BÜHLMANN Quantum Blue Calprotectin assays, the ideal way to start a partnership.....

The value of faecal calprotectin in diagnosing IBD:

- 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® fCAI
- 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
- 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

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

 "EC levels measured by ELISA and OPOCT showed very close correlation in both LIC (r = 0.874, p.
 - "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
- 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:

- 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
 - 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
- 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
- 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® fCAL

• 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

• 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 IBDoc®
- 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

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". Compares BÜHLMANN fCAL® ELISA and Quantum Blue® fCAL

• 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

• 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

 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 $54\mu g/g$ 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 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® fCAL

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

BÜHLMANN calprotectin assays in other applications:

- 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
- 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
- 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
- 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



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