

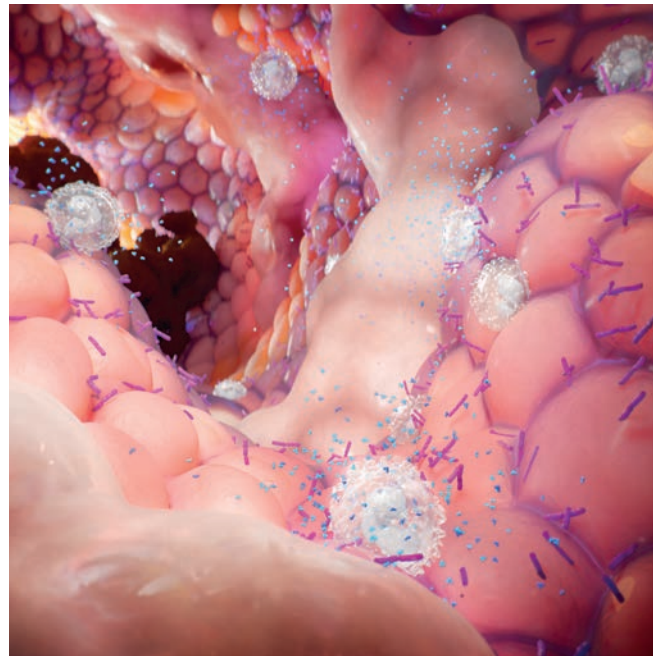
PUBLICATION SPOTLIGHT

Fast and reliable – the CALiaGold[®] test

Irritable bowel syndrome (IBS) is one of the most common disorders of gut–brain interactions and is estimated to affect around 1 in 10 people globally (~75 million in Europe). IBS is a disorder in which a person experiences chronic, recurrent bowel problems and abdominal pain. IBD, which stands for inflammatory bowel disease, includes Crohn’s disease (CD) and ulcerative colitis (UC), which are two serious, chronic digestive diseases that affect 5 million people worldwide (2.5–3 million in Europe). IBD is a chronic inflammatory disease of the gut which presents with periods of inflammatory activity (flares) and quiescent phases (remission) as can be seen with many chronic diseases.

Calprotectin is a protein mainly found in the cytoplasm of neutrophilic granulocytes. In cases of gastrointestinal (GI) inflammation, neutrophils migrate through the intestinal wall, and calprotectin is released due to degranulation. It accumulates in the faeces and is excreted from the body. The concentration of calprotectin directly correlates with the number of neutrophils in the intestinal lumen, making it an ideal biomarker for GI inflammation. It helps in the differential diagnosis of IBD and IBS, can predict IBD relapses and can be used for monitoring and optimising the therapy in IBD patients.

Automated quantitative calprotectin determination in human faeces with CALiaGold[®] on SENTiFIT[®] 270 or SENTiFOB[®] analyser – patient’s home-sampling with the dedicated CALiaGold[®] pierceTube – improves calprotectin stability in CALiaGold[®] buffer, offers a more hygienic procedure for lab personnel and reduces their workload.



Neutrophil granulocytes migrate through the inner wall of the patient's colon due to inflammation, and calprotectin released from dead and dying neutrophils creates a high concentration of protein in the intestinal lumen.

List of references

Publications

[1] **Schoorl M. et al. (2023):** Normal reference ranges and cut off values for performing and considering endoscopy using the improved Sentinel CaliaGold® Calprotectin assay. ECCO Copenhagen poster P305.

Key message: After home-sampling with the dedicated CALiaGold pierce Tube it is recommended for the CALiaGold assay to adjust the cut-off for differential diagnosis to <70 µg/g, whereas in case of IBD monitoring the cut-off for performing an endoscopy should be set to >355 µg/g calprotectin.



[2] **Dijkhuis L. et al. (2022):** The Reliability of Patient-Performed Fecal Calprotectin Testing in Inflammatory Bowel Disease. *The Journal of Applied Laboratory Medicine* (2022) 7(6): 1401–1411.

Key message: Patient-performed fecal calprotectin extraction with the CALiaGold pierceTube at home protects calprotectin from degradation, reduces lab workload and represents a more hygienic procedure.



[3] **Hamer H.M. et al. (2022):** Impact of Preanalytical Factors on Calprotectin Concentration in Stool: A Multiassay Comparison. *The Journal of Applied Laboratory Medicine* 0: 1–11. 7(6): 1401–1411.

Key message: Faecal calprotectin concentration in stool samples declines over time (generally not stable for 3–7 days at room temperature), is most stable in extracted faeces stored at 4°C and it depends on the assay used how long extracted faeces stored at 4°C give reliable test results (CALiaGold used among 5 different assays in total).



[4] **Schoorl M. et al. (2022):** Analytical performance of the new Sentinel CALiaGold pierce Tube and Quantitative Calprotectin latex immunoassay on the S270 analyzer. EML Munich poster M063.

Key message: The preservation of stability and the conservation of functionality of the new Sentinel CALiaGold pierceTube in a laboratory setting have been approved and are more user-friendly for faecal sampling by patients at home.



[5] **Mérida F.J. et al. (2020):** Comparative Study of Three Different Fecal Calprotectin Immunoassays: TriCAL Study. *Annals of Clinical and Laboratory Science* 50(6): 55–60.

Key message: The CALiaGold assay demonstrated a high concordance and correlation with two other current commercial fast immunoassays, fCAL turbo and Quantum Blue fCAL, whereas a better correlation and agreement between the immunoturbidimetric assays were achieved.



[6] **Huijgen j.R. et al. (2020):** Analytical performance of the CALiaGold Quantitative latex immunoassay for Calprotectin measurement on the SENTIFIT 270 analyzer. NVKC Papendal poster.

Key message: After evaluating the analytical performance of the CALiaGold assay on the SENTIFIT 270 platform and performing a method comparison vs the EliA Calprotectin 2 assay, CALiaGold was judged to meet the requirements for the quantitative determination of calprotectin in human stool.

[7] **Silva B. et al. (2019):** Method comparison of CALiaGold (a new assay for quantitative determination of fecal calprotectin) and BÜHLMANN fCAL™ turbo. EML Barcelona poster; *Clinica Chimica Acta* 493: 13–75.

Key message: CALiaGold on the SENTIFIT 270 analyser shows a good performance compared with the other turbidimetric fCAL™ turbo assay and is therefore judged to be eligible for the measurement of calprotectin in routine settings that offers a unique solution to analyse both faecal calprotectin and occult blood on a single instrument (SENTIFIT 270).



[8] **Rasmussen HY. et al. (2019):** Comparison of two automated assays and extraction techniques for analyzing fecal calprotectin. IBD Nordic conference Malmö poster.

Key message: The method comparison showed an overall acceptable correlation between the two methods (CALiaGold vs EliA Calprotectin 2), particularly in the calprotectin < 500 µg/g range.

[9] **Finazzi S. et al. (2018):** Comparison between two automated assays for the quantitative determination of fecal calprotectin. ELAS 2018 poster.

Key message: Clinical performance of the CALiaGold assay on the SENTIFIT 270 compared with the EliA Calprotectin 2 assay showed high concordance at the same cut-off of 50 µg/g.

[10] **Paparella C. et al. (2018):** Evaluation of a new assay for the quantitative determination of calprotectin in human feces (CALiaGold). UEG week poster P1721.

Key message: Analytical and clinical performances of the CALiaGold assay on the SENTIFIT 270 analyser meet the requirements for its use in the quantitative determination of calprotectin in human faeces.



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