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## **BÜHLMANN Calprotectin Assays Key Literature**

## **Diagnosis**

 Burri, E. et al. Monoclonal antibody testing for fecal calprotectin is superior to polyclonal testing of fecal calprotectin and lactoferrin to identify organic intestinal disease in patients with abdominal discomfort. Clinica Chimica Acta 416, 41-47 (2013).

"Monoclonal testing of calprotectin is superior to both polyclonal calprotectin testing and fecal lactoferrin in identifying symptomatic patients with organic intestinal

Sydora, M. J., Sydora, B. C. & Fedorak, R. N. Validation of a point-of-care desk top device to quantitate fecal calprotectin and distinguish inflammatory bowel disease from irritable bowel syndrome. Journal of Crohn's and Colitis 6, 207-214 (2012).

"Quantum Blue Reader® calprotectin levels were available within 30 min and correlated well with results derived from standard ELISA assays."

• Jensen, M. D. et al. Fecal calprotectin is equally sensitive in Crohn's disease affecting the small bowel and colon. Scandinavian journal of gastroenterology 46, 694-700 (2011).

"The first study to show that fCal is equally sensitive in colonic and small bowel CD."

• Pavlidis, P., Chedgy, F. J. & Tibble, J. A. Diagnostic accuracy and clinical application of faecal calprotectin in adult patients presenting with gastrointestinal symptoms in primary care. Scandinavian journal of gastroenterology 48, 1048-1054 (2013).

"This study provides the first evidence on the use of fCal testing inprimary care.....to be used as part of the pathway for management of patients with suspected IBS."

 Labaere, D. et al. Comparison of six different calprotectin assays for the assessment of inflammatory bowel disease. United European Gastroenterology Journal 2, 30-37 (2014).

"The EliA cut off for diagnosis was optimal at a level of 15 mg/g. This is as low as the detection limit of the assay, which is analytically unacceptable."

 Oyaert, M. et al. Comparison of two immunoassays for measurement of faecal calprotectin in detection of inflammatory bowel disease: (pre)-analytical and diagnostic performance characteristics. Clinical chemistry and laboratory medicine: CCLM / FESCC 52, 391-7 (2013).

"The Thermo Fisher device is not reliable for extraction of faecal calprotectin."

 Mindemark, M. & Larsson, A. Ruling out IBD: Estimation of the possible economic effects of pre-endoscopic screening with F-calprotectin. Clinical Biochemistry 45, 552-555 (2012).

"The estimated demand for colonoscopies was reduced by 50% to 67%. This corresponded to a cost avoidance of approximately up to €2.13 million."

## **IBD Patient Monitoring**

 Lobatón, T. et al. A New Rapid Quantitative Test for Fecal Calprotectin Predicts Endoscopic Activity in Ulcerative Colitis. Inflammatory bowel diseases 19, 1034-1042 (2013).

"FC determined by QPOCT was an accurate surrogate marker of "endoscopic remission" in UC and presented a good correlation with the FC-ELISA test."

 Lobatón Ortega, T. et al. A new rapid test for fecal calprotectin predicts endoscopic remission and postoperative recurrence in Crohn's disease. Journal of Crohn's & colitis 7, e641-51 (2013).

"FC determined by rapid quantitative test predicts "endoscopic remission" and endoscopic postoperative recurrence in CD patients."

 Naismith, G. D. et al. A prospective evaluation of the predictive value of faecal calprotectin in quiescent Crohn's disease. Journal of Crohn's and Colitis (2014). doi:10.1016/j.crohns.2014.01.029

"An optimal cut off FC value of 240  $\mu$ g/g to predict relapse had sensitivity of 80.0% and specificity of 74.4%. FC  $\geq$  240  $\mu$ g/g was associated with likelihood of relapse by 12-months 12.18 (95%CI 2.55–58.2) times higher than lower values (p = 0.002)."

 Guardiola, J. et al. Fecal Level of Calprotectin Identifies Histologic Inflammation in Patients with Ulcerative Colitis In Clinical And Endoscopic Remission. 1-26 (2014). doi:10.1016/j.cgh.2014.06.020

"Histologic inflammation is common among patients with UC in clinical and endoscopic remission. Patients with histologic features of inflammation can be reliably identified based on fecal level of calprotectin."

 Coorevits, L., Baert, F. J. & Vanpoucke, H. J. M. Faecal calprotectin: comparative study of the Quantum Blue rapid test and an established ELISA method. Clinical chemistry and laboratory medicine: CCLM / FESCC 51, 825-31 (2013).

"The point of care test can serve as a reliable alternative in the differential diagnosis. Furthermore it seems to be reliable in the follow up of inflammatory bowel disease patients."

 Voiosu et al. Rapid Fecal Calprotectin Level Assessment and the SIBDQ Score Can Accurately Detect Active Mucosal Inflammation in IBD Patients in Clinical Remission: a Prospective Study. J Gastrointestin Liver Dis 2014 Vol. 23 No 3: 273-278

"FC levels appears to be a practical method for monitoring disease activity in these patients, possibly reducing the need for repeat endoscopic examinations"

## **Further BÜHLMANN Assays Calprotectin Literature**

- Manz, M. et al. Value of fecal calprotectin in the evaluation of patients with abdominal discomfort: an observational study. BMC Gastroenterology 12, 5 (2012).
- Hessels, J. et al. Evaluation of Prevent ID and Quantum Blue rapid tests for fecal calprotectin. Clinical Chemistry and Laboratory Medicine 50, (2012).
- Whitehead, S., French, J. & Brookes, M. Between-assay variability of faecal calprotectin enzyme-linked immunosorbent assay kits. Annals of clinical (2013).
- Kok, L. et al. Diagnostic Accuracy of Point-of-Care Fecal Calprotectin and Immunochemical Occult Blood Tests for Diagnosis of Organic Bowel Disease in Primary Care: The Cost-Effectiveness of a Decision Rule for Abdominal Complaints in Primary Care (CEDAR) Study. Clinical chemistry 58, 989-998 (2012).
- Kolho, K. L. et al. Rapid test for fecal calprotectin levels in children with Crohn disease. Journal of Pediatric Gastroenterology and Nutrition 55, 436-9 (2012).
- Waugh N,. et al. Faecal calprotectin testing for differentiating amongst inflammatory and non-inflammatory bowel diseases: systematic review and economic evaluation. 1-236 (2013). doi:10.3310/hta17550
- Paul, S. et al. Therapeutic Drug Monitoring of Infliximab and Mucosal Healing in Inflammatory Bowel Disease. Inflammatory bowel diseases 19, 2568-2576 (2013).
- Vermunt R, et al., Eurofins Medinet B.V Department of Biomarkers & Biopharmaceuticals, Calprotectin in biomarker-mediated drug development (2011).
- Prell, C., Nagel, D., Freudenberg, F., Schwarzer, A. & Koletzko, S. Comparison of three tests for faecal calprotectin in children and young adults: a retrospective monocentric study. BMJ Open 4, e004558-e004558 (2014).
- Yoon et al. Fecal calprotectin concentration in neonatal necrotizing enterocolitis. Korean J Pediatr;57(8):351-356 (2014)
- Wassell, J., Wallage, M. & Brewer, E. Evaluation of the Quantum Blue® rapid test for faecal calprotectin. Annals of clinical biochemistry 49, 55-8 (2012).
- Dolci, A. & Panteghini, M. Comparative study of a new quantitative rapid test with an established ELISA method for faecal calprotectin. Clinica chimica acta; international journal of clinical chemistry 413, 350-1 (2012).
- Burri, E., Schulte, F., Muser, J., Meier, R. & Beglinger, C. Measurement of calprotectin in ascitic fluid to identify elevated polymorphonuclear cell count. World journal of gastroenterology: WJG 19, 2028-36 (2013).
- Wang, S. et al. Faecal calprotectin concentrations in gastrointestinal diseases. The Journal of international medical research 41, 1357-61 (2013).
- Liu, J. et al. Fecal calprotectin levels are higher in rural than in urban Chinese infants and negatively associated with growth. BMC Pediatrics 12, 129 (2012).