

IBDoc® Key Literature - Calprotectin Home Testing

IBDoc® Publications

- Orfanoudaki E. et al., 2021, 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*.
"On the basis of our results, the FC home test could be used as a reliable alternative to ELISA as it meets patients' acceptance and shows satisfactory accuracy and efficacy, better than other bio-markers, in predicting endoscopic active disease."
- Jere M. et al., 2021, Point-of-care faecal calprotectin testing in patients with paediatric inflammatory bowel disease during the COVID-19 pandemic, *BMJ Open Gastroenterology*.
"This demonstrates the potential usefulness of home testing during the COVID-19 pandemic and suggests this modality may be of continued utility as part of routine services for patients with IBD."
- Östlund I. et al., 2021, Self-monitoring with home based fecal calprotectin is associated with increased medical treatment. A randomized controlled trial on patients with inflammatory bowel disease, *Journal of Clinical Medicine*.
"Telemedicine and selfmonitoring for IBD have proven themselves safe and feasible with several positive effects."
- Haisma S. et al., 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. et al., 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 M., 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..."
- 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 smart-phone-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.”

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

- D'Amico F. et al., 2020, Setting up a Virtual Calprotectin Clinic in Inflammatory Bowel Diseases: Literature Review and Nancy Experience, *Journal of Clinical Medicine*.
"...the FC home test could be a valuable tool for monitoring patients in clinical remission."
- 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..."
- Bossuyt P. et al., 2017, Primetime for e-health in IBD?, *Gastroenterology & Hepatology*
"By closer (self-)monitoring, flares can be predicted and treated more effectively, resulting in a continuous response to therapy with subsequent better outcomes."
- 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® Posters

- **Edwards D. et al., 2021, Compliance with Faecal calprotectin home testing as standard during COVID-19 pandemic compared to laboratory based testing pre-COVID, ECCO 2021 Poster.**

"Adopting rapid FC home testing as standard provides patients with increased locus of control regarding their care, whilst also, providing healthcare professionals with rapid results, thus, will improve management of IBD."

- **Sugrue K. et al., 2020, An evaluation of the impact of IBDoc® in clinical practice 5 years after introduction, ECCO 2020 Poster.**

"IBDoc® facilitates better allocation of resources and results in cost savings."

- **Avery P. et al., 2020, IBDoc® Faecal calprotectin self-test retrospective audit in a District General Hospital (DGH), ECCO 2020 Poster.**

"This information helps separate well from unwell patients, offering further opportunities to promote supported self-management in people with IBD and prioritisation of clinic appointments."

- **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..."

- **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."

- **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."

- **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."

- **Beyer A. et al., 2015, Usability Study of a Smartphone-Based Calprotectin Home Test, UEGW 2015 Poster.**

"This study shows that calprotectin home testing using a smartphone as measuring system was well accepted among IBD Patients."

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Health Canada Licence: 98903, Device class: 3

IBDoc® is not available for sale in the US.

Ordering code:

BI-IBDOC

IBDoc Starter Kit

LF-IBDOC8

IBDoc Calprotectin Kit (8 tests)