

BÜHLMANN Calprotectin assays, used by hundreds, trusted by thousands.....

The value of faecal calprotectin in diagnosing IBD:

- Jensen, M.D. *et al. Scandinavian Journal of Gastroenterology* 2011. Faecal calprotectin is equally sensitive in Crohn's disease affecting the small bowel and colon.
"Levels and sensitivities of fCal are equal in patients with colonic and small bowel CD. Due to its high sensitivity and negative predictive value, fCal is a useful marker to rule out CD and select patients for endoscopy". Uses BÜHLMANN fCAL® ELISA
- Mindemark. M *et al Clinical Biochemistry* 2012. Estimation of the possible economic effects of pre-endoscopic screening with F-calprotectin.
"The use of F-calprotectin as a screening test substantially could reduce the number of invasive measurements necessary in the diagnostic work-up of patients with suspected IBD, as well as the associated costs". Uses BÜHLMANN fCAL® ELISA
- Wassell. J *et al Annals of Clinical Biochemistry* 2011. Evaluation of the Quantum Blue rapid test for faecal calprotectin.
" In our hands, the Quantum Blue method was a suitable screening test for excluding inflammatory bowel disease. It may be of value to laboratories wishing to offer calprotectin but who do not have sufficient numbers to warrant ELISA methodology or in 'one stop' gastrointestinal clinics where an immediate result is required. Uses BÜHLMANN fCAL® ELISA and Quantum Blue
- Al-Bahrani. A *et al. Frontline Gastroenterology* 2011. Calprotectin and Inflammatory Bowel Diseases (IBD) Isle of Wight experience.
"Calprotectin is a useful marker in ruling out IBD and stratifying patients with suspected IBD that require further investigation and rapid access for endoscopy". Uses BÜHLMANN Quantum Blue
- Manz. M *et al BMC Gastroenterology* 2012. Value of fecal calprotectin in the evaluation of patients with abdominal discomfort: An observational study.
"In patients with abdominal discomfort, fecal calprotectin is a useful non-invasive marker to identify clinically significant findings of the gastrointestinal tract, irrespective of age". Uses BÜHLMANN fCAL® ELISA
- Dhaliwal *et al. Frontline Gastroenterology* 2015. Utility of faecal calprotectin in IBD. What cut-offs should we apply
"FC is beneficial in distinguishing between functional GI conditions (IBS) and organic disease (IBD). In those with IBD, a 250 µg/g cut-off aids in determining clinical disease activity". Uses BÜHLMANN fCAL® ELISA

- Hui Won Jong *et al.* 2016. Accuracy of three different fecal calprotectin tests in the diagnosis of inflammatory bowel disease.
“Overall accuracy for differentiating IBD from IBS or “other colitis” was the best for Quantum Blue® Calprotectin (97%/91%),” Uses BÜHLMANN Quantum Blue
- Pavlidis *et al.* *Scandinavian Journal of Gastroenterology* 2013. Diagnostic accuracy and clinical application of faecal calprotectin in adult patients presenting with gastrointestinal symptoms in primary care.
“this is the first study to provide evidence on the use of fCal testing for patients presenting in the primary care setting with gastrointestinal symptoms of IBS. Correct use of the test and adherence to usage/referral protocols are likely to lead to fewer referrals to secondary care and consequent fewer investigations with potential cost savings.” Uses BÜHLMANN fCAL® ELISA

BÜHLMANN fCAL® Assays in IBD:

- Labaere, D. *et al.* *United European Gastroenterology Journal* 2014, Comparison of six different calprotectin assays for the assessment of inflammatory bowel disease.
Quantum Blue was one of the assays achieving the highest discriminatory power between IBD and non-IBD samples. “The EliA [Phadia] 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.” Uses BÜHLMANN Quantum Blue
- Burri, E. *et al.* *Clinica Chimica Acta* 2013. 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.
“...we demonstrated, that the diagnostic accuracy of monoclonal antibody testing of calprotectin is superior to both polyclonal antibody testing...”
- Sydora, M. J. *et al.* *Journal of Crohn’s and Colitis* 2012. Validation of a point-of-care desk top device to quantitate fecal calprotectin and distinguish inflammatory bowel disease from irritable bowel syndrome.
“The point-of-care desk-top Quantum Blue Reader® is the instrument of choice for fast and reliable determination of fecal calprotectin levels.” Uses BÜHLMANN Quantum Blue
- Lobatón, T. *et al.* *Inflammatory bowel diseases* 2013. A New Rapid Quantitative Test for Fecal Calprotectin Predicts Endoscopic Activity in Ulcerative Colitis.
“FC determined by QPOCT was an accurate surrogate marker of “endoscopic remission” in UC and presented a good correlation with the FC-ELISA test”. Uses BÜHLMANN fCAL® ELISA and Quantum Blue
- Kok, L *et al.* *Clinical Chemistry* 2012. 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.
“Diagnostic accuracy of the tests alone or combined was insufficient when all adenomas were considered OBD. When only adenomas ≥ 1 cm were considered OBD, all tests could rule out

OBD to a reasonable extent, particularly the combined POC tests. The tests were less useful for inclusion of OBD". Uses BÜHLMANN fCAL® ELISA and Quantum Blue

- Schulz. C *et al. Clinical Lab July 2016*. Validation of Two Calprotectin Rapid Tests in Daily Routine.
" Both rapid tests analyzed in this study revealed a high sensitivity in comparison to ELISA defined as gold standard (93.0% PreventID, 99.9% Quantum Blue). The negative predictive value in comparison to ELISA of Quantum Blue was better than of PreventID® (99.8% vs. 84.2%)". Uses BÜHLMANN and Quantum Blue
- Nilsen T. *et al. Journal of Clinical Laboratory Analysis 2016*. A novel turbidimetric immunoassay for fecal calprotectin optimized for routine chemistry analysers.
"Our study shows that the turbidimetric reagent had a good agreement with the BÜHLMANN fCAL ELISA with a slope close to 1.0. We observed no interference problems, the reagents had good stabilities and the method had a good linearity and precision on the investigated assay platforms.
In conclusion, the fCal Turbo PETIA is well suited for rapid analysis of fecal calprotectin on Mindray BS-380 or Cobas c501 analyzers providing short test turn-around times". Uses BÜHLMANN fCAL® turbo
- Sunde K. *et al. Poster EuroMedLab 2015*. Analytical Performance of a fecal calprotectin PETIA (fCAL) test.
" The new latex turbidimetric procedure for determining calprotectin is an attractive alternative to ELISA allowing random access and full automation of fecal calprotectin quantitation. Moreover, it represents an accurate and precise method to determine calprotectin levels in fecal extracts in a measuring range from 15 to 10'000 µg/g." Uses BÜHLMANN fCAL® turbo
- Coorevits. L. *et al. Clinical chemistry and laboratory medicine: CCLM / FESCC 2012*. Faecal calprotectin: comparative study of the Quantum Blue rapid test and an established ELISA method.
"...we may conclude that the POCT can serve as reliable alternative to the time consuming ELISA...". Uses BÜHLMANN fCAL® ELISA and Quantum Blue
- Turvill. J *et al. British Journal of General Practice 2016*. Faecal calprotectin in patients with suspected colorectal cancer: A diagnostic accuracy study.
"FC has a high NPV for colorectal cancer and significant polyps in patients with suspected cancer. In total, 27.8% of patients had a normal FC and could safely have been spared a '2-week wait' referral. The addition of FC testing into the current symptom-based assessment has the potential to increase colorectal cancer detection rate yet be clinically and cost effective". Uses BÜHLMANN fCAL® ELISA
- Chayut. D *et al. ECCO 2016 P351*. Faecal calprotectin correlates well with extent of active endoscopic inflammation in patients with ulcerative colitis.
"FC is reasonably accurate in predicting active disease location. This may be improved by adding clinical markers such as rectal bleeding and PMS. Pending larger studies validation, FC may be useful to direct topical vs systemic therapy in UC". Uses BÜHLMANN Quantum Blue®
- Alzoubaidi. D *et al. DDF 2015 Poster*. Is a false positive calprotectin as false as you think?

“In our unit capsule endoscopy highlighted a pathological explanation in 71.4 % and possible small bowel Crohn’s Disease in 57.14 % of these patients”. Uses BÜHLMANN fCAL® ELISA

- Paul. S *et al. Inflammatory Bowel Disease 2013*. Therapeutic drug monitoring of Infliximab and mucosal healing in IBD: A Prospective study.
Uses BÜHLMANN Quantum Blue®
- Abej. E *et al. Canadian Journal of Gastroenterology and Hepatology 2016*. Utility of faecal calprotectin in the real-world clinical care of patients with inflammatory bowel disease.
“We found that in a referral population of persons with IBD, positive FCAL was significantly associated with abnormal endoscopy, elevated serum CRP, low serum Hg, and low serum albumin”
- Lobatón Ortega, T. *et al. Journal of Crohn's & colitis 2013*. A new rapid test for fecal calprotectin predicts endoscopic remission and postoperative recurrence in Crohn's disease.
“FC determined by rapid quantitative test predicts “endoscopic remission” and endoscopic postoperative recurrence in CD patients.” Uses BÜHLMANN fCAL® ELISA and Quantum Blue

Monitoring of IBD patients:

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

“The FC result obtained by non-invasive means (fCAL ELISA) can provide prognostic information for both the patient and clinician alike”. Uses BÜHLMANN fCAL® ELISA

- Wright. E *et al. Inflammatory Bowel Disease 2016*. Comparison of Fecal Inflammatory Markers in Crohn’s Disease

“FC appeared to be the optimal marker for identification of endoscopic postoperative recurrence, with high sensitivity and NPV. FC measurement is sufficiently sensitive in the postoperative setting after resection of all macroscopic disease to monitor for CD recurrence”
Uses BÜHLMANN fCAL® ELISA

- Wright. E *et al. Gastroenterology 2015; 148: 938- 947*. Measurement of faecal calprotectin improves monitoring and detection of recurrence of Crohn’s disease after surgery.

“FC measurement has sufficient sensitivity and NPV values to monitor for CD recurrence after intestinal resection. Its predictive value might be used to identify patients most likely to relapse. After treatment for recurrence, the FC level can be used to monitor response to treatment. It predicts which patients will have disease recurrence with greater accuracy than CRP level or CDAI score.” Uses BÜHLMANN fCAL® ELISA

- Lasson. A *et al. J of Crohn's and Colitis 2014*. The intra-individual variability of faecal calprotectin: A perspective study in patients with active ulcerative colitis.

“ Since the levels of calprotectin increased with longer time between bowel movements, it seems most appropriate to analyse stool from the first bowel movement in the morning”.
Uses BÜHLMANN fCAL® ELISA

- Kosiara. M *et al.* *ECCO Poster 2009*. The Usefulness of fecal calprotectin in distinguishing between non-active inflammatory bowel diseases and functional bowel disorders.
“Testing calprotectin levels in stools can help distinguish between functional and inflammatory bowel diseases, as well as differentiate between active and non-active form”.
Uses BÜHLMANN fCAL® ELISA
- Dhanda. A *et al.* *ECCO Poster 2012*. Faecal Calprotectin is a Cost-Effective Method of Assessing Activity of Inflammatory Bowel Disease.
“In this observational study a management decision was made based on the FC result in 76% of patients. It has reduced the use of expensive and invasive investigations and delivered a cost benefit to our service saving £11646 in 1 year. We recommend FC as a cost efficient test to assess disease activity in IBD”.
- Ferreiro-Iglesias. R *et al.* *Scandinavian J of Gastroenterology 2015*. Usefulness of a rapid faecal calprotectin test to predict relapse in Crohn’s disease patients on maintenance treatment with adalimumab.
“In CD patients on ADA maintenance therapy, FC levels measured with a rapid test allow relapse over the following months to be predicted with high accuracy. Low FC levels exclude relapse within at least 4 months after testing, whereas high levels are associated with relapse in three out of every four patients”. Uses BÜHLMANN Quantum Blue®
- Lee. S *et al.* *ECCO 2017 P148*. Fecal calprotectin as a non-invasive indicator for ulcerative colitis disease activity in the Korean cohort.
“Fecal calprotectin could be used as a reliable non-invasive indicator to evaluate the disease activity and mucosal healing of UC”. Uses BÜHLMANN Quantum Blue®
- Guardiola. J *et al.* *Clinical Gastroenterology and Hepatology 2014*. Fecal level of calprotectin identifies histologic inflammation in patients with ulcerative colitis in clinical and endoscopic remission.
“An FC value less than 155ug/g is a reliable indicator of the absence of acute inflammatory infiltrate (NPV 89%)”. Uses BÜHLMANN fCAL® ELISA
- Wright. E *et al.* *World Journal of Gastroenterology 2016*. Cost-effectiveness of Crohn’s disease post-operative care.
“When used at 6 and 18 month to select patients for colonoscopy, measurement of FC would have reduced the cost of post-operative care by \$1010 over 18 months based on average colonoscopy costs from our cohort and the cost of FC testing”. Uses BÜHLMANN fCAL® ELISA
- Pavlidis. P *et al.* *Poster at DDF 2015 from Kings College Hospital*. Faecal calprotectin identifies non-responders to anti-TNF α therapy when measured after induction in inflammatory Crohn’s disease.

"fCAL measurement after anti-TNF α induction predicts non-response, providing the opportunity to identify those patients who require further treatment tailoring early". Uses BÜHLMANN fCAL[®] ELISA

- Huang. V *et al. Poster at ECCO 2015 P269*. Fecal calprotectin is elevated with clinical disease activity during pregnancy in women with inflammatory Bowel Disease.

"Women with IBD who had clinical active disease during preconception and pregnancy had higher fecal calprotectin levels than those in who had clinically inactive disease. Fecal calprotectin has the potential to be able to be used as a biomarker for assessing disease activity during pregnancy". Uses BÜHLMANN Quantum Blue

- Roblin *et al Poster at ECCO 2015 DOP038*. Faecal calprotectin measurement and infliximab trough levels predict therapeutic evolution CD patients in clinical remission.

" In IFX-treated CD patients and in clinical remission, a combination of TLI (< 2 μ g/ml) and faecal calprotectin (>250 μ g/g of stools) enable the prediction of LOR within 6 months in 95% of cases." BÜHLMANN calprotectin assay used

- Parr *et al Poster at BSG 2016 PTH-054*. Home-testing of faecal calprotectin using the IBDoc[™] system: a comparative pilot study
"85% of respondents preferred the IBDoc test over other methods" Uses BÜHLMANN IBDoc and BÜHLMANN fCAL[®] ELISA

- Raker. J *et al ECCO 2017 P599*. Home testing for faecal calprotectin: follow-up results from the first UK trial.

"A negative fCAL (<100 μ g/g) by either method is a useful test to exclude a flare within four months....." Uses BÜHLMANN IBDoc and BÜHLMANN fCAL[®] ELISA

- Fitzgerald. D *et al. ECCO 2017 N804*. An evaluation of patient satisfaction with IBDoc calprotectin home test system.

"Calprotectin home testing using a smartphone as measuring system was very well received among the tested users (100% satisfaction). IBDoc offers patient empowerment for IBD patients who can remotely monitor their disease from the convenience of their own home". Uses BÜHLMANN IBDoc

- Heida. A *et al. ECCO 2017 P374*. Home or hospital-based analysis of stool calprotectin: assessing two methods for monitoring inflammatory bowel disease.

"80% of all paired measurements were concordant". Uses BÜHLMANN IBDoc and BÜHLMANN fCAL[®] ELISA

- Ungar. B *et al ECCO 2017 P181*. Home smart-phone based measurement of fecal calprotectin by IBD patients: correlation with laboratory assay and applicability as patient-friendly monitoring tool.

" the results of the home fecal calprotectin test (IBDoc) correlate well with values-ranges obtained using conventional lab-based calprotectin test. Smart-phone based fecal calprotectin test may be a useful patient-friendly tool for monitoring of IBD patients at home, with minimal interference to their routine." Uses BÜHLMANN IBDoc and BÜHLMANN Quantum Blue[®]

- Bello. C *et al ECCO P169 2017*. Usability of a home-based test for measurement of fecal calprotectin in IBD patients.

“Usability scores for the home-based test were high. There was a very good correlation with the centrally measured FC by ELISA”. Uses BÜHLMANN IBDoc

- Voiosu *et al. Rom J Intern Med 2015*. Rapid faecal calprotectin testing predicts mucosal healing better than CRP and serum TNFα in patients with ulcerative colitis

“In conclusion, this study shows that FC provides better diagnostic and prognostic accuracy than serum biomarkers, and it should become a routine test in the management of UC patients, thus reducing the need for invasive investigations such as colonoscopy”. Uses BÜHLMANN Quantum Blue®

- Lee *et al. ECCO P148 2017*. Fecal calprotectin is a non-invasive indicator for ulcerative colitis disease activity in the Korean cohort.

“UCEIS showed a better correlation with FC level than Mayo endoscopic subscore. Fecal calprotectin could be used as a reliable non-invasive indicator to evaluate the disease activity and mucosal healing of UC”. Uses BÜHLMANN Quantum Blue®

- Pavlidis *et al. Scand J of Gastroenterology 2016*. Early change in faecal calprotectin predicts primary non-response to anti-TNFα therapy in Crohn’s disease

“A drop in fCAL <70% after induction predicts primary non-response to anti-TNFα in CD” Uses BÜHLMANN fCAL® ELISA

- Lobaton. T *et al. J of Crohn’s and Colitis 2013*. A new rapid test for faecal calprotectin predicts endoscopic remission and postoperative recurrence in Crohn’s disease.

“We observed that FC, measured both with fCAL ELISA and the rapid Quantum Blue, was able to discriminate between the different levels of endoscopic activity, as well as to detect the presence or absence of ulcers” Uses BÜHLMANN fCAL® ELISA and Quantum Blue

- Voiosu *et al. J Gastrointestin Liver Dis 2014*. Rapid faecal calprotectin level assessment and the SIBDQ score can accurately detect mucosal inflammation in IBD patients in clinical remission: A prospective study.

“FC levels appears to be a practical method for monitoring disease activity in these patients, possibly reducing the need for repeat endoscopic examinations”. Uses BÜHLMANN Quantum Blue

BÜHLMANN calprotectin assays in paediatrics:

- Kolho *et al. J of Paediatric gastroenterology and nutrition 2012*. Rapid test for faecal calprotectin levels in children with Crohn’s Disease.

“We show here that the rapid calprotectin test has good performance in children with CD and is feasible for monitoring therapeutic We show here that the rapid calprotectin test has good

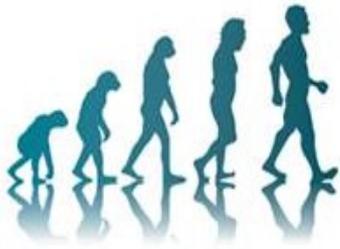
performance in children with CD and is feasible for monitoring therapeutic". Compares fCAL ELISA and Quantum Blue assays

- Davidson. F *et al.* *FOCUS poster 2015*. Paediatric for faecal calprotectin.
"FC cut-off used for the diagnosis of IBD in adults may safely be applied to children over the age of 4. However, the adult cut-off is unlikely to be appropriate for use in children under the age of 4". Uses BÜHLMANN fCAL® ELISA
- Oord. T *et al.* *Scandinavian Journal of Clinical and lab investigations 2014*. Fecal calprotectin in healthy children.
"Results clearly show that healthy, younger children have higher FC concentrations than adults and older children". Uses BÜHLMANN fCAL® ELISA
- Shentova. R *et al.* *Merit Research journals of medicines and medical science 2016*. Diagnostic value of fecal calprotectin point of care testing in paediatric practice.
"Fecal calprotectin point of care testing is a useful screening tool to detect children with intestinal inflammation and to identify those requiring further endoscopic assessment. It is simple and has a good diagnostic performance comparable to the time consuming ELISA assay". Uses BÜHLMANN Quantum Blue
- Feng. L *et al.* *PLOS ONE 2015*. Faecal calprotectin concentrations in healthy children aged 1 – 18 months
"The FC levels of children aged 1–18 months show a downward trend with age and are greater than the normal levels observed in healthy adults and older children". Uses BÜHLMANN fCAL® ELISA
- Bin-Nun. A *et al.* *American Journal of Perinatology 2015*. Rapid fecal calprotectin analysis: Point of care testing for diagnosing early necrotising enterocolitis.
"...it is feasible to perform the rapid FC assay on stool samples from premature infants at risk; that elevated rapid assay FC values are associated with clinical NEC; and that elevated rapid assay FC values are correlated with FC levels as determined by ELISA in this population". Uses BÜHLMANN fCAL® ELISA and Quantum Blue
- Davidson F *et al.* *Annals of Clinical Biochemistry 2017*. Paediatric reference ranges for faecal calprotectin. A UK study.
"Children aged 1–3.9 years had higher concentrations of faecal calprotectin than adults, but there was no significant difference in faecal calprotectin between older children and adults. FC cut-offs used for the diagnosis of IBD in adults may safely be applied to children over the age of 4. However, the adult cut-off is unlikely to be appropriate for use in children under the age of 4". Uses BÜHLMANN fCAL® ELISA
- Szczepański *et al.* 2014. Faecal calprotectin is a good biomarker of mucosal healing in monitoring children with IBD.
"FC is a good biomarker of mucosal healing in monitoring of children with IBD. Values below 54µg/g enable to select 77% patients with full mucosal healing." Uses BÜHLMANN Quantum Blue

- Goncalves *et al. Paediatric Research, Nature 2011*. Fecal calprotectin determination in preterm neonates: Evaluation of two methods.
"FC values found in this preliminary cohort of preterm neonates have been similar to those reported in the literature. The finding of a good correlation between the two techniques suggests the potential clinical usefulness of Quantum Blue at this age group (after validation)." Compares BÜHLMANN fCAL® ELISA and Quantum Blue
- Wael. EM *et al. Frontiers in Pediatrics 2017*. Impact of fecal calprotectin measurement on decision-making in children with inflammatory bowel disease.
" Based on high FCal, the majority of children had treatment escalation that resulted in clinical improvement. FCal measurements were useful and reliable in decision-making and clinical care of children with IBD." Uses BÜHLMANN Quantum Blue
- Savino. F *et al. Excellence in Paediatrics 2014*. Faecal calprotectin during treatment of severe infantile colic with *Lactobacillus reuteri* DSM 17938: A randomised, double blind, placebo controlled trial.
"fecal calprotectin assay after probiotic treatment with *Lactobacillus reuteri* DSM 17938 is a marker to predict sustained clinical response and monitor gut health in infants." Uses BÜHLMANN Quantum Blue

BÜHLMANN calprotectin assays in other applications:

- Jieun Kim *et al Ann Lab Med 2017* Fecal calprotectin level reflects severity of *Clostridium difficile* infections.
"we suggest fecal calprotectin as a predictive marker for assessing *C. difficile* infection severity, which is expected to improve the clinical management " Uses BÜHLMANN fCAL® ELISA
- Duran. A *et al Bosnian Journal of basic medical sciences 2015*. Faecal calprotectin is associated with disease activity in patients with ankylosing spondylitis.
"We found a correlation between fecal calprotectin levels and AS symptoms and its activity parameters. Calprotectin is a significant biomarker for AS and may have an important role in disease pathogenesis". Uses BÜHLMANN Quantum Blue and BÜHLMANN sCAL® ELISA
- Klingberg.E *et al Arthritis Research and Therapy 2017*. A longitudinal study of fecal calprotectin and the development of inflammatory bowel disease in ankylosing spondylitis.
"The results support a link between inflammation in the gut and the musculoskeletal system in AS. We propose that fecal calprotectin may be a potential biomarker to identify patients with AS at risk of developing IBD". Uses BÜHLMANN fCAL® ELISA
- Melchior. C *et al United European Gastroenterology Journal 2016*. Does calprotectin level identify a subgroup among patients suffering from irritable bowel syndrome? Results of a prospective study.
"Elevated faecal calprotectin was observed in one third of patients in this series, without any significant association with a specific clinical phenotype (except age) or specific abnormalities". Uses BÜHLMANN fCAL® ELISA



Future-proof your calprotectin testing with BÜHLMANN:

IBDoc[®], Quantum Blue, fCAL[™] ELISA and fCAL[™] turbo