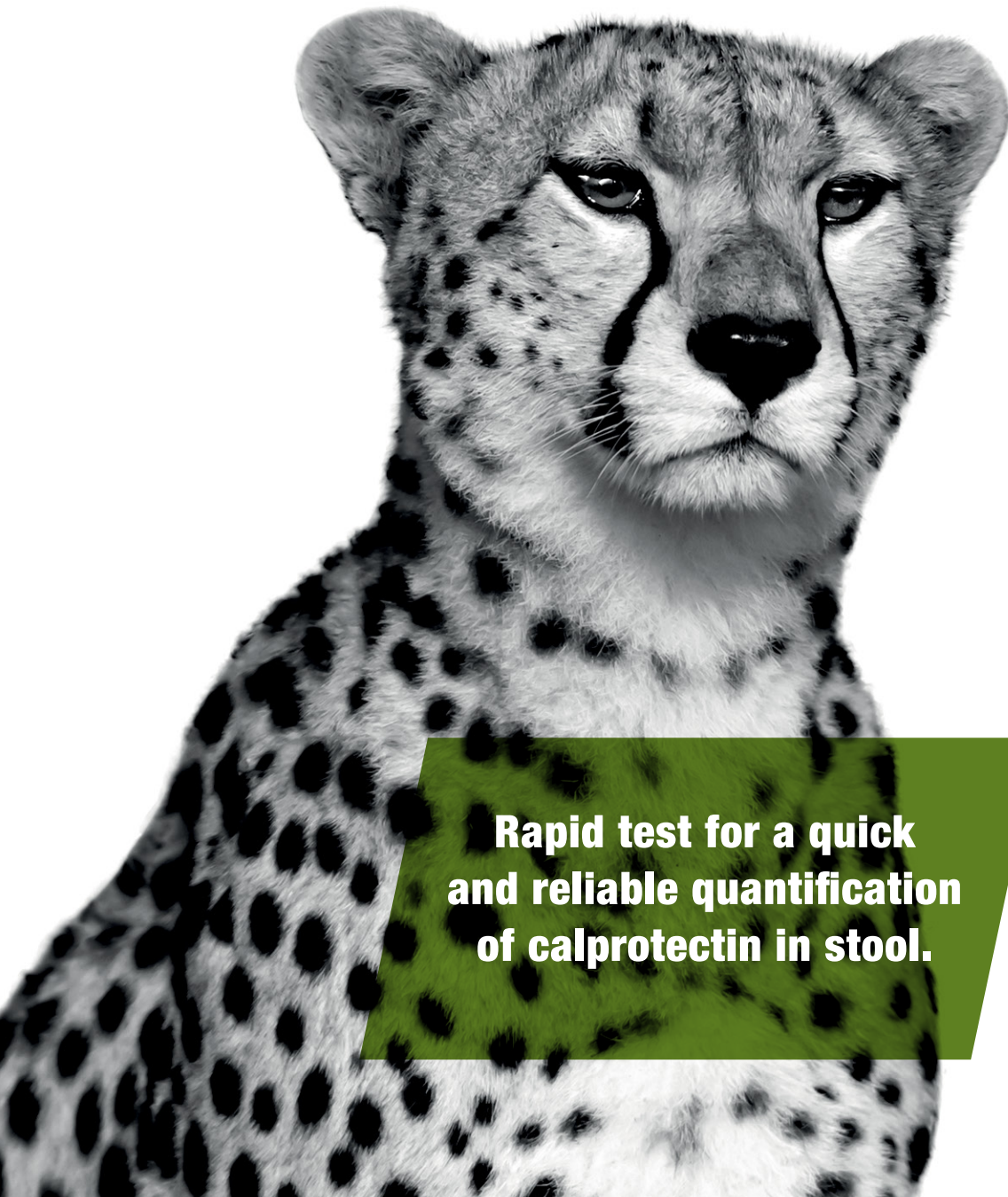


CalFast

*The quickest test
for calprotectin in stool.*



**Rapid test for a quick
and reliable quantification
of calprotectin in stool.**



Quantitative
results



Rapid
screening



Controls
included

CalFast

Rapid test for the quantitative determination of calprotectin in stool.

WHAT IS CALPROTECTIN?

Calprotectin is a protein present in the neutrophils and can be found in stool with elevated concentration in case of Inflammatory Bowel Disease (IBD), specifically Crohn's disease and Ulcerative 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.

THE IMPORTANCE OF USING *CalFast*

Only a small portion of patients with intestinal disorders referring to the gastroenterology clinic have an organic disease. The majority of population (35-50%) is affected by a functional disease called Irritable Bowel Syndrome (IBS), which is probably the most common cause of intestinal disorders. The symptoms of intestinal disorders are relatively unspecific, i.e. diarrhea, abdominal pains and, therefore, it is important and cost effective to differentiate those patients with functional disease, not needing invasive methods, from those suffering from organic diseases such as IBD. This also applies to the pediatric population, where anesthesia is normally required before submitting the child to colonoscopy.

The measurement of Calprotectin is a support in the "in vitro diagnosis" of IBD (Crohn's disease and Ulcerative Colitis) and allows accurate laboratory diagnosis and appropriate follow-up of IBD patients, by screening out IBS patients. The negative predictive value of the test is around 99% in the diagnosis of IBD. The presence of an organic disease diagnosis is extremely unlikely under a "normal" concentration of calprotectin.

CalFast is a Rapid, Reliable and Quantitative assay to differentiate patients with organic disease (IBD) from those with functional disease (IBS).

CalFast is a non-invasive screening test for reliable detection of the presence of an inflammation of the intestinal mucosa and can be used in the following conditions:

- Differential diagnosis (IBD/IBS)
- Follow up the disease (IBD) and treatment monitoring
- Prediction of clinical relapses



CalFast TEST

The great experience gained in the development of Calprest (Calprotectin in ELISA) allowed Eurospital to contrive a rapid test comparable to the traditional ELISA assay, designing an innovative solid phase where an appropriate mixture of mono and polyclonal antibody is used. **CalFast** is a rapid assay and provides with quantitative results of Calprotectin concentration in stool by means of the dedicated **CalFast** Reader. In a few minutes **CalFast** provides with faecal concentration of Calprotectin using lateral flow technology applied to a support (Card) on which the sample is dispensed; the coloured band resulting in the Card will be detected and quantified by a dedicated

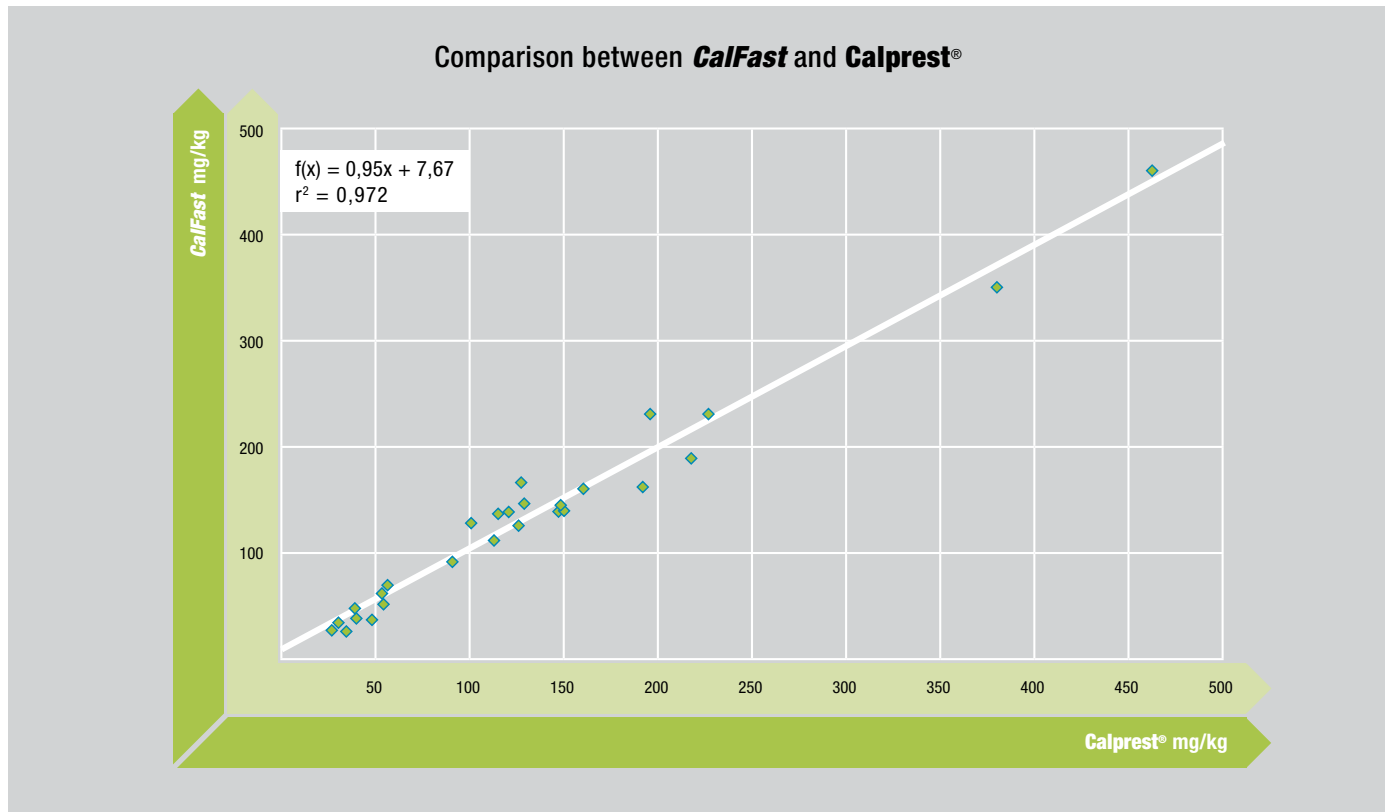
reader (**CalFast** Reader). The quantification of the Calprotectin is referred to a lot specific standard curve. The lot specific data can be uploaded by reading the bar code printed inside the package. Once the reaction occurs, each Card can be read within a short time with no risk of wrong results and allowing to run a significant number of tests. **CalFast** fits the needs of medium/small laboratories.

CalFast provides with Calprotection results in the range between 30 and 300 mg/kg. Taking advantage of the experience with Calprest (ELISA method), the following references values have been defined:

VALUE	INTERPRETATION
< 70 mg/kg	Negative
70-100 mg/kg	Grey area, it is advisable to repeat
> 100 mg/kg	Positive

CalFast RELIABILITY

The performance of **CalFast** was compared to Calprest, which represents the mostly used calprotectin assay in Europe and is quoted in more than 90% of all scientific studies made on this subject. Twenty seven samples of patients with values falling in the detectable range were analyzed by **CalFast** and the values compared to those obtained with Calprest. The comparison showed a very good correlation and an overlapping performance. Reporting the data in a diagram, the regression line showed excellent values: correlation coefficient $R^2=0,972$, slope =0,9542, intercept=7,67 $\mu\text{g/g}$ (see graph below).



Sensitivity 90%

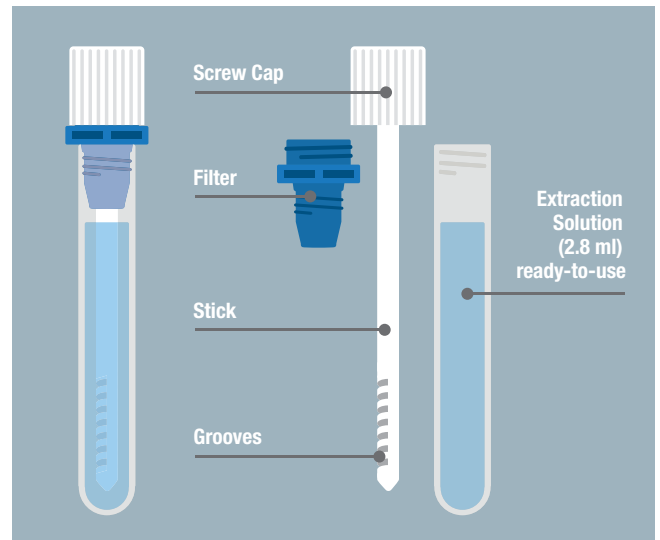
Specificity 92%

COLLECTION AND EXTRACTION OF SAMPLE

To simplify the collection and extraction steps, Eurospital provides with **EasyCal**, a dedicated device, which significantly reduces the pre-analytical phase, allowing the operator to have an easy sample extraction avoiding any stool handling.

EasyCal is a ready-to-use device (see picture) and consists in a test tube containing the extraction solution and a specifically designed dipstick with seven horizontal grooves for sample collection.

It is easy-to-use: it is in fact sufficient to take the sample through the shaped dipstick and reintroduce it into the device in order to start the extraction. Once the extraction is completed, the sample can be transferred into a clean test tube for immediate or later use.



TIPS AND PRECAUTIONS FOR A BETTER USE OF **CalFast**

Elevated values of **CalFast**, if other infections can be excluded, is a strong indication for Inflammatory Bowel Disease (IBD). Conversely, negative test results suggest almost certain exclusion of IBD.

In patients with infections in the airways respiratory **CalFast** may test positive due to swallowing of mucus, which contains neutrophils, and the consequent presence of calprotectin. If this occurs, the test should be repeated when the infection of the upper airways is gone.

Antinflammatory drugs may induce a reduction in the activation of granulocytes and therefore **CalFast** could be negative.

Patients with IBD in clinical remission but tested positive with **CalFast**, may experience a relapse within a short period of time (6 months).

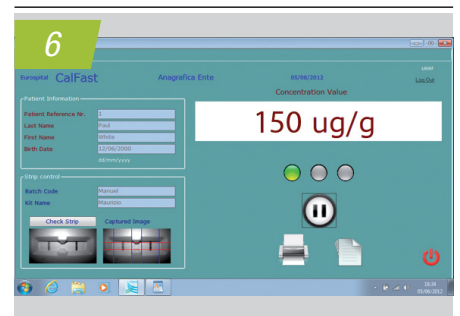
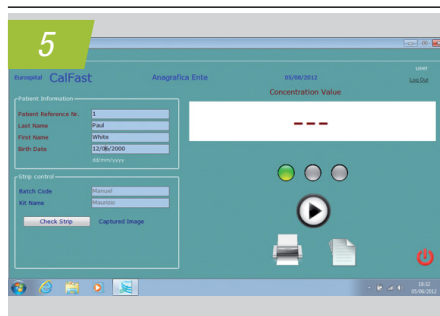
CalFast - Kit content

- 20 Cards
- 20 Devices to collect and extract the sample (ready-to-use)
- Dilution buffer (ready-to-use)
- Controls

CalFast - Codes

- **CalFast** - code 9191
- **CalFast Reader** - code 9190

OPERATION PHASES




1. Set-up: connect the CalFast reader to the PC through the provided USB cable. Switch on the PC. Once the set-up is completed, reboot the PC, double-click on the application icon and start using the dedicated CalFast Client software.

2. Calibration and set up of batch specific parameters: place the strip with the batch specific barcode inside the dedicated slot of the reader. The batch specific calibration parameters will be loaded.

3. Sample collection and extraction: using the device contained in the kit, proceed with the preparation of the sample as shown in the package insert. Then, dilute the faecal extract 1:50 (i.e. 20 µl extracted sample + 980 µl dilution buffer).

4. Sample dispensation: take 100µl of diluted sample and place it in the circular window on the cassette. Incubate for 20 minutes at room temperature.

5. Cassette Loading: at the end of the incubation time, check that the green LED lights up on the software. Place the cassette in the slot, check it is properly positioned.

6. Reading the results: press  to read it. Once the reading is completed, the results, expressed as mg/kg, will appear on the display of the PC.

User friendly software



Maintenance free



Literature available on:
www.calprotectintest.com

Eurospital SpA

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

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