

IBDoc® Key Literature - Calprotectin Remote Monitoring

Health Canada Licence: 98903, Device class: 3

Not Available for Sale in the US.

Overview Articles:

- Sherwood R. A., 2012 Faecal markers of gastrointestinal inflammation. *Journal of Clinical Pathology*.
- Louis E. et al., 2015, Fecal calprotectin: towards a standardized use for inflammatory bowel disease management in routine practice. *Journal of Crohn's and Colitis*.

Calprotectin as a surrogate marker in IBD Monitoring:

- Naismith G. D. et al., 2014, A prospective evaluation of the predictive value of faecal calprotectin in quiescent Crohn's disease, *Journal of Crohn's and Colitis*.

"The FC result, obtained by non-invasive means, can provide prognostic information for both the patient and clinician alike."

- Pavlidis P. et al., 2016, Early change in faecal calprotectin predicts primary non-response to anti-TNF α therapy in Crohn's disease, *Scandinavian Journal of Gastroenterology*.

"The Δ FCAL could act as an 'early warning' to consider alternatives such as dose optimisation or another biologic with a different mode of action, rather than persisting for several months."

- 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."

- 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..."

- 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."

- 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..."

Benefits of Remote Monitoring

- 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."

- 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..."

IBDoc® Publications

- Weber J. et al., 2015, Validation of a smartphone-based patient monitoring system measuring calprotectin as the therapy follow-up marker. UEGW 2015 Poster.
"The performance of the smartphone-based IBDoc® home testing system is comparable to professional, laboratory-based methods"
- Reinhard C. et al., 2016, Performance and Usability Testing of IBDoc®, a Novel Smartphone-Based monitoring system for measuring fecal calprotectin, DDW 2016 Poster.
"IBDoc® is the first complete and validated (CE/IVD) test system which allows the IBD patient to monitor and follow his inflammatory status by measuring the IBD biomarker, fecal calprotectin, using his/her own smartphone. It is the first self testing device of its kind."
- 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 tool, ECCO 2017 Poster.
"...the results of the home fecal calprotectin test (IBDoc) correlate well with values-ranges obtained using conventional lab-based calprotectin test."
- Fitzgerald D. et al., 2017, An evaluation of patient satisfaction with IBDoc calprotectin home test system, ECCO 2017 Poster.
"This study shows that calprotectin testing at home using a smartphone as the measuring system was very well received among the tested users (100% satisfaction)"
- Raker J. et al., 2017, Home testing for faecal calprotectin: follow-up results from the first UK trial, ECCO 2017 Poster.
"...a negative FCAL of < 100 µg/g by either method (IBDoc or ELISA) is a useful test to exclude a flare within four months"
- Elsafi G. et al., 2017, Cost effective of IBDoc as a surrogate marker of mucosal healing in IBD patients post induction of biological agents, UEGW 2017 Poster.
"This study demonstrate a significant cost effectiveness of using IBDoc faecal calprotectin post induction of anti-TNF therapy, as well as reducing the waiting time for both clinic visits and colonoscopies."
- 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. "
- 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%."
- 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."

Ordering code:

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