

# BÜHLMANN fCAL<sup>®</sup> ELISA

Screening of Organic vs. Functional  
Disease & Therapy Follow-Up

Reliable and  
Non-Invasive  
Screening  
Marker

Calprotectin is the best IBD marker

Excellent negative predictive value  
to rule out IBD

Supports Therapy Follow-Up of IBD  
patients

Particularly interesting for pedia-  
tric gastroenterology

Dynamic Range 10 - 1800 µg/g

# In vitro Diagnosis of Bowel Inflammation

## Calprotectin

Calprotectin is a very abundant heterodimeric calcium binding protein belonging to the S100 family. It is derived predominantly from the cytosolic fraction of neutrophils and to some extent from monocytes and activated macrophages.

Plasma calprotectin (MRP8/14) levels are increased in various inflammatory conditions. Calprotectin concentration in feces is higher than in plasma and significantly increased levels of calprotectin in stool are found in patients with bowel inflammation (e.g. IBD), whereas it is not elevated in patients with non organic, rather functional diseases like irritable bowel syndrome (IBS).

## Inflammatory Bowel Disease IBD

IBD includes Crohn's disease (CD) and ulcerative colitis (UC). IBD is a chronic disease with forms involving lower bowel parts or the entire GI tract, and causing symptoms like abdominal pain, diarrhea, fever and weight loss. An estimated two million people in Europe suffer from IBD. These pathologies seem to be caused by an overactive mucosal immune system, thus the therapies are mediated by immunosuppressants as well as biologics and steroids.

## Irritable Bowel Syndrome IBS

IBS is a non organic functional disorder. It can cause several symptoms like cramping, bloating, diarrhea and constipation, seriously affecting the patients lifequality. IBS is highly prevalent (15-20%) worldwide and makes up to half the visits to gastroenterologists.

## Clinical Value of Calprotectin:

### Prediction of Relapse in IBD

The clinical course of most patients with IBD is marked by periods of remission with intermittent relapses characterized by increased intestinal inflammation.

Numerous published studies, among others by Tibble et al., studied the levels of calprotectin in patients during the course of the disease.

The results show that calprotectin appears to be a good predictor of relapse in patients with IBD, thus giving the clinicians an effective tool to prepare the patients treatment accordingly to ease the relapse intensity.

BÜHLMANN fCAL® ELISA offers a dynamic range from 10 to 1800 µg/g and thus cover the requirements for both, screening for IBD/IBS and Therapy Monitoring of IBD patients.

### Functional/Organic Screening

A severe problem in clinical gastroenterology is to differentially diagnose patients with inflammatory intestinal disease from functional disorders like IBS. The symptoms of IBD are very much the same as in functional GI disease IBS that has no inflammatory origin.

Calprotectin is considered a reliable indicator of inflammation in several diseases. Numerous studies show that while fecal calprotectin concentrations are significantly elevated in patients with IBD, and are correlating well with endoscopic and histological assessment of disease activity, patients suffering from IBS do not have increased fecal calprotectin values.

## Cut-off recommendation

Taking into consideration numerous studies performed with BÜHLMANN fCAL® ELISA during the course of over ten years to distinguish IBD from IBS with thousands of clinically characterized patients, including endoscopic data, the results for cut-offs, grey zone and diagnostic accuracy are finally summed up and sharpened in the most recent BÜHLMANN fCAL® ELISA US validation study published by Berinstein<sup>1</sup>.

478 patients, adults and children, were analysed within this multicenter prospective case-control study. Differentiation of potentially IBD patients from individuals affected by IBS at a cut-off at 80 µg/g shows a very high sensitivity of 93.3%. To keep the indecisive region as small as possible a higher cut-off at 160 µg/g shows an ideal trade-off for a combination of specificity (85.4%) and sensitivity (84.4%).

<sup>1</sup>Berinstein et al., Crohn's & Colitis 360, Vol. 1, 2019

## Interpretation of Results:

Fecal calprotectin values **<80 µg/g** are not indicative of inflammation in the gastrointestinal tract and patients are not likely to be in need of invasive procedures to determine the inflammation cause.

Mid-fecal calprotectin levels **between 80 and 160 µg/g** are not directly indicative of an active inflammation. Re-evaluation of fecal calprotectin levels after 4 to 6 weeks is recommended to determine the inflammatory status.

Calprotectin values **>160 µg/g** are indicative of active organic disease with inflammation. Appropriate further investigative procedures by specialists are suggested.

BÜHLMANN fCAL® ELISA can clearly distinguish functional from organic disorders, and assist the clinicians with disease-targeted treatments for the patients. On top of that, this *in vitro* diagnostic tool allows to avoid numerous expensive and invasive examinations.

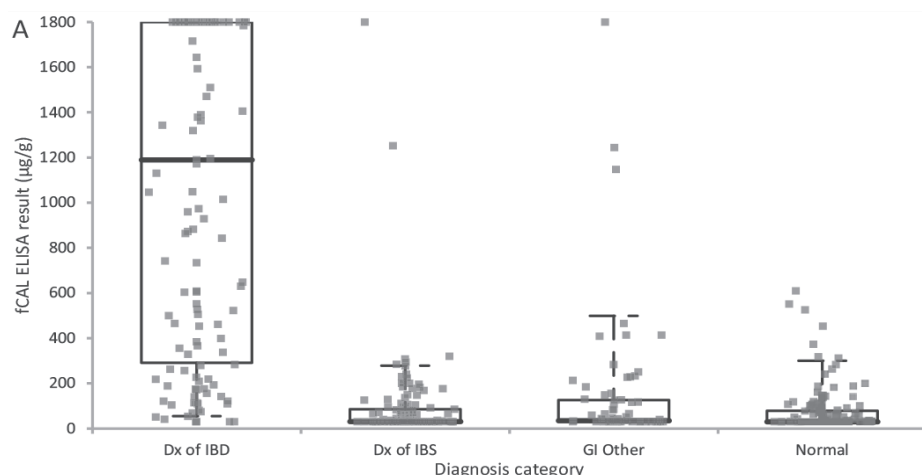


Figure 1:

Boxplot of BÜHLMANN fCAL® ELISA test results by diagnostic category. From Berinstein et al. 2019



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BÜHLMANN fCAL® is a registered trademark of BÜHLMANN in many countries.

Parts of the BÜHLMANN fCAL® kit are patent protected by:  
EP2947459(B1); US10620216(B2);  
AU2015261919(B2); JP6467436(B2)

## Ordering codes:

EK-CAL	96 wells
EK-CAL2	192 wells
EK-CAL2-WEX	192 wells

