

# Calprest<sup>®</sup>NG

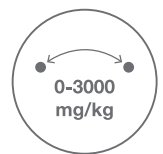
*The most accurate test  
for calprotectin in stool.*



**Extended range  
ELISA assay for  
calprotectin in stool.**



Human Recombinant  
Calprotectin



Extended  
range



Improved patient  
management

# Calprest® NG

*The New Generation reference test for quantitative detection of Calprotectin in stool.*

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## WHAT IS CALPROTECTIN?

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Calprotectin is a protein present into the neutrophils and can be found in stool with elevated concentrations in case of Inflammatory Bowel Disease (IBD), namely Crohn's Disease, Ulcerative Colitis and Intermediate Colitis. Calprotectin is stable in stool samples for several days at room temperature and much longer periods at -20°C.

The faecal concentration of Calprotectin correlates with the histologic and endoscopic patterns of the intestinal inflammation in IBD patients.

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## THE IMPORTANCE OF DETECTING CALPROTECTIN

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Only a small proportion of patients with intestinal disorders referring to the gastroenterology clinic have an organic disease. The majority of population referring to a gastroenterologist (35-50%) is affected by a functional disease called Irritable Bowel Syndrome (IBS), which is probably the most common cause of intestinal disorders.

Therefore it is necessary to differentiate those patients with functional disease (IBS) that do not need invasive researches, from those who are suffering from organic diseases and in particular from Inflammatory Chronic Intestinal Diseases.

**Calprest® NG** is a non-invasive screening test that reliably detects the presence of an inflammatory status in the intestinal mucosa and can be used in the following conditions:

- Differential diagnosis (IBD/IBS)
- Control of the correct course of IBD and monitoring of the therapeutic strategy
- Prediction of clinical relapses

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## **Calprest® NG: THE TEST**

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**Calprest® NG** the new diagnostic test for detection of Calprotectin in stool, was developed by exploiting the experience gained by the use of Calprest in clinical laboratories.

The use of **Calprest®** (FDA 510k clearance 130945), the most widespread test for calprotectin detection throughout different countries, along the years has generated a continuous and increased awareness of the benefits for the patients and related cost savings for the health systems by both reducing the number of unnecessary endoscopies and, on the other hand, a better patient's management.

Today, **Calprest® NG** is the new generation reference test for detection of Calprotectin in stool.

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## TECHNICAL FEATURES

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**Calprest®NG** is a microplate based enzyme immunoassay that exploits the use of polyclonal antibodies directed against the calprotectin to capture Calprotectin present in the diluted stool sample. The calibration curve is based on human recombinant Calprotectin.

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## HUMAN RECOMBINANT CALPROTECTIN

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The use of the human recombinant calprotectin has several advantages if compared to the use of the fecal extracted antigen:

- Higher intra-batch reproducibility
- Higher stability
- Better precision

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## EXTENDED RANGE

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**Calprest®NG** provides with results in the range between 0 and 3000 mg/kg (or µg/g) of stool, the widest available range of detection for calprotectin assay, calculated from a 6 calibrator reference curve (0-150 ng/ml). The initial stool extraction is based on a 1:50 dilution and the extracted sample is then further diluted 1:400. If higher levels of Calprotectin are expected, the measurement range of **Calprest®NG** may be extended by using further dilutions of the initial extracted sample.

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## INTERPRETATION OF RESULTS

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CALPROTECTIN CONCENTRATION	INTERPRETATION
< 50 mg/kg	Negative
50 - 120 mg/kg	Borderline: the patient should be retested within a short period of time
>120 mg/kg	Positive

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## INTERPRETATION

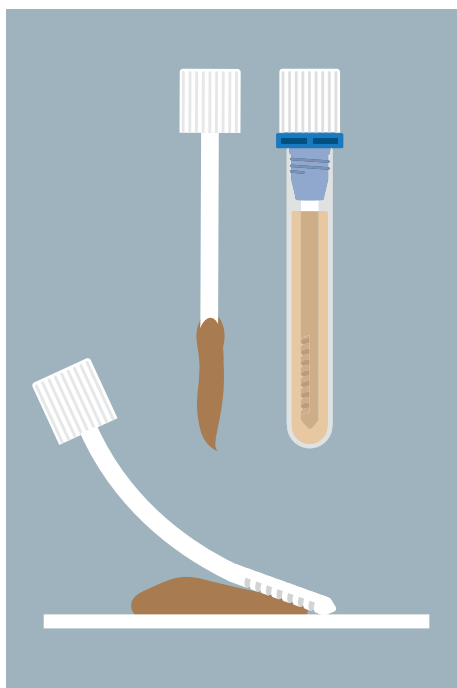
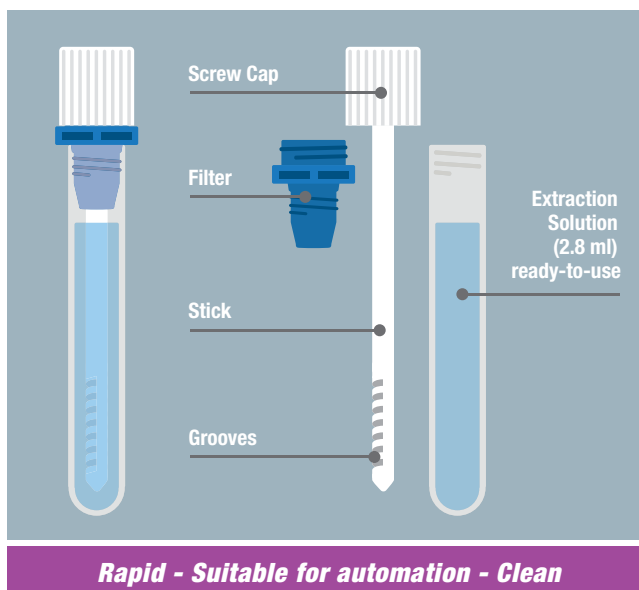
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Diagnostic sensitivity	94.6%
Diagnostic specificity	90.2%
Positive Predictive Value	89.8%
Negative Predictive Value	94.9%

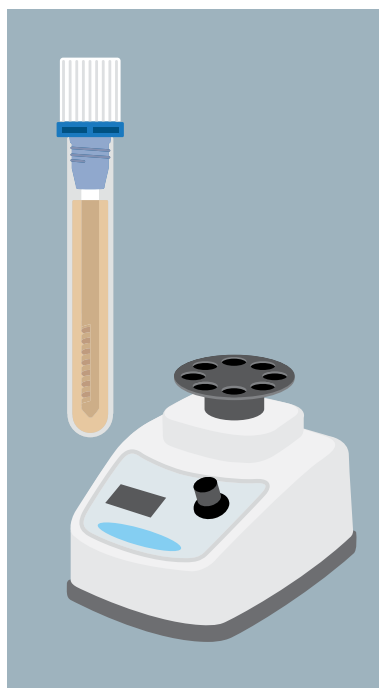
## COLLECTION AND EXTRACTION OF SAMPLE

To optimize the use of **Calprest®NG** during stool collection and extraction, Eurospital provides with **EasyCal**, a standardized and CE marked device for Calprotectin, that significantly reduces the pre-analytical phase, allowing the operator to have already extracted samples that do not require any stool manipulation.

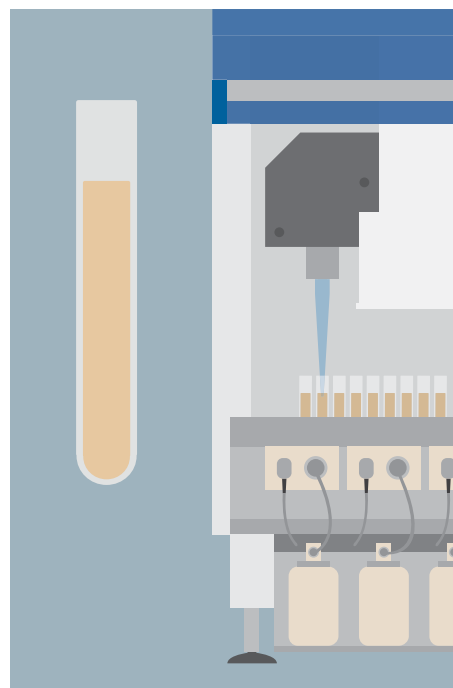
**EasyCal** is a ready-to-use device (see picture) which consists in a test tube containing the extraction solution and a shaped dipstick with seven grooves for stool sample collection. It is easy-to-use: dip the dipstick into the stool sample and then reintroduce it into the device in order to start the extraction. The sample thus obtained can be immediately tested or transferred into a clean test tube for later use.



Dip the shaped stick in the stool sample, and repeatedly rotate it until all grooves are filled with faecal material. Fully insert the stick into the device and screw it by rotating clockwise. The blue separator will retain the stool excess. The extraction process starts immediately.



Vortex each device for at least 60 seconds in order to properly homogenate the content. Place the device on a roller shaker for tubes and shake for 20 minutes.



Remove the cap and the blue separator by rotating them clockwise. The sample is ready to be used immediately, by placing the device directly into the sample rack, or stored at -20°C for a later use.

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## TIPS AND PRECAUTIONS FOR A BETTER USE OF **Calprest®NG**

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**Calprest®NG** shows high sensitivity and high negative predictive value.

Elevated values of **Calprest®NG**, excluding serious infectious diseases, are a possible indication of Inflammatory Bowel Disease (IBD). Conversely, a negative test result suggests an almost certain exclusion of Inflammatory Bowel Disease.

In patients with infectious diseases or upper respiratory tract disorders, **Calprest®NG** may be positive due to swallowing of mucus and consequent presence of activated neutrophils in the stool: in this case the patient should repeat the test when the infection is over.

IBD patients undergoing specific anti-inflammatory therapy, may show decreased levels of Calprotectin due to anti inflammatory drugs driven reduction in the activation of granulocytes and, therefore, **Calprest®NG** could be negative.

**Calprest®NG** is highly indicated for disease monitoring and patient's follow-up.

IBD patients in clinical remission, but tested positive with **Calprest®NG**, may experience relapses within 6 months.

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## **Calprest®NG** CONFIGURATION

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• **Calprest®NG** - 96 tests - code 9069



• **EasyCal** Device to collect stool - 100 pc - code 9062





Literature available on:  
[www.calprotectintest.com](http://www.calprotectintest.com)

### **Eurospital SpA**

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loudadv.com - WGA016 Calprest®NG Rev. 0 - 16.10.31