

Calprotectin ELISA

Non-Invasive Screening of
Organic vs. Functional Disease

Reliable and
Non-Invasive
Screening
Marker

Calprotectin is the best marker
for IBD

Excellent negative predictive value
to rule out IBD

Simple and reliable, highly cost
efficient application

Particularly interesting for pedia-
tric gastroenterology

Fastest ELISA test on the market



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.

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.

A recent study at the University Hospital Basel, Switzerland proves that calprotectin levels measured by the **BÜHLMANN Calprotectin ELISA** are highly correlating with the clinics and the current gold standard endoscopy.

405 symptomatic patients were included.

The BÜHLMANN Calprotectin assay confirmed with a **sensitivity of 84%** and a **specificity of 95%** the nature of the pathology behind the symptoms. In this study the performance of the BÜHLMANN monoclonal ELISA was superior to polyclonal Calprotectin determinations (Fig.1) and to Lactoferrin measurements (not shown). The **cut off is 50 µg/g** calprotectin in feces. One highlight of this study is the prove that the BÜHLMANN Calprotectin test has an **excellent negative predictive value of 93%** in ruling out organic inflammation.

The results confirm the work of Tibble et al. 2002 and different other studies, also showing high comparability between the tests used.

Therefore, the BÜHLMANN ELISA for Calprotectin in feces 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.

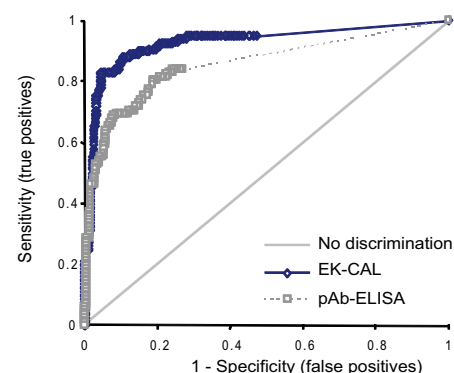


Figure 1:

ROC analysis of the ability of BÜHLMANN Calprotectin ELISA and of a polyclonal ELISA to discriminate between patients with CD and IBS. From Lehmann, et al. (in prep).



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