Faecal Calprotectin

BIOHIT HealthCare Innovating for Health

elisa

46927EN2019/04



| Product Code | Description |
|--------------|---|
| K6927 | IDK Faecal Calprotectin ELISA. 96 wells |
| K6999 | IDKextract Prefilled Stool Sample extraction system. 100 pcs. |

For Secondary Care ²

In the identification of active Crohn's Disease: Sensitivity 90.2%, Specificity 79.2%

IDK Faecal Calprotectin ELISA for the differential diagnosis of IBS and IBD, and

For Primary Care ¹

Validated Primary Care pathway for excluding IBD in patients presenting with gastrointestinal symptoms (NPV =

monitoring of disease activity

In the identification of active Ulcerative Colitis: Sensitivity 97.8%, Specificity 79.2%

Product Specifications

Clinical use

98.9%).

- Double monoclonal Ab sandwich ELI-SA, 96 wells
- 5 standards, 2 controls
- Range: 5.25 to 2100µg/g
- Assay time 70 minutes
- IDKextract univeral stool extraction system

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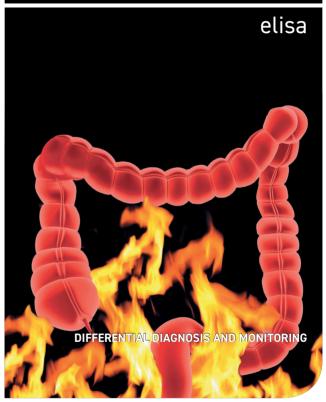
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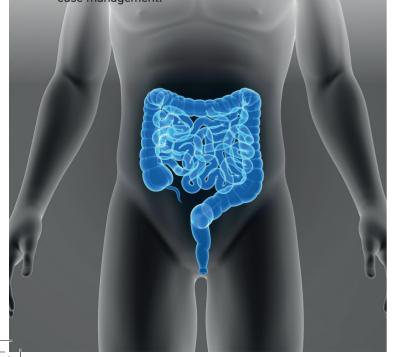
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Accurate marker of intestinal inflammation

Calprotectin is the major protein of the neutrophil cytosol and has been established as a faecal marker of inflammatory bowel disease (IBD).

It is excreted in excess in stools during disease activity active in IBD and so the measurement of faecal calprotectin enables the differentiation of organic and functional intestinal diseases.

The acute phase protein also helps in monitoring disease activity helping clinicians to implement effective patient care with a proactive approach to disease management.



For differentiating irritable bowel syndrome and inflammatory bowel disease

Calprotectin enables the cost effective differentiation of organic and functional diarrhoea in patients suffering with IBS-like symptoms in Primary Care. Whilst colonoscopy remains the gold standard diagnostic tool



for the diagnosis of colonic inflammation, non-invasive markers of intestinal inflammation add value to the clinical investifation of patients with abdominal symptoms.

Faecal Calprotectin concentrations of <50mg/g reliably rule-out intestinal inflammation enabling patients with IBS to be managed more effectively and directed to appropriate investigations, possibly averting invasive and costly imaging procedures such as colonoscopy and flexible sigmoidoscopy.

Patients with elevated faecal calprotectin can be selected for further investigation and referral thus making effective use of secondary care resources.

NICE diagnostic guidance DG11 (2013) recommends Faecal Calprotectin as an option to help physicians differentiate bowel diseases non-invasively. ³

- 1. Walker et al. Aliment Pharmacol Ther. 2018; 1-14.
- Loitsch et al. Gastroenterol. 2010: 138:5. Suppl 1. S-528.
- Faecal calprotectin diagnostic tests for inflammatory diseases of the bowel, NICE 2013 (DG11).
- BSG Guidance on Faecal Calprotectin. Oct 2016. British Society of Gastroenterology.

For monitoring disease activity in IBD

Crohn's disease and ulcerative colitis are characterised by periods of remission flanked by episodes of clinical relapse. Predicting which patients with IBD are likely to relapse allows targeted and individualised



therapy at an earlier stage to avoid relapse and maintain deep remission.

Faecal Calprotectin has been shown to be an effective predictive marker of clinical relapse in numerous clinical trials in both ulcerative colitis and Crohn's disease. This enables therapy to be optimised by monitoring the course of disease and rivides an ojective indication of response to treatment.

Furthermore, faecal calprotectin is also useful in the evaluation of mucosal healing, post intervention, with anti-TNF α therapy and other biologic treatments, adding to the cost effectiveness of these personalised therapies. Clinical studies have evaluated decision-making algorithms aimed to support the safe withdrawal from biological treatments.

The British Society of Gastroenterology has published useful guidance on the use of faecal calprotectin in diagnosis and management of IBD. ⁴