

Gastroenterology

Calprest[®] NG

www.calprotectintest.com

The new reference ELISA test for the in vitro diagnosis of Inflammatory Bowel Disorders (IBD) Quantitative non invasive method for the determination of Calprotectin in stool by means of an extended calibration curve.

Configuration

code 9069	Calprest[®] NG Reagents for 96 tests
code 9062	Stool collection device 100 pieces

Application field

In association with clinical findings, Calprest[®] NG can be used for the in vitro diagnosis, follow-up and treatment monitoring of patients affected by Inflammatory Bowel Disease (IBD), Irritable Bowel Syndrome as well as for screening and surveillance of high risk CRC patients.

Structure, function, location of Calprotectin

Calprotectin belongs to the group of Ca-binding proteins of the S100 family and is present in large amounts in neutrophilic granulocytes, where it accounts for 5% of total proteins and 60% of the proteins of the cytoplasmic portion. The increase of faecal Calprotectin appears to be due to faecal excretion of neutrophils and macrophages migrated from the blood stream into the intestinal lumen through the inflamed mucosa. A strict correlation has been demonstrated between the Calprotectin levels and the clinical indexes of disease activity in patients with IBD.

Calprest[®] NG: Extent of the problem

Crohn's disease (CD) and ulcerous colitis (UC) are chronic inflammatory bowel diseases (IBD) with unknown aetiology. Their prevalence is extremely variable in the different case studies: about 40/100.000 for CD and 100/100.000 for UC. The annual incidence rate is about 4/100,000 inhabitants for CD and 8/100,000 for UC. Colorectal cancer (CRC), whose known main risk factors are genetic predisposition, diet, presence of IBD and age, has an yearly rate incidence of 25/100.000 in Western Europe and USA populations.

Features of the products

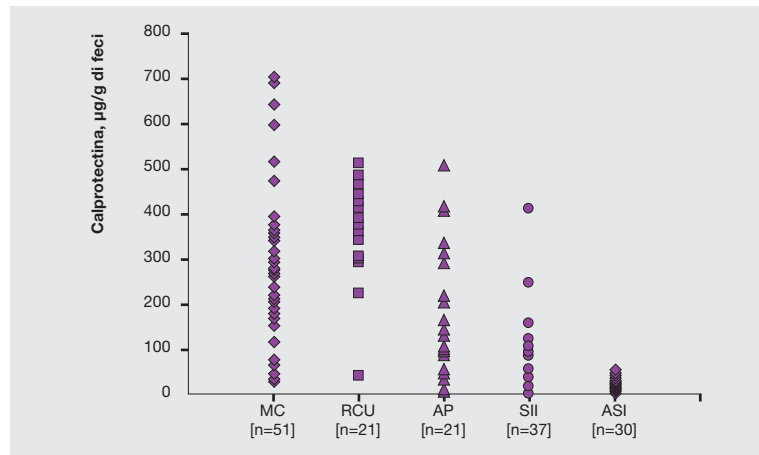
- 6 calibrators
- Range of linearity 0-3000 mg/kg
- 2 controls
- Incubation at room temperature (no shaking)
- Quantitative results expressed in mg/kg

Procedure outline

- Extraction and dilution of stool samples (final dilution 1:20000)
- Addition of calibrators, positive and negative controls, diluted extracted samples
- 60 minutes incubation at room temperature
- Washing step by means of diluted wash buffer
- Addition of conjugate
- 30 minutes incubation at room temperature
- Washing step by means of diluted wash buffer
- Addition of substrate
- 30 Minutes incubation at room temperature
- Reading at 450 nm

Table 1

Calprotectin values in groups of patients (MC: Crohn Disease; RCU: Ulcerative colitis; AP: other intestinal pathologies; SII: Irritable Bowel Syndrome; ASI: Asymptomatic patients¹)



Performance

Several studies have been performed to assess Calprest[®] NG diagnostic sensitivity and specificity. The data reported below relate to an evaluation study including clinically diagnosed IBD and IBS patients as well as other patients affected by other disorders.

Calprest	Patients	
	Positive	Negative
Positive	96	5
Negative	4	47
Total	100	52

Sensitivity	96.0%
Specificity	90.4%
PPV	95.1%
NPV	92.2%

Results

Calprest provides with results in the range between 15.6 and 500 mg/kg. Studies on Calprest have been useful in defining the following references values:

Value	Interpretation
<50 mg/kg	Negative
50-100 mg/kg	Borderline area, to be repeated (within 4-6 weeks)
>100 mg/kg	Positive

Why Calprest[®] NG?

The detection of faecal calprotectin is an useful diagnostic stool in the following conditions^{2,3,4}:

- To differentiate IBD from IBS
- To prevent from clinical relapses
- Follow-up of IBD patients to define the most suitable treatment approach
- Screening of patients suffering from acute diarrhoea.

Literature

1. Ciarrocchi G., et al.: Calprotectina fecale: un prezioso esame non invasivo nella Malattia Infiammatoria Cronica Intestinale (MICI). *biochimica clinica*, 2006, vol. 30, n. 1.
2. Berni Canani R. et al.: Fecal calprotectin is a useful diagnostic tool in pediatric gastroenterology. *Ital J Pediatr* 2005; 31:89-94.
3. Berni Canani R. et al.: Combined Use of Non-invasive Tests is Useful in the Initial Diagnostic Approach to a Child with Suspected Inflammatory Bowel Disease. *J Pediatr. Gastroenterol. Nutr.*, vol. 42, n.1, January 2006.
4. Roseth A.G., Aadland E., Grzyb K.: Normalization of Faecal Calprotectin: a Predictor of Mucosal Healing in Patients with Inflammatory Bowel Disease. *Scan. J Gastroenterol.* 2004; 39:1017-1020.