

# BÜHLMANN fCAL<sup>®</sup> ELISA

Screening of IBD/IBS  
for Organic Inflammation  
vs. Functional Syndrome\*

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 pediat-  
ric gastroenterology

Dynamic Range 10 - 1800 µg/g

\*Canada: Registered as an *in vitro*  
diagnostic device. Health Canada  
Licensed (No. 80726).

This flyer is not intended for distribution in the US.

# 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 subjects with bowel inflammation (e.g. IBD), whereas it is not elevated in subjects 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 North America 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 subjects 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

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 subjects during the course of the disease.

The results show that calprotectin appears to be a good predictor of relapse in subjects with IBD, thus giving an effective tool to prepare the subjects 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 subjects.

## Functional/Organic Screening

A severe problem in clinical gastroenterology is to differentially diagnose subjects 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 subjects with IBD, and are correlating well with endoscopic and histological assessment of disease activity, subjects suffering from IBS do not have increased fecal calprotectin values.

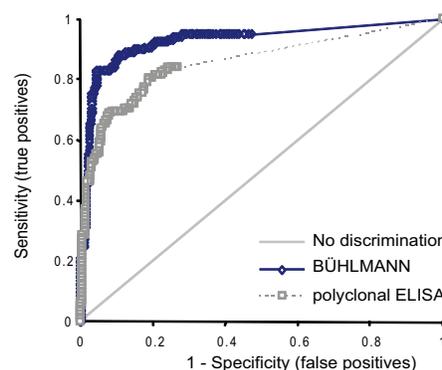


Figure 1:

ROC analysis of the ability of BÜHLMANN fCAL® ELISA and of a polyclonal ELISA to discriminate between patients with CD and IBS. From Burri et al. 2012.

Over 550 subjects presenting with abdominal problems at the University Hospital Basel were prospectively investigated at a secondary care centre. All underwent endoscopy and were tested for calprotectin with the monoclonal BÜHLMANN fCAL® ELISA over a period of 4 years and numerous kit lots. Calprotectin reliably discriminates organic from non organic disease subjects with high sensitivity and specificity. The overall diagnostic accuracy was 85% when 50 µg/g was used as cut off value. In a follow up paper by Burri et al., it shows that the BÜHLMANN fCAL® ELISA discriminates IBD from IBS significantly better than a competitor polyclonal ELISA (Fig. 1).

## Interpretation of Results:

Subjects with Calprotectin values **<50 µg/g** likely need not to be further investigated by invasive procedures.

Calprotectin values **between 50 and 200 µg/g** can represent mild organic disease such as inflammation, mild diverticulitis and IBD in remission phase. The low inflammatory response may suggest repeating the measurement and doing further investigations.

Calprotectin values **>200 µg/g** are indicative of active organic disease with inflammation. Appropriate further investigative and curative procedures by specialists are suggested.

Therefore, BÜHLMANN fCAL® ELISA can clearly distinguish functional from organic disorders, and aid disease-targeted treatments.

Registered as *in vitro* diagnostic device in Canada.  
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EK-CAL 96 wells  
EK-CAL2 192 wells  
EK-CAL2-WEX 192 wells

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