

LAB

CALiaGold[®]

Quantitative latex immunoassay for
Calprotectin measurement

SENTINEL
DIAGNOSTICS

Fast and reliable measurement of fecal Calprotectin in stool specimen.

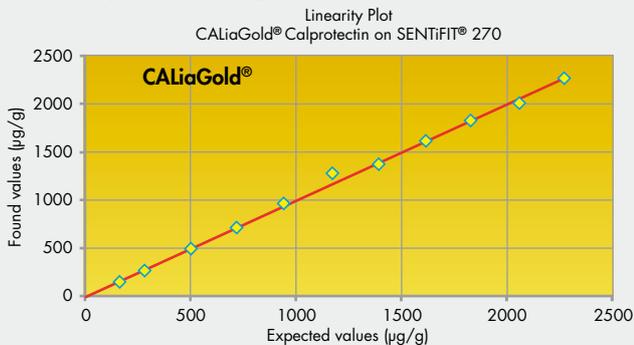
Features and Advantages

- Assists in the differential diagnosis of inflammatory bowel disease (IBD) and irritable bowel syndrome (IBS)
- Particle Enhanced Latex ImmunoAssay
- Results available in about 10 minutes
- Reagent, calibration and controls liquid and ready to use
- 60 days on-board reagent stability
- Measuring range 22 to 2200 µg/g
- Established cut off in IBD diagnosis and monitoring
- From sampling to analysis with a single collection tube
- Standardized stool sampling
- Available together with FOBGold® assay on dedicated SENTiFIT® 270 automated analyzer

Reference intervals and cut-off

Calprotectin values <50 µg/g are not indicative of inflammation in the gastrointestinal tract. Patients with low Calprotectin levels are likely not to be in need of invasive procedures to determine the inflammation cause. Calprotectin values between 50 and 200 µg/g can represent mild organic disease such as inflammation caused by NSAIDs, mild diverticulitis and IBD in remission phase. Calprotectin values >200 µg/g are indicative of active organic disease with inflammation in the gastrointestinal tract. Appropriate additional investigative and curative procedures by specialists are recommended.

Linearity of the assay



Ref.	Description	Kit size
1159000	CALiaGold®	1x16 mL; 1x5 mL; 1x8 mL
1159100	CALiaGold® Calibrator Set	6x(1x1) mL
1159200	CALiaGold® Control Set	2x(1x1) mL
1159300	CALiaGold® Tube Set	100 tubes

Summary

Calprotectin, a calcium-binding protein produced in cells such as neutrophils, is released during inflammation.

Fecal calprotectin works as a biomarker of gastrointestinal inflammation and neoplasia.

In the presence of an inflammatory bowel disease (IBD), neutrophils influx into the intestinal lumen and release calprotectin, which is excreted in the feces.

Consequently, the fecal calprotectin concentration can be used as a measure of the number of neutrophils in the bowel lumen and as an indicator of the severity of intestinal inflammation.

Fecal calprotectin measurement provides a reliable indication of the presence of inflammatory bowel disease.

Through the use of this biomarker, many patients with irritable bowel syndrome can therefore avoid unnecessary colonoscopy.

In several publications, fecal calprotectin concentrations have been shown to be strongly correlated with histological and endoscopic parameters of disease activity in patients with chronic inflammatory bowel disease.

Therefore, measurement of fecal calprotectin provides a means of objectively assessing the response to treatment of chronic inflammatory bowel disease and are useful for monitoring IBD patients during clinical remission phase providing early detection and treatment of IBD relapses.

Principle

CALiaGold® test is a particle enhanced latex immunoassay (PETIA) and allows quantification of calprotectin in faecal extracts. The turbidimetric assay is based on the agglutination reaction between latex particles coated with antibody and the antigen in solution.

CALiaGold® reagents are developed to obtain a high sensitivity and high linearity method.

Precision

Total Precision	Level 1	Level 2	Level 3	Level 4
N	92	92	92	92
Mean (µg/g)	60.3	161.4	496.7	1421.0
Within-Day (CV)	6.6%	2.3%	1.1%	1.5%
Between Day (CV)	1.6%	1.2%	0.6%	1.8%
Total CV	6.8%	2.6%	1.3%	2.4%

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