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Key Literature – BÜHLMANN fecal Calprotectin Citations in IBD Monitoring

Monitoring of IBD Patients:

Gastroenterol

Abej, E. et al., 2016, The Utility of Fecal Calprotectin in the Real-World Clinical Care of Patients with Inflammatory Bowel Disease, Canadian Journal of Gastroenterology and Hepatology

Quantum Blue® fCAL

"...positive FCAL was significantly associated with abnormal endoscopy, elevated serum CRP, low serum Hg, and low serum albumin."

 Coorevits, L. et al., 2012, Faecal calprotectin: comparative study of the Quantum Blue rapid test and an established ELISA method, Clinical chemistry and laboratory medicine: CCLM / FESCC

BÜHLMANN fCAL® ELISA

Quantum Blue® fCAL

Ferreiro-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

"...we may conclude that the POCT can serve as reliable alternative to the time consuming ELISA..."

Quantum Blue® fCAL

"...time interval to the next FC measurement should be probably shorter than 4 months after a FC result of 130 to 300 mg/g..."

 Ferreiro-Iglesias, R. et al., 2015, Fecal Calprotectin as Predictor of Relapse in Patients With Inflammatory Bowel Disease Under Maintenance Infliximab Therapy, J Clin Gastroenterol

Ouantum Blue® fCAL

"We found FC to be a very accurate marker to exclude relapse within the following 2 month after administration of Infliximab."

• Guardiola, J. et al., 2014, Fecal Level of Calprotectin Identifies Histologic Inflammation in Patients with Ulcerative Colitis In Clinical And Endoscopic Remission, Clinical Gastroenterology and Hepatology

BÜHLMANN fCAL® ELISA

Quantum Blue® fCAI

"...an FC value less than 155 mg/g is a reliable indicator of the absence of acute inflammatory infiltrate (negative predictive value, 89 %)." $^{\prime\prime}$

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Jusué, V. et al., 2018, Accuracy of fecal calprotectin for the prediction of endoscopic activity in patients with inflammatory bowel disease, *Dig Liv Dis*

/i-

"Fecal calprotectin concentration has good diagnostic accuracy for the detection of endoscopic activity in inflammatory bowel disease..."

Kostas, A. et al., 2017, Fecal calprotectin measurement is a marker of short-term clinical outcome and presence of mucosal healing in patients with inflammatory bowel disease, World J Gastroenetrol

BÜHLMANN fCAL® ELISA

"...In our patient cohort, we were able to define an optimal cut-off FC value of 261 mg/g, which had a strong predictive value for the discrimination of future relapses vs maintenance of remission."

 Kristensen, V. et al., 2017, Fecal Calprotectin: A Reliable Predictor of Mucosal Healing after Treatment for Ulcerative Colitis, Gastroenterol Res Pract

BÜHLMANN fCAL® ELISA

"...f-calprotectin < 250 μ g/g predicts endoscopic mucosal healing with high positive predictive value and may therefore be regarded as a relible noninvasive biomarker."



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Lasson, A. et al., 2014, Pharmacological intervention based on fecal calprotectin levels in patients with ulcerative colitis at high risk of relapse: A prospective, randomized, controlled study, United European | BÜHLMANN FCAL® ELISA Gastroenterology Journal

"In patients with UC, FC-guided dosing of the patient's 5-ASA agent showed significantly lower relapse rates than for patients in the control group."

· Lee, S. H. et al., 2017, Fecal calprotectin predicts complete mucosal healing and better correlates with the ulcerative colitis endoscopic index of severity than with the Mayo endoscopic subscore in patients with ulcerative colitis, BMC Gastroenterol

Quantum Blue® fCAL

"The FC cut-off level of 187.0 mg/kg indicated complete mucosal healing (MES = 0; UCEIS =0) with a sensitivity and specificity of 0.857 and 0.891, respectively (area under the curve, 0.883; 95% confidence interval. 0.772-1.000)."

Lee, Y. W. et al., 2019, The usefulness of fecal calprotectin in assessing inflammatory bowel disease activity, Korean J Intern Med

Quantum Blue® fCAL

"The FC-QPOCT (Quantum Blue® fCAL) is easy to perform and able to produce more rapid quantitative results than the FC-ELISA method. Therefore, the FC-QPOCT appears to be more suitable for real practice and could be more widely used in the future."

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

BÜHLMANN fCAL® ELISA

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

Quantum Blue® fCAL

Lobatón Ortega, T. et al., 2013, A New Rapid Quantitative Test for fecal Calprotectin Predicts Endoscopic Activity in Ulcerative Colitis, Inflammatory bowel diseases

RÜHI MANN fCAI® FUSA

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

Quantum Blue® fCAL

Louis Edouard, 2015, Fecal calprotectin: towards a standardized use for inflammatory bowel disease management in routine practice, Journal of Crohn's and Colitis

Quantum Blue® fCAL

"...fecal calprotectin as a unique first line test would be sufficient to decide in which patient to perform further endoscopic or medical imaging explorations."

Magro, F. et al., 2018, Comparison of different histological indexes in the assessment of UC activity and their accuracy regarding endoscopic outcomes and faecal calprotectin levels, Inflamm bowel dis

Quantum Blue® fCAL

"...81 %, 93 % and 88% of the patients that have an FC level below 150µg/g (using the QB method) are in histological remission according to NI, RHI and GS (using 3.1 as the cut-off)."

Moniuszko, A. et al., 2017, Rapid fecal calprotectin test for prediction of mucosal inflammation in ulcerative colitis and Crohn disease: a prospective cohort study, Pol Arch Int Med

Quantum Blue® fCAL

"This noninvasive diagnostic tool should be implemented in everyday clinical practice, because earlier detection of disease flares may help optimize the care of patients with IBDs."

Monteiro, S. et al., 2018, Low fecal calprotectin predicts clinical remission in Crohn's disease patients: the simple answer to a challenging question, Scan J Gastroenterol

Quantum Blue® fCAL

"Values of FC ≤ 327 µg/g can exclude relapse at least at six months follow-up period."



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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*

BÜHLMANN fCAL® ELISA

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

 Nakov, R. V. et al., 2018, Fecal Calprotectin for Assessment of Inflammatory Bowel Disease Activity, Clin Res Immunology

Quantum Blue® fCAL

"The ROC analysis found that a cufoff FCP level of 315 μ g/g differentiates quiescent CD from active ileal disease with 94 % sensitivity, 98% specificity, and area under the curve (AUC) 0.984."

Nakov, R. V. et al., 2018, Role of Fecal Calprotectin as a Noninvasive Indicator for Ulcerative Colitis Disease Activity, Folia Med

Quantum Blue® fCAL

"In the present study FCP was analyzed in stool samples by means of point-of- Quantum Blue® method. We find this test really useful, because it is simple to use, can be done in doctor's office and is quite fast (results can be obtained in less than 30 min including protein extraction)."

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

BÜHLMANN fCAL® ELISA

"The ΔFCAL 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."

Roblin, X. et al., 2017, Development and Internal Validation of a Model Using Fecal Calprotectin in Combination with Infliximab Trough Levels to Predict Clinical Relapse in Crohn's Disease, Inflamm Bowel Dis

Quantum Blue® fCAL

"In IFX-treated patients with CD in clinical remission, a combination of TLI ($<2 \mu g/mL$) and fecal calprotectin ($>250 \mu g/g$ of stools) is a good model for predicting loss of response."

Rosenfeld, G. et al., 2016, Focus: Future of fecal calprotectin utility in inflammatory bowel disease, World I Gastroenterol

Quantum Blue® fCAL

"...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

BÜHLMANN fCAL® ELISA

"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

BÜHLMANN fCAL® ELISA

"...the PPV of 0.85 and a NPV of 0.97 of this clinical validation are compelling..."

Voiosu, T. et al., 2014, 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

Quantum Blue® fCAL

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



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Wright, E. K. et al., 2016, Comparison of Fecal Inflammatory Markers in Crohn's Disease, Inflamm Bowel
Dis

BÜHLMANN fCAL® ELISA

"This study shows that FC is the optimal marker for diagnosing and monitoring endoscopic postoperative recurrence."

Wright, E. K. et al., 2015, Measurement of Fecal Calprotectin Improves Monitoring and Detection of Recurrence of Crohn's Disease After Surgery, Gastroenterology

BÜHLMANN fCAL® ELISA

"The present study has shown that FC concentration is sufficiently sensitive to monitor for recurrence of Crohn's disease."

Zhulina, Y. et al., 2016, The prognostic significance of faecal calprotectin in patients with inactive inflammatory bowel disease, Aliment Pharmacol Ther

BÜHLMANN fCAL® ELISA

"Our data suggest that longitudinal monitoring of faecal calprotectin is informative in predicting relapse in IBD."

• Zittan, E. et al., 2015, Low Fecal Calprotectin Correlates with Histological Remission and Mucosal Healing in Ulcerative Colitis and Colonic Crohn's Disease, *Inflamm Bowel Dis*

Quantum Blue® fCAL

"Low FC correlates well with histological remission and mucosal healing in colonic inflammatory bowel disease and is thus a clinically useful surrogate for inflammatory activity."