



## Calprotectin ELISA



- Sensitive marker for chronic inflammatory bowel diseases (CIBD)
- Non-invasive assay for clear differentiation from irritable bowel syndrome (IBS)
- Ideal marker for monitoring therapy success e.g. in Crohn's disease or after polypectomy

### Technical data

<b>Coating</b>	Monoclonal anti-calprotectin antibody
<b>Calibration</b>	Quantitative, in microgramme per gramme ( $\mu\text{g/g}$ ), 6 calibrators
<b>Sample material</b>	Stool sample, diluted 1:50 in extraction buffer
<b>Reagents</b>	Ready to use, with the exception of the wash buffer (10x) and extraction buffer (5x); colour-coded solutions
<b>Test procedure</b>	30 min / 30 min / 15 min (sample/ conjugate/ substrate incubation), room temperature, fully automatable
<b>Measurement</b>	450 nm, reference wavelength between 620 nm and 650 nm
<b>Test kit format</b>	96 break-off wells; kit includes all necessary reagents
<b>Order no.</b>	<b>EQ 6831-9601 W</b>

### Clinical significance

Calprotectin is a calcium- and zinc-binding protein, which is produced by neutrophil granulocytes and monocytes. In case of an inflammatory intestinal disease, granulocytes move into the gut lumen and release calprotectin, which is secreted with stool. The calprotectin concentration in stool is a measure of the number of neutrophil granulocytes in the gut lumen and shows the extent of an inflammation in the intestine. The detection of calprotectin in stool is thus helpful to delimit gastrointestinal diseases of inflammatory and neoplastic genesis from an irritable colon (irritable bowel syndrome, IBS). In chronic inflammatory bowel diseases (CIBD) such as Crohn's disease and ulcerative colitis, calprotectin levels in stool are typically increased. Indications for the determination of calprotectin in stool: 1. Differential diagnosis of irritable colon from CIBD; 2. Exclusion of an organic disease of the intestinal tract (CIBD, infectious bowel disease, polyps, colon carcinoma), in the presence of clinical signs of a functional bowel disease; 3. Clarification of serologically detected inflammation parameters with respect to an acute/chronic bowel disease; 4. Evaluation of the severity of a bowel inflammation; 5. Suspected case of colon/rectal carcinoma; 6. Monitoring of the disease course (also under treatment) of Crohn's disease, ulcerative colitis, or after polypectomy.

### Diagnostic application

As the results in stool of the Calprotectin ELISA correlate very well with the histological and endoscopic findings in patients with CIBD, this assay spares the patient complicated and time-consuming imaging procedures, biopsies and the cost-intensive and radiation-intensive stool test (in-patient measurement of faecal excretion of  $^{111}\text{indium}$ -labelled neutrophil granulocytes). As opposed to the standard markers for inflammation used up until now (C-reactive protein, erythrocyte sedimentation rate, haemoglobin), increased calprotectin values indicate with great certainty an acute or chronic IBD or a recurrent IBD. Calprotectin is an ideal marker to monitor the disease course e.g. in Crohn's disease or after removal of colorectal polyps. Comparative measurements of calprotectin and faecal occult blood for the detection of colon carcinoma yielded a clear diagnostic advantage of calprotectin. In case of lowered calprotectin levels in stool ( $< 50 \mu\text{g/g}$ ) in adults and children from the age of 4 years, an organic disease of the intestine can be excluded with high probability. In case of higher levels of calprotectin, further diagnostic measures for investigation of the intestine are required.



## Detection limit

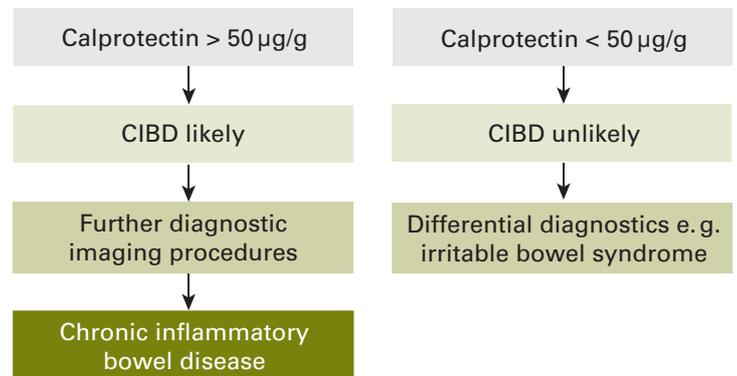
The lower detection limit is defined as the mean value of an analyte-free sample plus three times the standard deviation and is the smallest clearly detectable calprotectin concentration. The lower detection limit of the calprotectin ELISA is approximately 6.5 µg/g.

## Linearity

The linearity of the test was investigated by diluting 3 stool samples (192, 793, 1953 µg/g calprotectin) with sample buffer in a linear 1:2500 dilution series in 10% steps. The mean concordance with respect to the expected value was 101% (87-119%), with a mean correlation coefficient of  $R^2 = 0.98$ .

## Stepwise diagnostics

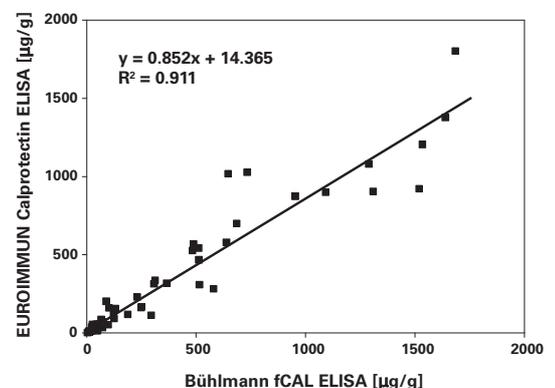
The measurement of the calprotectin level is particularly suited for the diagnostic differentiation between irritable bowel syndrome (IBS) and chronic inflammatory bowel diseases (CIBD) due to its high predictive value. The marker is useful to substantiate a suspected clinical diagnosis and to quickly determine the appropriate continuative diagnostic procedures (e.g. endoscopy).



## Correlation

The EUROIMMUN ELISA was compared with the commercially available calprotectin ELISA from Bühlmann Laboratories AG. The linear regression analysis yielded a regression coefficient of  $R^2 = 0.911$ .

Calprotectin results >50 µg/g should be considered as conspicuous. However, every laboratory should use their own normal values established under specific ambient conditions.



## Literature

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6. Zamani H, Barzin G, Yousefinia M, Mohammadkhani A, Ostovaneh MR, Sharifi AH, Tayebi S, Malekzadeh R, Ansari R. Diagnostic value of fecal calprotectin in patient with ulcerative colitis. *Middle East J Dig Dis* 5 (2013) 76-80