

# BÜHLMANN fCAL<sup>®</sup> ELISA

Aid in the Diagnosis of IBD

Reliable and  
Non-Invasive  
Diagnostic  
Marker

**Because Accuracy is What Matters**  
**ROBUST, VALIDATED, AND PUBLISHED**

Calprotectin is the marker of  
choice for IBD

High diagnostic accuracy with AUC  
of 0.933 for discrimination of IBD  
from IBS

Excellent sensitivity of 93.3% at  
cut-off 80 µg/g

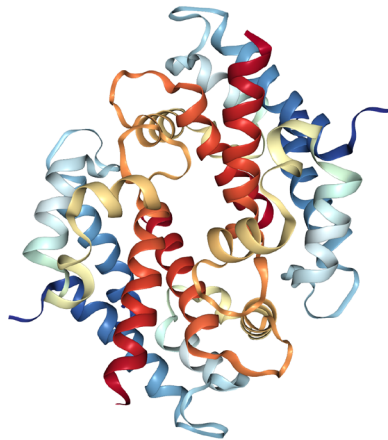
Highly referenced with more than  
75 peer reviewed scientific articles

Dynamic Range 30 - 1800 µg/g

# In vitro Assay for the Aid in Diagnosis of IBD

## Calprotectin and Inflammatory Bowel Disease IBD

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. It has been shown to be extremely useful as an aid in diagnosis of inflammatory bowel disease (IBD).



Crystal structure of human calprotectin, adapted from Korndorfer *et al.*, 2007.

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.

## Result Interpretation

Calprotectin concentration	Interpretation	Follow-up
< 80 µg/g	Normal	None
80 - 160 µg/g	Gray-zone/Border-line	Follow-up within 4 to 6 weeks
> 160 µg/g	Elevated	Repeat as needed

## Limitations

Test results should be interpreted in conjunction with information available from clinical assessment of the patient and other diagnostic procedures.

Fecal calprotectin results may not be clinically applicable to children less than 4 years of age.

Patients taking non-steroidal anti-inflammatory drugs (NSAID) may have elevated fecal calprotectin levels.

Patients with granulocytopenia may have false negative results due to bone marrow depression.

## BÜHLMANN fCAL® ELISA

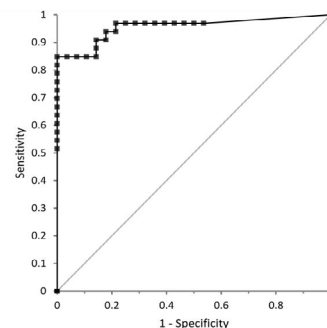
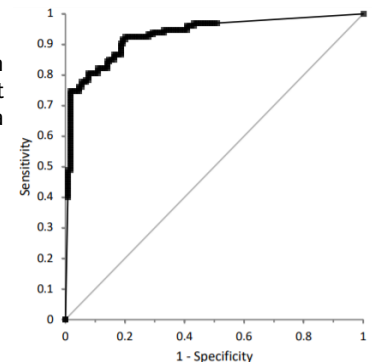
The BÜHLMANN fCAL® ELISA is an *in vitro* diagnostic assay intended for the quantitative measurement of fecal calprotectin in human stool. The BÜHLMANN fCAL® ELISA aids in the diagnosis of inflammatory bowel disease (IBD), specifically Crohn's disease (CD) and ulcerative colitis (UC) and aids in the differentiation of IBD from irritable bowel syndrome (IBS) in conjunction with other laboratory and clinical findings.

### Benefits

- High diagnostic **accuracy** for discrimination of IBD from IBS with AUC of 0.933 obtained in a clinical study with 265 adult and pediatric patients aged 4-85 years
- Excellent **sensitivity** at cut-off 80 µg/g of 93.3%: avoid false negatives in IBD diagnosis!
- Stable and equal **standardization** since 2006
- Narrow **clinical grey zone** between 80 µg/g and 160 µg/g
- More than **75 clinical peer-reviewed publications**
- The only **global assay** with IVD registrations in the US (FDA), Canada (HC), Europe (CE-IVD), Japan (PMDA), China (SFDA), Australia (TGE), Brazil (ANVISA) etc.

### Accuracy

ROC curve for discrimination of IBD from IBS in 204 adult patients aged 22+ (area under the curve of 0.925).



ROC curve for discrimination of IBD from IBS in 61 children aged 4-21 years (area under the curve of 0.956).

### References

1. Korndorfer, I.P. *et al.*, 2007, The crystal structure of the human (S100A8/S100A9) heterotetramer, calprotectin, illustrates how conformational changes of interacting alpha-helices can determine specific association of two EF-hand proteins, *J Mol Bio*



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### Ordering code:

EK-CAL 96 wells  
EK-CAL2 192 wells