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

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).

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.

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.

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.

Key message: The CALiaGold assay on the SENTiFIT 270 analyser showed a good correlation with the Phadia EliA assay (Passing-Bablok analysis showed a slope of 1.38 (1.25-1.60) with an intercept of 4.0 (–2.0–9.6)).

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 analyze both faecal calprotectin and occult blood on a single instrument (SENTiFIT 270).

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.

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.

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.