

# BÜHLMANN Calprotectin Quality Assays Clinical Publications



CALPROTECTIN ELISA



QUANTUM BLUE®



## 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 discriminated 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 follow up publication by Burri et al. shows that the BÜHLMANN assay discriminates IBD from IBS significantly better than a polyclonal ELISA (Fig.2).

**Conclusion:** The group around Prof. Beglinger conclude that in patients with abdominal discomfort, fecal calprotectin is an useful non-invasive marker to identify clinically significant findings of the gastrointestinal tract, irrespective of age, and that the monoclonal BÜHLMANN ELISA better distinguishes IBD from IBS than the polyclonal Calpro PhiCal test.

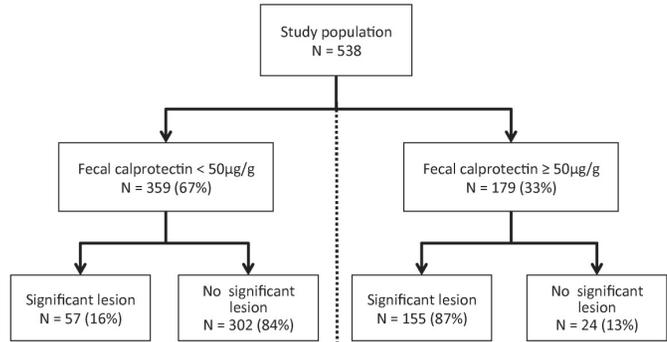


Figure 1a (after Manz et al.)

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

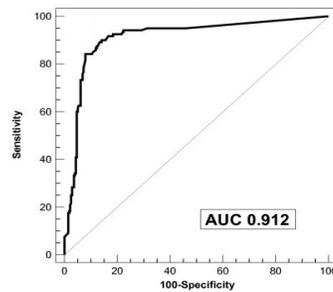


Figure 1b (after Manz et al.)

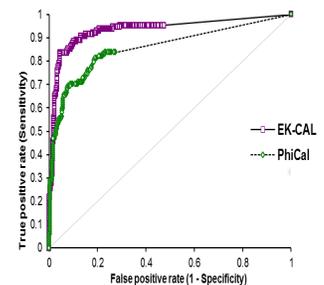


Figure 2 (after Burri et al.)

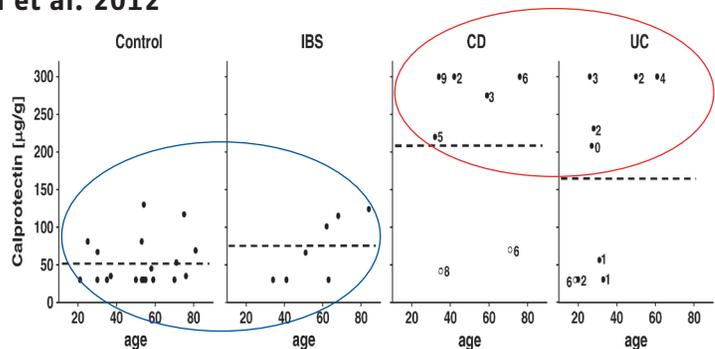
#### Validation of A Point-Of-Care Desk Top Device to Quantitate Fecal Calprotectin and Distinguish Inflammatory Bowel Disease from Irritable Bowel Syndrome

Sydora et al. 2012

A Canadian study by Richard Fedorak at the University of Alberta, comparing fecal calprotectin levels in patients with IBD and IBS (Fig.1) and to compare the results obtained from the standard BÜHLMANN ELISA-based method with those obtained from Quantum Blue® shows very clear distinction by calprotectin levels.

**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 publication from Enschede in Holland by Hessels et al., where it is concluded that Quantum Blue® correlates very well with the gold standard (Fig.2) and demonstrated better analytical performance than the Prevent ID CalDetect.



**Figure 1** Correlation of calprotectin concentration 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 of each group.

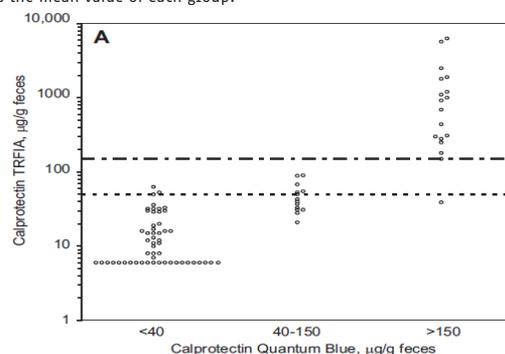
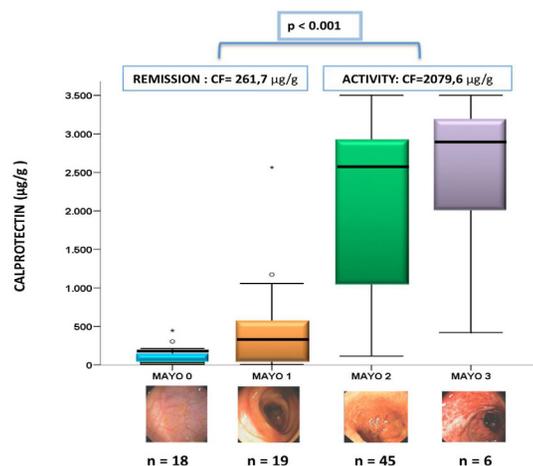
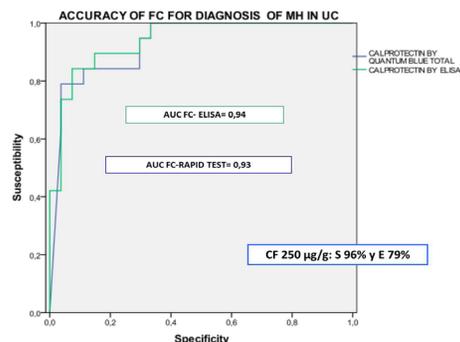


Figure 2 (after Hessels et al.)

## A New Rapid Test for fCalprotectin Predicts Mucosal Healing in Crohn's Disease and UC Lobaton et al. 2013

The group around Dr. Guardiola (Lobaton et al.) 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).

**Conclusion:** 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 the use of the rapid test to take fast and adequate decisions.



## A Prospective Evaluation of the Predictive Value of Faecal Calprotectin in Quiescent Crohn's Disease Naismith et al. 2014

Graham Naismith et al. examined in a prospective study, using the BÜHLMANN fCAL™ ELISA, whether higher fecal calprotectin levels in patients during apparent remission phase is a signal for a coming relapse within 12 months. 92 patients were tested for the full period of time. 11% of the patients relapsed within this time. Patients who experienced a relapse within 12 months exhibited as significantly higher median level of fecal calprotectin ( $p=0.005$ ).

**Conclusion:** In this prospective dataset, fecal calprotectin is a useful tool to help identify quiescent Crohn's disease patients at a low risk of relapse over the ensuing 12 months. Fecal calprotectin of 240 µg/g was the optimal cutoff in this cohort.

In another study performed by Coorevits et al. from Roseselare in Belgium, the BÜHLMANN fCAL™ ELISA and the Quantum Blue® Calprotectin tests showed better sensitivity than the CALPRO polyclonal assay to differentiate between IBD and IBS, and are very useful for follow up of IBD patients (Fig.3).

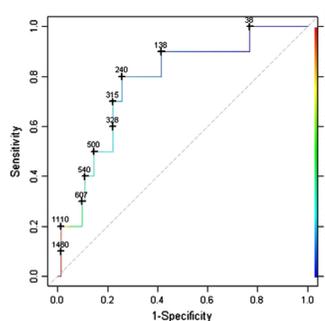


Figure 1 ROC curve of calprotectin predicting relapse at 12 months.

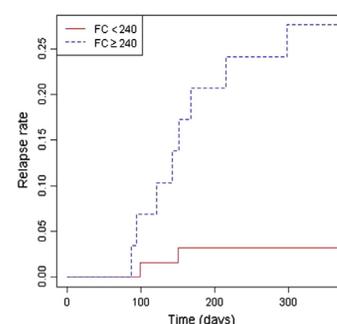


Figure 2 Kaplan Meyer curves of time to relapse in days by using cutoff 240 µg/g.

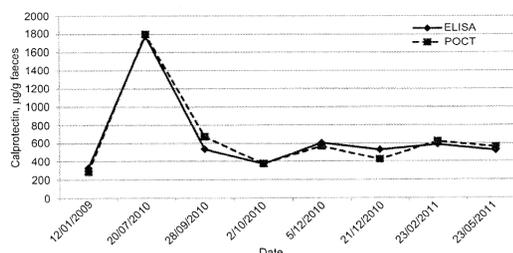
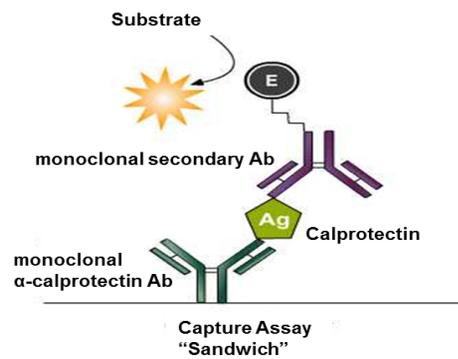


Figure 3 Comparison of ELISA and Quantum Blue® fC concentrations in the follow up of a patient over a period of 28 months during medication.

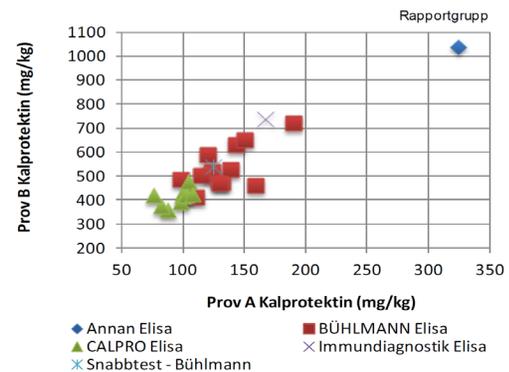
## Monoclonal Antibody

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 and the Quantum Blue®, thus covering all levels of calprotectin measurements, from the central laboratory to the doctor's office.



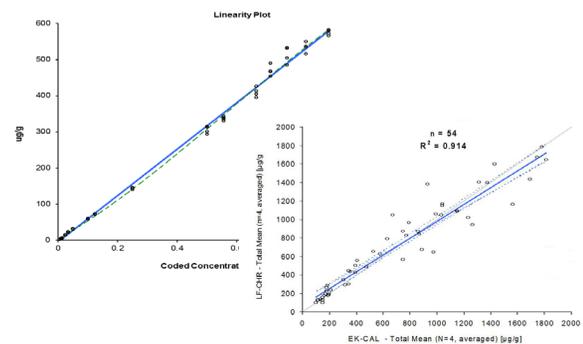
## BÜHLMANN Quality Standards

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.



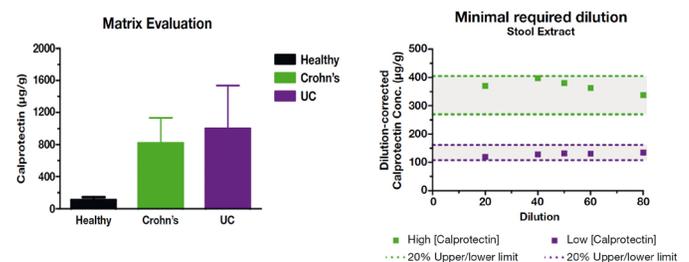
## BÜHLMANN Linearity Range and Method Comparison

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.



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