allowing quick treatment decisions to be made saving at least one hospital admission during this small trial of the product..."

- Wei S. et al., 2018, Experience of patients with inflammatory bowel disease in using a home fecal calprotectin test as an objective reported outcome for self-monitoring, Intestinal Research.

"Our results demonstrated the reliability and feasibility as well as patient acceptance of a smartphone-based home fC test."

- Kim YH., 2018, Home-based fecal calprotectin test is expected to play an important role in patients with inflammatory bowel diseases, Intestinal Research.

"Home-based FC testing is expected to play an important role for patients with IBD in the future..."

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

"The sensitivity, specificity, negative predictive value and positive predictive value of the home-based test to predict a fecal calprotectin > 300 µg/g by ELISA were, 89.8%, 95.5%, 91.4% and 94.6%."

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

"We found sufficient agreement between IBDoc® home test and hospital-based ELISA in the lower ranges of calprotectin to use this new test for disease monitoring."

- Hejl J. et al., 2017, Point of care testing of fecal calprotectin as a substitute for routine laboratory analysis, Practical Laboratory Medicine.

"This study suggests that IBDoc® is a suitable alternative for the assessment of disease activity in IBD patients. Point of care testing would reduce the turnaround time significantly and potentially improve the quality of treatment by enabling rapid responses to relapses."

- Ungar B. et al., 2017, 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.

"...the results of the home fecal calprotectin test (IBDoc) correlate well with values-ranges obtained using conventional lab-based calprotectin test."

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Ordering code:

BI-IBDOC

IBDoc Starter Kit

LF-IBDOC8

IBDoc Calprotectin Kit (8 tests)