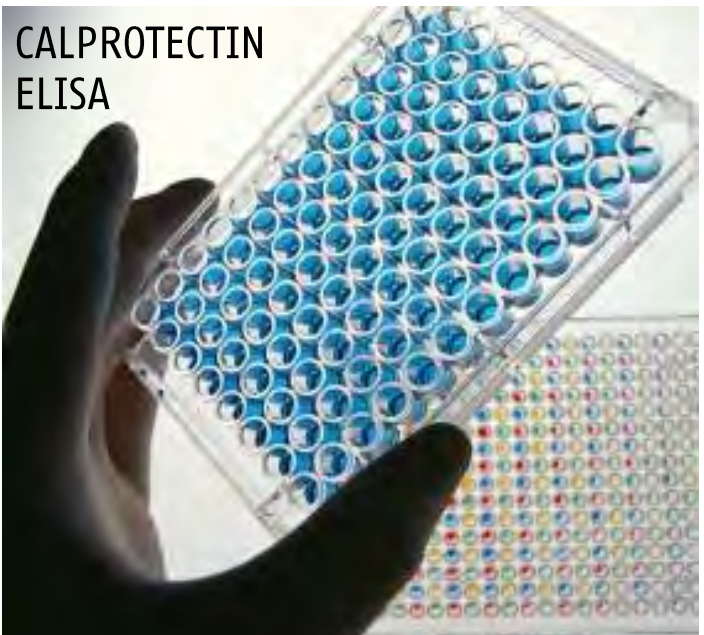


BÜHLMANN Calprotectin Quality Assays Clinical Publications



Selected BÜHLMANN Calprotectin Publications

Diagnosis of IBD

Value of fecal calprotectin in the evaluation of patients with abdominal discomfort: an observational study. Manz et al. 2012

Over 550 patients presenting with abdominal problems at the University Hospital Basel were prospectively investigated in this study that very well reflects the situation at a secondary care centre. All patients underwent endoscopy and were tested for calprotectin with the BÜHLMANN test. The work was done over a period of 4 years and numerous lots. Calprotectin reliably discriminates organic from non-organic disease patients with high sensitivity and specificity. The overall diagnostic accuracy was 85% when 50 µg/g was used as cut off value (see Fig.1a and b). The labwork showed that the BÜHLMANN test discriminated IBD from IBS assay significantly better than a polyclonal ELISA (Fig2).

The group of Beglinger and Manz conclude that 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.

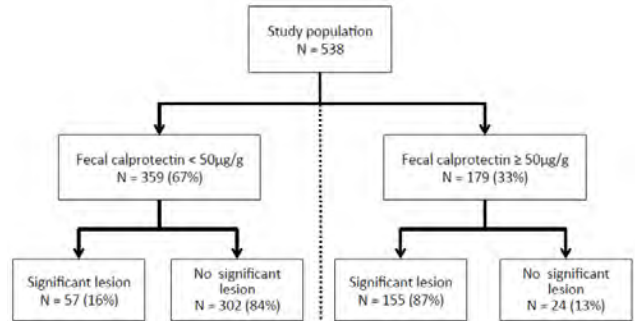


Fig.1a (after Manz et al.)

ROC curve for IBD diagnosis at cutoff 50 µg/g:

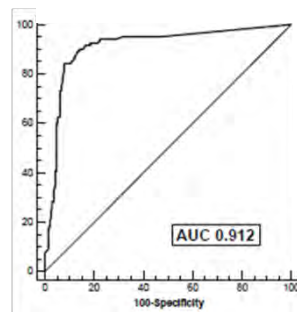


Fig.1b (after Manz et al.)

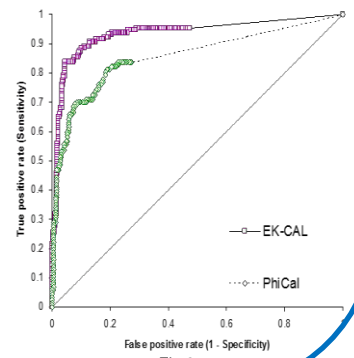


Fig.2

Validation of a point-of-care desk top device to quantitate fecal calprotectin and distinguish inflammatory bowel disease from irritable bowel syndrome Sydora et al. 2012

A Canadian study within the group of Richard Fedorak at Univ. of Alberta to contrast fecal calprotectin levels in patients with inflammatory and non-inflammatory intestinal diseases (Fig.1) and compare the results obtained from the standard BÜHLMANN ELISA-based method with those obtained from Quantum Blue®.

Conclusion: The desk top BÜHLMANN Quantum Blue® Reader exhibits a fast, non-invasive, and reliable way of identifying an inflammatory intestinal disease.

This is in tune with a new publication from Enschede in Holland by Hessels et al, where it is concluded that Quantum Blue® correlates very well with the gold standard (Fig2) and demonstrated better analytical performance than the Prevent ID CalDetect.

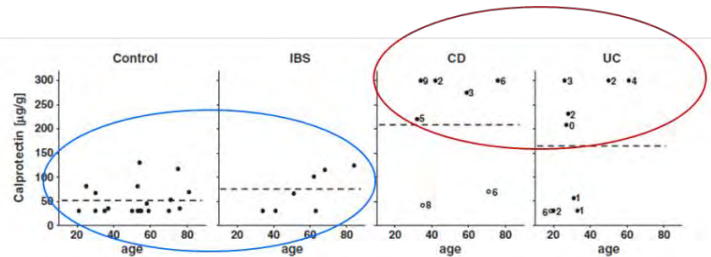


Figure 1 Correlation of calprotectin concentrations with age and clinical activity as determined by HBI score (CD) and Mayo score (UC). Each dot represents the concentration of fecal calprotectin as determined with the Bühlmann Quantum Blue Reader® in individual UC, CD, and IBS patients and control subjects without intestinal diseases. Numbers represent clinical activity scores and open circles represent patients with recent surgery. The dotted line denotes the mean value in each group.

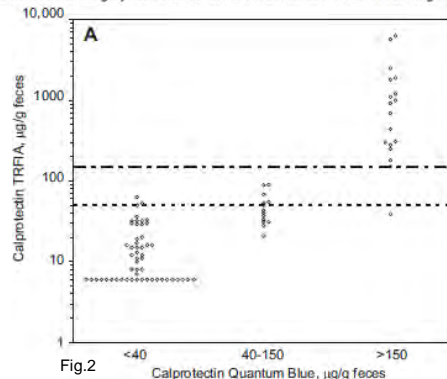


Fig.2

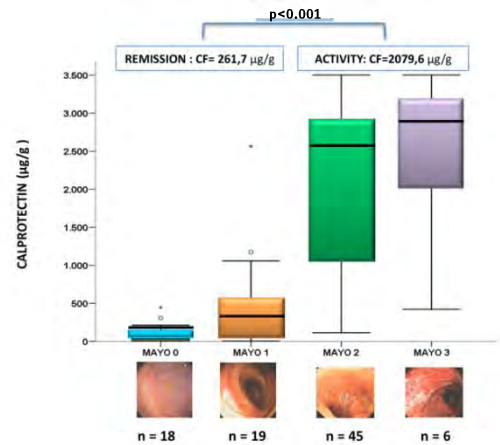
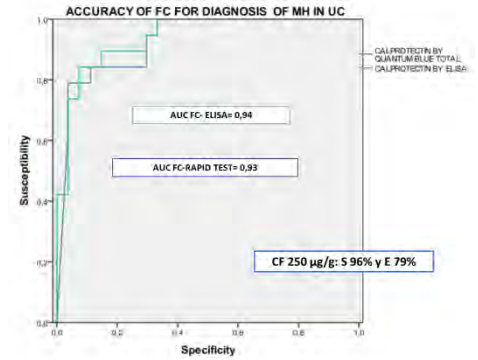
Selected BÜHLMANN Calprotectin Publications

IBD Patient Monitoring

A New Rapid Test for fCalprotectin Predicts Mucosal Healing in Crohn's disease and UC Lobaton et al. 2012

The group around Drs. Guardiola and Lobaton presented very interesting data on the capability of the Quantum Blue® and the BÜHLMANN ELISA to gain calprotectin results that correlate well with the mucosal healing in Crohn's Disease and also UC patients, here corresponding to the Mayo score classifications (shown in figures).

The conclusion is that calprotectin is an accurate biomarker for endoscopic activity/mucosal healing superior to CRP. The cutoff level of 250 µg/g offers high sensitivity and specificity to predict mucosal healing. Lastly, the good correlation between the Quantum Blue® and the BÜHLMANN ELISA enables to use the rapid test to take fast and adequate decisions.



Faecal Calprotectin: Comparative Study of the Quantum Blue® rapid Test and an Established ELISA Coorevits et al. 2012

Coorevits et al. from Roeselare, Belgium performed a comparative study between Quantum Blue® and the BÜHLMANN ELISA, both used routinely by the department of gastroenterology. The ELISA, which showed superior sensitivity compared to the CALPRO polyclonal assay, shows good correlation to the rapid test for the discrimination of functional vs. organic diseases as well as for the follow up of diagnosed IBD patients during therapy (Fig1.)

Conclusion: Quantum Blue® can serve as reliable alternative to the ELISA, thus a colonoscopy can be postponed awaiting the Quantum Blue® result known within an acceptable timeframe.

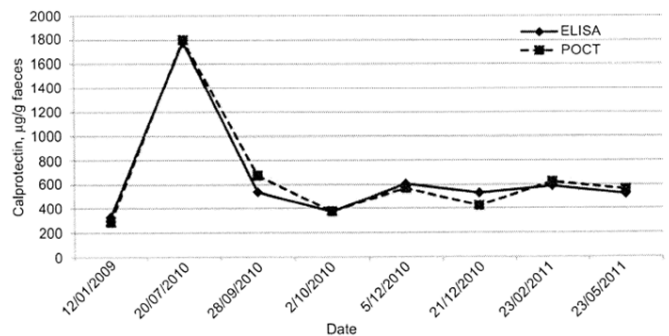
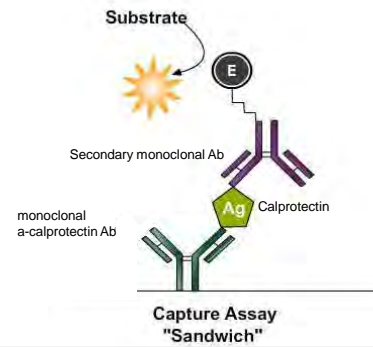


Fig.1 Comparison of ELISA and Quantum Blue® fC concentrations in the follow up of a patient over a period of 28 months during medication.

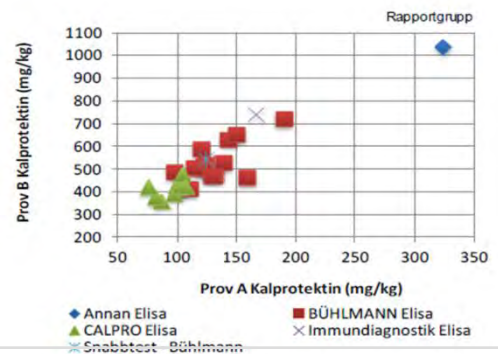
Monoclonal Antibody

The BÜHLMANN assays are based on the application of a highly sensitive and specific monoclonal Antibody to the active form of calprotectin. This provides the tool for high clinical accuracy in the test portfolio that includes the ELISA, the Quantum Blue® and as new addition the CALcheck Blue™, thus covering all levels of calprotectin measurements, from the central laboratory to the doctor's office.



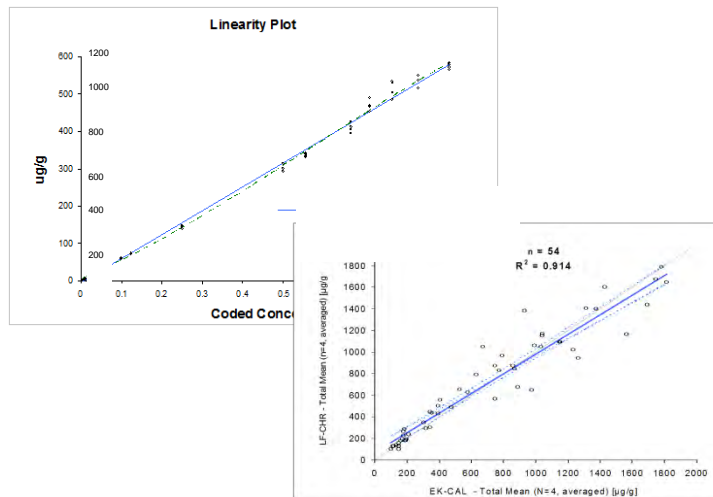
BÜHLMANN Quality Standards

All BÜHLMANN assays go through very tight quality controls and standardisation stability tests before release and additionally participate in external national and international quality ring schemes. Tight quality control is a BÜHLMANN commitment for persistence in the diagnostic market.



BÜHLMANN Linearity Range and Method Comparison

The BÜHLMANN calprotectin ELISA is the only such assay in the market that can provide a linear range up to very high concentration levels thus providing reliable calprotectin results especially for active inflammatory disease. The ELISA and the Quantum Blue® methods correlate very well, thus comparing well results made within these BÜHLMANN technologies.



BÜHLMANN Quality for CROs

Eurofins a leading international CRO adopted the BÜHLMANN ELISA assay after very convincing quality assessments over other calprotectin tests on the market. BÜHLMANN calprotectin assays are thus increasingly applied for large clinical studies and pharmaceutical trials all over the globe.

