**BÜHLMANN Calprotectin assays, used by hundreds, trusted by thousands……**

**The value of faecal calprotectin in diagnosing IBD:**

* A El Ela *et al. Swiss Medical Weekly 2023*. Faecal calprotectin increases the diagnostic yield in patients with suspected small bowel disease. A multicentre retrospective study

“In our study, most patients with clinically significant findings in small bowel capsule endoscopy also had elevated faecal calprotectin values (81.2%) due to inflammatory lesions in the small bowel in most cases (86.9%). Faecal calprotectin levels were higher in patients with small bowel capsule endoscopy clinically significant findings (226 μg/g) than with normal findings (126.0 μg/g), and patients with positive faecal calprotectin test results were more likely to have small bowel capsule endoscopy clinically significant findings”. Uses BÜHLMANN fCAL® Turbo

* Kan YM *et al. Journal of Gastroenterology and Hepatology 2021.* Diagnostic accuracy of fecal calprotectin in predicting significant gastrointestinal diseases.

“FC is a reliable marker for ruling out organic bowel diseases. A single negative FC test could be used as a triage tool to prioritize the need and urgency of further investigation, particularly in the setting of altered bowel habits and abdominal pain” Uses BÜHLMANN Quantum Blue® fCAL

* Rimmer P *et al ECCO 2023 P126*. Ask Twice: the importance of a repeated faecal calprotectin testing prior to diagnostic colonoscopy in an adult inception cohort.

“Median initial FCP was 949ug/g in those subsequently diagnosed with IBD (Ulcerative colitis 1162ug/g, Crohn’s 893ug/g) vs 353ug/g in those without IBD. This difference heightened on retesting, with median IBD FCP 749 vs 34ug/g in non-IBD. FCP fell between 1st and 2nd measurement in 88.6% of patients who had IBD excluded”. Uses BÜHLMANN fCAL® Turbo

* Turvill, J *et al. Frontline Gastroenterology 2019*. Audit of the impact of the York faecal calprotectin care pathway on colonoscopy activity.

“This audit of FC activity and colonoscopy outcomes provides substantial supportive evidence for the effectiveness of the YFCCP. Popular in primary care, it has led to a reduction in referrals”. Uses BÜHLMANN fCAL® ELISA

* Turvill, J *et al. Frontline Gastroenterology 2018*. Evaluation of the clinical and cost effectiveness of the York Faecal Calprotectin care pathway.

“In the roll-out of the YFCCP, compliance was 85% and so the actual rather than optimal saving amounts to between £60 000 and nearly £100 000 per 1000 patients. By correctly supporting the diagnosis of IBS within primary care, it avoids 100–150 colonoscopies and 140–190 gastroenterology outpatient appointments”. Uses BÜHLMANN fCAL® ELISA

* Hicks. A. *et al. Inflammatory Intestinal Diseases 2020*. The Association of Introducing a Faecal Calprotectin Testing Pathway for Suspected Inflammatory Bowel Disease in Primary Care and Time to Diagnosis or Treatment.

“FC testing can direct patients to the most appropriate service (direct referral to gastroenterology)”. They use BÜHLMANN fCAL® ELISA in the lab

* Berinstein. J *et al. Crohns and Colitis 360 2019*. The clinical accuracy of the BÜHLMANN fCAL ELISA in the differentiation of IBD from IBS: A multicentre prospective case control study.

“The BÜHLMANN fCAL ELISA demonstrates excellent discriminating between IBD and IBS”. Uses BÜHLMANN fCAL® ELISA

* 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….The estimated demand for colonoscopies was reduced by 50% with the 50 μg/g cut-off and 67% with the 100 μg/g cut-off’’. 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 Quantum Blue® fCAL

* 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® fCAL

* 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® fCAL

* Turvill. J *et al Primary Health Care research and development 2016.*Evaluation of a faecal calprotectin care pathway for use in primary care.

“The care pathway for FC in primary care had a 97% NPV and a 40% PPV. This was better than GP clinical judgement alone and doubled the PPV compared with the standard FC cut-off”. Uses BÜHLMANN fCAL® ELISA

* Evans. E *et al FOCUS Poster 2017*. Verification and implementation of faecal calprotectin using the BÜHLMANN fCAL turbo assay.

“the BÜHLMANN fCAL® turbo assay on the Abbott ARCHITECT platform is fit for purpose and we have recently received UKAS accreditation for this assay”. Uses BÜHLMANN fCAL® turbo

* Njegovan *et al EuroMedLab Poster 2017*. Verification of BÜHLMANN faecal calprotectin test fCAL turbo on Abbot Architect c8000 analyzer. Uses BÜHLMANN fCAL® turbo
* Khir. M *et al IBMS Poster 2019*. Evaluation of the BÜHLMANN fCAL turbo assay on the Abbott Architect C8000.

“The CALEX cap extraction devices and fCAL turbo method on the Abbott Architect analyser demonstrate good comparability with other established methods, with no significant interference with other chemistries and has led to improved workflow for faecal calprotectin analysis”. Uses BÜHLMANN fCAL® turbo

* 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® fCAL

* 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® fCAL

* 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® fCAL

* 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® fCAL

* 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 Quantum Blue® fCAL

* Nilsen T. *et al. Journal of Clinical laboratory Analysis 2016.* A novel turbidmetric 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

* Bowe. P *et al. FOCUS 2017*. Evaluation of the BÜHLMANN fCAL™ turbo calprotectin method on the Roche Cobas 6000 (c501).

Comparison of patient results showed good correlation (R2 = 0.97) with intra assay precision at 3.1% and 1.3% for concentrations of 48µg/ml and 247µg/ml respectively. Uses BÜHLMANN fCAL® turbo and BÜHLMANN fCAL® ELISA

* 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® fCAL

* 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® fCAL

* 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® fCAL

* 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” Uses BÜHLMANN Quantum Blue® fCAL

* Hejl. J *et al 2017 Practical Laboratory Medicine*. Point of care testing of fecal calprotectin as a substitute for routine laboratory analysis.

“We found a strong correlation coefficient of 0.887 between FC measured on IBDoc® and

the laboratory assay BÜHLMANN fCAL® turbo”. Uses BÜHLMANN IB*Doc* and fCAL turbo®

* Fellay. B *et al. ECCO 2018* Quantum Blue fCAL extended POC user performance evaluation.

“Quantum Blue® fCAL extended POC test, which determines calprotectin levels in a complex stool specimen matrix, is easy-to-use, the given instructions are comprehensive, and results obtained by POC sites are comparable to each other and to those obtained by a laboratory”. Uses BÜHLMANN fCAL® ELISA and Quantum Blue® fCAL

* Bello. C *et al Digestive and Liver Disease 2017*. Usability of a home-based test for measurement of fecal calprotectin in asymptomatic 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 IB*Doc*

* Woon Lee. Y *et al Korean Journal of internal medicine 2018*. The usefulness of fecal calprotectin in assessing inflammatory bowel disease activity.

“FC levels measured by ELISA and QPOCT showed very close correlation in both UC (r = 0.874, p = 0.000) and CD (r = 0.908, p = 0.000)…. both calprotectin assays could predict MH with high sensitivity (> 81%) and specificity (100%) in UC patients. Therefore, FC may be a useful alternative to repeated endoscopies. In addition, QPOCT can be used more conveniently than ELISA to assess FC in clinical practice”. Uses BÜHLMANN fCAL® ELISA and Quantum Blue® fCAL

* Cannatelli. R *et al ECCO 2020.* Defining faecal calprotectin thresholds to predict endoscopic & histologic healing in UC using advanced optical enhancement techniques. Uses BÜHLMANN fCAL turbo®
* 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® fCAL

**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® fCAL

* Wei. S *et al. Intestinal Research Journal 2018*. Experience of patients with inflammatory bowel disease in using a home fecal calprotectin test as an objective reported outcome for self-monitoring.

“Correlation between the IBDoc and the Quantum Blue was good (r = 0.776) and 80% of patients had a strong preference for using the IBDoc for future testing”. Uses BÜHLMANN IB*Doc*® and Quantum Blue® fCAL

* 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® fCAL

* 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-TNFα therapy when measured after induction in inflammatory Crohn’s disease.

‘’fCAL measurement after anti-TNFα 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® fCAL

* 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 (< 2µg/ml) and faecal calprotectin (>250µg/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 IB*Doc*™ system: a comparative pilot study

‘’85% of respondents preferred the IBDoc test over other methods’’ Uses BÜHLMANN IB*Doc* and BÜHLMANN fCAL® ELISA

* Elsafi. G *et al UEGW 2017*. Cost effective of IBDoc as a surrogate marker of mucosal healing in IBDF patients post induction of biological agents.

“In total 53 clinical visits and 62 colonoscopies were saved….. 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”. Uses BÜHLMANN IB*Doc*

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

“A negative fCAL (<100µg/g) by either method is a useful test to exclude a flare within four months………….” Uses BÜHLMANN IB*Doc* and BÜHLMANN fCAL® ELISA

* Fitzgerald. D *et al. ECCO 2017 N804*. An evaluation of patient satisfaction with IB*Doc* 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 IB*Doc*

* 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 IB*Doc* 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 IB*Doc* and BÜHLMANN Quantum Blue® fCAL

* 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 IB*Doc*

* 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® fCAL

* 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® fCAL

* Moniuszko. A *et al. Polish Archives of Internal Medicine 2017*. Rapid fecal calprotectin test for prediction of mucosal inflammation in ulcerative colitis and Crohn disease: a prospective cohort study.

“This rapid bedside test can facilitate clinical decisions on hospital admission, such as deciding whether the IBD treatment should be intensified. Similarly, in the ambulatory setting, it is crucial when determining whether a patient should undergo endoscopy or not.” Uses BÜHLMANN Quantum Blue® fCAL and BÜHLMANN fCAL® ELISA

* 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® fCAL

* Heida. A *et al. J of Gastroenterology and Hepatology 2017*. Agreement Between Home-Based Measurement of Stool Calprotectin and ELISA Results for Monitoring Inflammatory Bowel Disease Activity

“We found sufficient agreement between the home used lateral flow test and the hospital-based ELISA test in the lower ranges of calprotectin to use this new test for telemonitoring of patients with asymptomatic IBD” Uses BÜHLMANN fCAL® ELISA , Quantum Blue® fCAL and IB*Doc*®

* Orfanoudaki. E *et al UEGW 2019*. The real world use of fecal calprotectin home testing in patients with IBD under maintenance treatment with adalimumab.

“Our results confirm the important role of consecutive FC measurements at home, in combination with the endoscopic evaluation for the optimization of treatment in IBD patients

receiving maintenance treatment with adalimumab”

* Walmsley. R *et al ECCO 2019*. A non-inferiority randomised clinical trial of the use of the smartphone-based health applications IBD*smart* and IB*Doc*® in the care of inflammatory bowel disease patients.

“Use of IBD*smart* with IB*Doc* in routine clinical care of IBD patients over 12 months is acceptable, usable and non-inferior to standard clinic-based care”. Uses BÜHLMANN IB*Doc*®

* Sambuelli. A et al. UEGW 2019. Fecal calprotectin in IBD: An useful and non-invasive predictor of mucosal healing and clinical relapse.

“Fcal was a good predictor of MH in UC and CD according opt-MH cut-off (242 µg/g), Sensitivity: 76.4%, Specificity: 84.5%, PPV: 85.7%, PNV: 74.5%. FCal values were significantly lower in remission vs. activity, in UC and CD, but in endoscopically active colonic CD, FCal was higher vs. other locations”. Uses BÜHLMANN fCAL® ELISA

* Moore. A *et al Inflam Bowel Dis 2019*. IBDoc Canadian User Performance Evaluation.

“85% of patients strongly agreeing that they were willing use the home kit in the future. The IBDoc and ELISA measurement comparison showed an 88% agreement across all values. There were no false positives or negatives using qualitative comparison”. Uses

BÜHLMANN IB*Doc*®

* Hejl. J *et al. Practical Laboratory Medicine 2018*. Point of care testing for faecal calprotectin as a substitute for routine laboratory analysis.

“We found a strong correlation coefficient of 0.887 between FC measured on IBDoc® and the laboratory assay BÜHLMANN fCAL® turbo”. Uses BÜHLMANN IB*Doc*® and fCAL turbo®

* McCombie. A *et al Inflam Bowel Dis 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.

“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”. Uses BÜHLMANN IB*Doc*®

* Ben-Horin. S *et al The Lancet Gastroenterology & Hepatology 2019.* Assessment of small bowel mucosal healing by video capsule endoscopy for the prediction of short-term and long-term risk of Crohn’s disease flare: a prospective cohort study.

“the AUC for faecal calprotectin’s ability to predict a flare occurring within 24 months was 0·62, but progressively increased in accuracy as the target time-to-flare was shortened, reaching 0·76 within 6 months and 0.81 within 3 months”. Uses BÜHLMANN

* Haisma. S *et al ECCO 2019*. Head-to-head comparison of three stool calprotectin tests for home use.

“The IB*Doc* smartphone application out-performed the others in terms of error-friendliness and system usability”. Uses BÜHLMANN IB*Doc*®

* Cancela e Penna. *et al BMC Gastroenterology 2020*. Faecal calprotectin is the biomarker that best distinguishes remission from different degrees of endoscopic activity in Crohn’s disease.

“fCal had a greater diagnostic capacity since it allowed for a differential diagnosis between endoscopic remission and mild or moderate to severe activity”. Uses BÜHLMANN fCAL® ELISA

* D’Amico F *et al Journal of Clinical Medicine 2020*. Setting up a virtual clinic in inflammatory Bowel Diseases. A literature review and Nancy experience.

“ The IBDoc® is a simple tool to use and high satisfaction is found among IBDoc® users. IBD patients should be adequately informed and trained on the use of this test. FC home tests are an additional value for e-health approach in IBD patients. In the near future, these tests could allow not only tight monitoring of IBD patients but also their greater involvement in disease management.” Uses BÜHLMANN IB*Doc*®

* 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® fCAL

* Orfanoudaki. E *et al. European Journal of Gastroenterology and Hepatology 2021.* Real-life utility and diagnostic accuracy of a home-performed faecal calprotectin test to predict endoscopic activity in patients with inflammatory bowel disease under maintenance treatment with adalimumab.

“FC home test is a valuable tool with high compliance rates that performs better than other biomarkers in predicting disease endoscopic activity”. Uses BÜHLMANN IB*Doc*®

* Facciourusso. A *et al. Biomedicines Journal 2022.* Prognostic Role of Post-Induction Fecal Calprotectin Levels in Patients with Inflammatory Bowel Disease Treated with Biological Therapies.

“A substantial decrease in FC levels was noted at 14 weeks in patients who finally experienced mucosal healing and clinical remission.” BÜHLMANN fCAL® Turbo

* Romero-Mascarell. C *et.al. Diagnostics 2022.* Fecal calprotectin for small bowel Crohns Disease: Is it a cut-off issue?

“ FC has a good correlation with the presence of SB lesions, assessed by SBCE and/or MRE, in patients with established or suspected Crohn’s disease. However, the ideal cut-off seems to be higher than previously reported”. Uses BÜHLMANN

**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 BÜHLMANN fCAL® ELISA and Quantum Blue® fCAL

* 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® fCAL

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* 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® fCAL

* 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® fCAL

* 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® fCAL

* Wael. EM *et al. Frontiers in Paediatrics 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® fCAL

* Ataee. P *et al. Iranian J of Pediatrics 2017*. Relationship Between Fecal Calprotectin and Upper Endoscopy Findings in Children With Upper Gastrointestinal Symptoms.

“There was a statistically significant correlation between fecal calprotectin and gastritis and severity of H. pylori infection. Fecal calprotectin level measurement can avoid unnecessary endoscopies and is also useful for evaluation of therapy response”. Uses BÜHLMANN fCAL® ELISA

* Haisma SM *et al. Journal of Paediatric Gastroenterology and Nutrition 2019*. Time to reach Target Calprotectin Level in Newly diagnosed patients with IBD

“The findings of this prospective registry suggest that a quick response to conventional therapy predicts a favourable disease course in new onset paediatric CD, but not in UC”. Uses BÜHLMANN fCAL® ELISA

* Foster. AJ *et al World Journal of Gastroenterology 2019*. Consecutive fecal calprotectin measurements for predicting relapse in paediatric Crohn’s Disease patients.

“this prospective longitudinal paediatric study is the first to demonstrate that routine serial FC measurements are an independent valuable predictor of symptomatic relapse. Moreover, FC elevation was noted up to 3 months prior to the appearance of symptomatic relapse. Consequently, implementing a 3-monthly test to treat FC monitoring strategy would allow clinicians to make timely therapeutic adjustments in advance of disease relapse”. Uses BÜHLMANN fCAL® ELISA

* Piekkala. M *et al. Journal of Pediatric Gastroenterology and Nutrition 2018*. Fecal calprotectin test performed at home: A prospective study of pediatric patients with inflammatory bowel disease.

“PIBD patients and their families were interested in FC home monitoring and willing to adopt testing as a part of their disease management, but this approach requires thorough guidance”. Uses BÜHLMANN IB*Doc*®

* Orfei. M *et al PLOS ONE 2021*. Guidance on the interpretation of faecal calprotectin levels in children.

“Our findings further support the recommendation that FCP levels of 250 μg/g or more are required in children with GI symptoms suggestive of IBD to refer to a paediatric gastroenterologist”. Uses BÜHLMANN fCAL® ELISA

* Savino. F *et al. Excellence in Paediatrics 2014*. Faecal calprotectin during treatment of sever 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® fCAL

* Garnett. E *et al. Practical Lab medicine 2020*. Validation of the newly FDA approved fCAL turbo for measurement of fCAL in a pediatric population.

“The newly FDA-cleared fCal Turbo assay, with the Calex cap for sample extraction, represented a much more rapid and facile workflow for our laboratory than referring samples for analysis by ELISA”. Uses BÜHLMANN fCAL® ELISA and fCAL® turbo

* Jogendran. R *et al. Journal of Canadian Gastroenterology 2021*. Optimizing maternal and neonatal outcomes in IBD: Tight control management of IBD during pregnancy – Pilot study.

“A combination of both clinical scores and objective disease markers may better predict disease relapse compared to either clinical scores or objective markers in isolation. A home point-of-care FCP test is feasible among pregnant patients with IBD”. Uses

BÜHLMANN IB*Doc*®

* Jere. M *et al. British Medical Journal 2021*. Point of Care faecal calprotectin testing in patients with paediatric inflammatory bowel disease during the COVID-19 pandemic.

“85% stated that they preferred the home test to the laboratory testing method. Home calprotectin tests were useful in guiding clinical management during a time when laboratory testing was less available. They may offer benefits as part of routine paediatric IBD monitoring to help target appointments and reduce unnecessary hospital attendances in the future.” Uses

BÜHLMANN IB*Doc*®

* Lendvai-Emmert. D *et al. Frontiers in Paediatrics 2022*. Faecal calprotectin levels in paediatric cows milk protein allergy.

“FC can be an objective marker in confirming the diagnosis of CMPA. Significant improvement in clinical symptoms and in FC levels can only be expected after a strictly followed elimination diet”. Uses BÜHLMANN fCAL® Quantum Blue.

**BÜHLMANN calprotectin assays in other applications:**

* Beaufil. F *et al. Journal of Clinical Medicine 2020* Increase fCAL is associated with worse gastrointestinal symptoms and Quality of Life scores in children with Cystic Fibrosis

“Measurement of the FC level could help the clinician to better discriminate the origin (functional or organic) of gastrointestinal manifestation and impaired quality of life in CF, and thus allow to optimize or adapt the treatment.” Uses BÜHLMANN fCAL® ELISA

* 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. difficle* infection severity, which is expected to improve the clinical management”. Uses BÜHLMANN fCAL® ELISA

* Cypers. H et al. Annuals Rheuma Dis 2015. Elevated calprotectin levels reveal bowel inflammation in spondyloarthritis.

“Calprotectin measurements in stool and serum, in addition to CRP, may provide a promising strategy to identify patients with SpA at risk of bowel inflammation and could play a role in overall patient stratification.” Uses BÜHLMANN fCAL® ELISA and BÜHLMANN sCAL® 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® fCAL 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

* Bustinduy. A *et al. PLOS 2013*. Fecal occult blood and fecal calprotectin as point of care markers of intestinal morbidity in Ugandan children with Schistosoma mansoni infection.

“Fecal calprotectin proved useful as an inflammatory marker in correlation with S. mansoni infection………..” “The significant decline in calprotectin levels after PZQ treatment in children with egg patent S.mansoni at baseline, also suggests a positive response to anti-parasitic treatment”. Uses BÜHLMANN Quantum Blue® fCAL

* Beser. O *et al. Allergy, Asthma and Immunology Research 2014*. Can fecal calprotectin be used as a marker of inflammation in the diagnosis and follow-up of cow’s milk protein allergy?

“Fecal calprotectin levels may be a useful marker for follow-up treatment and recurrence determination in cow’s milk protein allergy”. Uses BÜHLMANN fCAL® ELISA

* Balint. A *et al. Turkish Journal of Gastroenterology 2017*. Pregnancy does not affect fecal calprotectin concentrations in healthy women.

“Since FC levels remained unchanged during pregnancy, it may be a useful non-invasive diagnostic tool in pregnancy for monitoring mucosal inflammation.” Uses BÜHLMANN Quantum Blue® fCAL

* Vavricka. S *et al. United European Gastroenterology Journal* *2018*. The Vampire study: Significant elevation of faecal calprotectin in healthy volunteers after 300 ml blood ingestion mimicking upper gastrointestinal bleeding.

“Ingestion of blood resulted in an increase in faecal calprotectin-positive tests. Gastrointestinal bleeding should be considered as a potential cause of mild faecal calprotectin elevation > 50 mg/g; however, increased faecal calprotectin above > 250–300 mg/g, the established cut-off for relevant intestinal inflammation in patients with inflammatory bowel disease, is rare”. Uses BÜHLMANN fCAL® turbo

* Wouthuyzen-Bakker *et al. Bone and Joint Journal 2017*. Synovial calprotectin A potential biomarker to exclude prosthetic joint infection.

“Synovial calprotectin may be a valuable biomarker in the diagnosis of a PJI, especially in the exclusion of an infection. With a lateral flow immunoassay, a relatively rapid quantitative diagnosis can be made. The measurement is cheap and is easy to use” Uses BÜHLMANN Quantum Blue® fCAL

* Manoppo. J *et al. Paediatrica Indonesia 2020*. Fecal calprotectin and its association with functional dyspepsia in children.

“elevated fecal calprotectin is associated with functional dyspepsia in children”. Uses BÜHLMANN fCAL® ELISA

* Polkowska-Pruszynska. B *et al. MDPI Journal 2020*. The role of fecal calprotectin in patients with systemic sclerosis and Small Intestinal Bowel Overgrowth.

“Our study suggests the potential value of FC in SSc in detecting gastrointestinal impairment and its promising role as an additional diagnostic tool for SIBO”. Uses BÜHLMANN fCAL® turbo

* Caenepeel. C *et al. ECCO 2019*. The impact of storage time and freeze–thaw cycles on faecal calprotectin concentration in inflammatory bowel disease patients and controls.

“Multiple freeze–thaw cycles and long-term storage of faecal samples and FCal extracts influence FCal concentrations only moderately, and without influence on clinical decision-making”. Uses BÜHLMANN fCAL® ELISA

* Nakov. R *et al. UEGW P0444 2019*. Fecal calprotectin levels are elevated in transthyretin amyloidosis patients with gastrointestinal manifestations.

Uses BÜHLMANN Quantum Blue® fCAL

* Mulak. A *et al. Frontiers in Neuroscience 2019*. Fecal calprotectin as a marker of the gut immune system activation is elevated in Parkinsons disease.

“The evaluation of fecal calprotectin level may be a useful tool to detect the signs of gut immune system activation present in a remarkable number of PD patients, also in the early stage of the disease. Calprotectin may constitute a critical link between amyloid formation and neuroinflammatory cascades serving as a prospective diagnostic and therapeutic target”. Uses BÜHLMANN fCAL® ELISA

* Larsson. G *et al. Austin Journal of Gastroenterology 2015.* A risk matrix model for the prediction of intestinal tuberculosis and differentiation from Crohn’s disease.

“A visual matrix model in which faecal calprotectin is combined with clinical and endoscopic risk factors could become a rapid, easy and point-of-care tool to differentiate between ITB and CD in clinics with limited resources”. Uses BÜHLMANN fCAL® ELISA and serum ELISA

* Lamot. L *et al. Frontiers in Medicine 2021*. The increased levels of faecal calprotectin in children with active enthesitis related arthritis and MRI signs of sacroiliitis: The results of a single centre cross sectional exploratory study in Juvenile idiopathic arthritis patients.

“the results of our study show that ERA patients have significantly higher fCAL levels than those with other form of JIA or children complaining musculoskeletal symptoms. Moreover, the concentration was highest in ERA patients with active disease and the MRI sign(s) of the inflammatory process in SIJ, which emphasizes that a parallel inflammation in musculoskeletal system and gut can occur not just in adults with SpA, but also in children with undifferentiated SpA”. Uses BÜHLMANN fCAL® turbo

* Turvill. J *et al. British Journal of General Practice 2016*. Faecal calprotectin in patients with suspected colorectal cancer. A diagnostic accuracy study.

“The NPV for colorectal cancer was 98.6% and 97.2% when including polyps ≥10 mm”. 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

