

# Normal reference ranges and cut-off values for performing and considering endoscopy using the improved Sentinel CaliaGold® Calprotectin assay

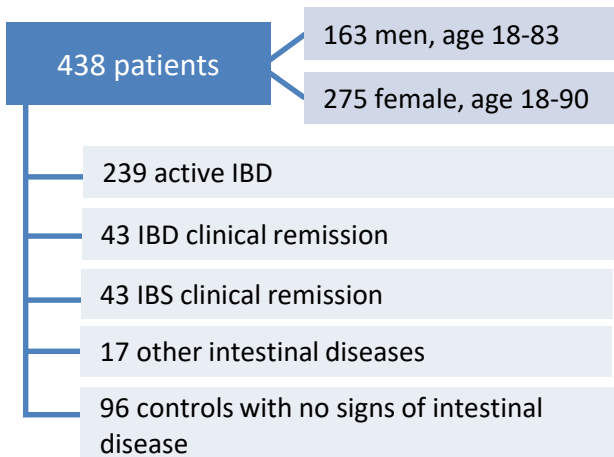
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## Background

Fecal calprotectin, a calcium-binding protein, is used as a sensitive marker for gastrointestinal mucosal inflammation. It is a simple, non-invasive test that can be used to distinguish irritable bowel syndrome (IBS) from inflammatory bowel disease (IBD), where significant overlap of clinical symptoms may occur. Recently, Sentinel Diagnostics launched an improved CALiaGold® pierce Tube combined with an improved latex immunoassay for calprotectin analysis on the SENTIFIT® 270 analyzer.

The **aim of the study** was to evaluate the currently used normal reference range for calprotectin (<60 µg/g\*) and the currently used cut-off values for performing or considering an endoscopy in case of IBD (perform endoscopy: calprotectin >250 µg/g\*, consider endoscopy: calprotectin 60-250 µg/g\*).



**Table 1:** Baseline characteristics of the patients enrolled in the study.

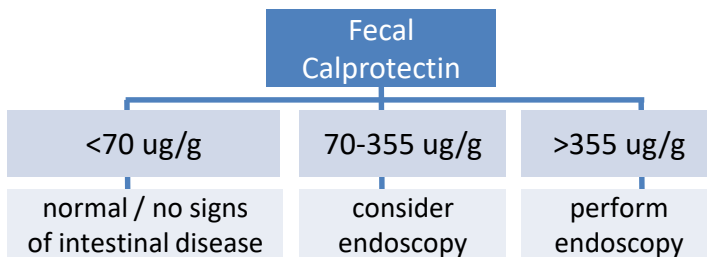


## Methods

- Patients received the improved CALiaGold® pierce Tube (Sentinel, ref. 1151300) along with the instruction protocol for stool collection at home. Within two days after fecal sampling, calprotectin was measured with the corresponding Quantitative Calprotectin latex immunoassay (Sentinel, REF 115100) on the SENTIFIT® 270 analyzer.
- Endoscopies were performed within one month around the fecal collection. Results of the endoscopies were independently registered and interpreted by the gastroenterologist.
- Calprotectin results were classified according to the clinical diagnosis.

## Results

- 1 In total 438 symptomatic patients participated in the study (Table 1).
- 2 Calprotectin **normal reference range**, and **cut-off values for performing and considering an endoscopy** are shown in Table 2.
- 3 Results of **Sensitivity, Specificity, NPV, PPV** are shown in Table 3.



**Table 2:** Algorithm for the use of calprotectin in the diagnosis of IBD, when using the CALiaGold® pierce Tube and assay.  
 - <70 µg/g (= p5 positive samples)  
 - >355 µg/g (= p95 negative samples)

Reference range	Sens (%)	Spec (%)	NPV (%)	PPV (%)
<60 µg/g <b>current use</b>	95	86	90	92
<70 µg/g <b>new</b>	92	93	88	95

**Table 2:** Sensitivity (Sens), specificity (Spec), negative predictive value (NPV) and positive predictive value (PPV) of the CALiaGold assay, using the current Calprotectin reference range (<60 µg/g\*) and the newly established normal reference range (<70 µg/g).

## Conclusions

- In case of stool collection at home with the improved CALiaGold® pierce Tube, the Sentinel CaliaGold® Calprotectin assay is highly sensitive in detecting mucosal inflammation.
- To differentiate between IBS and IBD, it is recommended to adjust the cut-off for differential diagnosis to <70 µg/g calprotectin.
- In case of IBD monitoring, it is recommended to adjust the cut-off for performing endoscopic examination to >355 µg/g calprotectin in order to reduce the risk of relapse.

\* Nederlandse Vereniging van Maag-, Darm- en Leverartsen: HANDLEIDING BEHANDELING IBD — 2014-2015; October 2015