

FROM THE PIONEERS IN CALPROTECTIN DETECTION, A LINE OF DIAGNOSTIC PRODUCTS FOR THE DETERMINATION OF THE INFLAMMATORY STATE

EasyCal CalFast NeXT Calprest NG Calprest Turbo

Eu-Fast Reader Eu-Turbo Analyzer





Why Eurospital

Eurospital is a family business with more than **20 years of experience** in the design, production and marketing of diagnostic tests for the quantitative measurement of calprotectin, based on the method developed by Prof. Fagerhol (University of Oslo - Norway) in 1992. Eurospital is the first company to receive **FDA clearance** for the use of the ELISA test for the detection of calprotectin for discrimination between patients affected by Inflammatory Bowel Disease (IBD) from subjects affected by Irritable Bowel Syndrome (IBS).

Calprotectin: What it is

Calprotectin, a 36 kDa heterodimer belonging to the S100 family of proteins, is produced by polymorphonuclear cells, monocytes and epithelial cells, having **proapoptotic**, **bacteriostatic** and **antimycotic** properties by sequestering metal ions. Calprotectin is secreted in the site of leisure or infection in order to exert its host-defence functions. Thanks to its properties, in recent years calprotectin has become an important **marker for inflammation**. Calprotectin can be detected in various biological matrices such as plasma, serum, synovial fluid and feces, and its concentration is proportional to the existing level of inflammation.

Calprotectin: Why detect it

Inflammatory diseases include a variety of disorders and conditions characterized by **chronic inflammation** triggered an excessive immune reaction, which leads to a consequent reduction in the functionality of the affected organs. The implication of calprotectin in the inflammatory process has been widely demonstrated, although its role in the pathogenesis, diagnosis and monitoring of inflammatory rheumatic diseases, as well as in other diseases such as obesity and colorectal cancer, has attracted great attention only in recent years. The role of calprotectin as an inflammatory marker has initially become relevant in chronic inflammatory bowel disease. This makes calprotectin fecal test the **gold standard** for the **differential diagnosis** of the organic disease (**IBD**) from the funcional disease (**IBS**), the most common cause of intestinal disorder that affects the majority of the population undergoing a gastroenterological examination (35-50%). Calprotectin determination became an important **non-invasive tool** that allows to avoid expensive and invasive analysis, with a faster outcome. Only patients with an organic disease will be directed to further diagnostic investigations in order to define the specific pathology. Subjects with functional diseases will therefore avoid invasive endoscopic procedures, which results in improved analysis experience and significant economic saving.

Calprotectin: Where to detect it

Calprotectin is highly resistant to degradation and can be easily extracted and quantified from **most varied biological matrices**, like stool, in which calprotectin remains undegraded for up to 3 days at room temperature. Not only from feces, calprotectin can also be determined from other human biological matrices, including serum, plasma, saliva, cerebrospinal fluid, synovial fluid and urine.

Calprotectin: What does it indicate

A high calprotectin level indicates the inflammatory state, which **severity** is **proportional to its concentration**. IBS subjects, facing a functional disease, have usually a very low fecal calprotectin level, whereas IBD patients with organic pathologies like Ulcerative Colitis or Chron's disease have fecal calprotectin level higher than the internationally established pathological cut-off. As for blood analysis, calprotectin determination can be used for IBD / IBS discrimination when the analysis from fecal samples is not possible, while in specific clinical situations a high calprotectin level can be an indication of systemic inflammation, such as that occurring in chronic inflammatory rheumatoid arthritis. Serum calprotectin can be also a useful marker for the monitoring of pathological metabolic conditions such as obesity. Finally, if it is not possible to obtain fecal samples, blood calprotectin can also be used for IBD monitoring.

Calprotectin: How to detect its concentration

After decades of experience with calprotectin testing, Eurospital has developed a wide range of products with different technologies, such as lateral flow, ELISA and turbidimetry, for the quantitative determination of calprotectin from various biological matrices. The characteristics of Eurospital portfolio of tests allow for rapid, accurate, quantitative, safe and non-invasive analysis. Besides being a valid support to the laboratory for the differential IBD / IBS diagnosis and other inflammatory diseases, calprotectin determination is also a precious non-invasive tool for monitoring the development of the identified inflammatory disease and the consequent optimization of the therapeutic treatment. Not only the analysis of the marker, Eurospital has made fecal pre-analytical processing of specimens easy, fast and safe, thanks to *EasyCal* ready-to-use device, which can be loaded directly into the automatic laboratory instrumentation for analysis after the quick extraction procedure.

Eurospital's test portfolio for the quantitative determination of calprotectin

LATERAL FLOW

CalFast® NeXT

REF. 9191NT

- Rapid immunochromatographic test on cassette for the quantitative determination of calprotectin from fecal sample
- Extended measuring range up to 2,100 μg/g
- · Quick and easy: results in 20'
- Perfect for the small/medium sized laboratory or for urgent analysis
- Dedicated *Eu-Fast Reader* for the reading, interpretation
 and reporting of test results for
 the identification and monitoring
 of IBD patients

ELISA

Calprest® NG

REF. 9069

- ELISA test for quantitative determination of fecal calprotectin
- The gold standard for the differential diagnosis between IBD and IBS
- High number of samples
- Recombinant human calprotectin for more accurate and reliable results
- Wide measurement range

 (0 3,000 µg/g) for both
 identification and monitoring of

 IBD patients
- Perfect for the medium/large laboratories

TURBIDIMETRY

Calprest® Turbo

REF. 9300

- Immunoturbidimetric test for quantitative determination of fecal calprotectin
- · High sample throughput
- High automation
- Results in 10'
- Measuring range up to 8,000 µg/g
- Implementable on all the different turbidimetric instruments already present in the laboratory
- Perfect for the medium/large laboratories
- Dedicated **Eu-Turbo Analyzer**

Test	CalFast [®] NeXT	Calprest [®] NG	Calprest® Turbo
Method	Lateral Flow	ELISA	Immunoturbidimetric
Nr. of calibrators	7	6	6
Quantification range	20 - 2,100 μg/g	0 - 3,000 μg/g	0 - 1,500 μg/g 0 - 8,000 μg/g (with 1:10 sample dilution)
Time to results	20'	< 1 hr 45'	< 10'
Sample analysed	10 μl fecal extract	5 μl fecal extract	2.5 - 14 µl fecal extract
Matrix	feces	feces	feces
Sensitivity	95.2%	94.6%	97.1%
Specificity	89.7%	90.2%	87.9%
Number of tests	20	96	200
Dedicated stool collection device	EasyCal (included)	EasyCal	EasyCal Turbo
Certification	CE-IVD	CE-IVD, FDA	CE-IVD

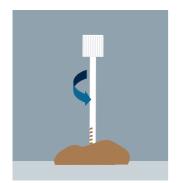
EasyCal® Family

THE COLLECTION DEVICES FOR PRE-ANALYTICAL PROCESSING OF FECAL SPECIMEN

EasyCal is a well established brand for a family of **ready-to-use** disposable *in vitro* diagnostic devices for the pre-analytical processing of fecal specimens. EasyCal devices consist of a test tube pre-filled with the extraction solution, a grey flexible rod and a blue coloured funnel. The diagonal grooves on the lower part of the stick have been designed to collect a precise amount of feces, of **any consistency**, from the most liquid to the most solid. The funnel permits **reproducible processing** by retaining the excess stool specimen present on the stick, therefore allowing to extract and preserve calprotectin from a very precise amount of fecal specimen. EasyCal and EasyCal Turbo differ for the number of grooves present on the stick, therefore for the amount of collected fecal specimen. Eurospital tests require a specific fecal extract concentration due to the different analytical method used for the quantitative determination of fecal calprotectin, therefore each EasyCal is associated with one or more specific IVD kits.

Calprotectin extraction protocol consists of just a few simple steps, providing users with an analyzable fecal extract in just a few minutes. EasyCal tubes containing the fecal extract can be diluted and analyzed with the rapid test and its dedicated Eu-Fast Reader, or loaded directly into the analytical instrument, without the need to further transfer the supernatant to a different tube.

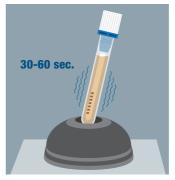
Quick and easy extraction protocol



 Collection of fecal specimen with the stick



2. Insertion of the stick into the tube through the filtering funnel



3. Vortexing for 30-60 seconds

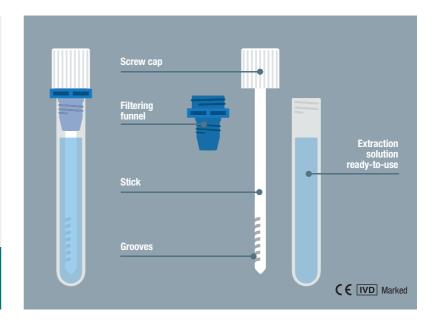


4. Removal of the stick and funnel and centrifugation for 10 minutes or left to sediment for 20 minutes

Characteristics of the device

- Highly standardized for reproducible sampling
- Ready-to-use device with pre-filled extraction solution
- For fecal specimens of any consistency
- Long collection stick for reduced risk of operator contamination
- Loadable directly into analytical instruments

EasyCal. 100 pcs - Ref. 9062 **EasyCal Turbo.** 100 pcs - Ref. 9302



Eu-Fast Reader

REF. 9190NT

Eu-Fast Reader has been designed as a ready-to-use **independent solution** for the quantitative analysis of Eurospital rapid tests: *CalFast NeXT* (calprotectin), *ElaFast* (pancreatic elastase), *IFX-Fast* (Infliximab) and *ADM-Fast* (Adalimumab).

Eu-Fast Reader is equipped with an **integrated external camera** for reading QR codes, allowing a quick and simple registration of the test- and lot-dependant calibration curve, directly from the kit's external label. The double-sided cassette slide can accommodate all the Eurospital rapid test cassette formats, avoiding the need to use cassette adapters. Eu-Fast Reader's **intuitive operating system** makes the device easy to use. Last generation components allow a rapid and efficient assessment of the test cassette, reducing the test's analytical step to just a **couple of seconds**.



MADE IN ITALY

Eu-Turbo Analyzer MADE IN ITALY

Eu-Turbo Analyzer

REF. 9194

In order to create an **independent station** for the analysis of fecal specimens with turbidimetric technology, Eurospital offers Eu-Turbo Analyzer: the **benchtop instrument** for the **quantitative determination of several fecal markers** such as calprotectin, pancreatic elastase, haemoglobin and Helicobacter pylori.

Eu-Turbo Analyzer makes the analysis quick and easy. EasyCal tubes used for the extraction of the diagnostic markers can be loaded directly into the instrument. Results will be available in less than 10 minutes as Eu-Turbo Analyzer can start the runs immediately by having the reagents stored refrigerated on board. Reagents consumption is dedicated to the analysis of the diagnostic markers as the calibration curve is stable for 30-days.



Watch the video



Eurospital SpA

Via Flavia 122, 34147 Trieste, Italy
Phone +39 040 8997.1 - Fax +39 040 280944
www.eurospital.com - info@eurospital.it

