

# ***Eurospital*** ***Turbidimetric Tests***



**CALPROTECTIN**

**PANCREATIC ELASTASE**

**FOB**

**HELICOBACTER PYLORI**

Turbidimetric tests and analyzer as a complete solution  
for the diagnostic determination of gastrointestinal markers

## Introduction

Calprotectin has nowadays become a well established marker for the determination of gastrointestinal inflammation, leading in these years to a significant increase in the number of calprotectin determination tests from fecal specimen. Fecal analysis is becoming fundamental for the characterization of the status of the gastrointestinal tract: the determination of diagnostic markers like **calprotectin**, **pancreatic elastase**, **haemoglobin** (Fecal Occult Blood, FOB) and **Helicobacter pylori** antigen provide clear insights about the presence of severe pathologies such as Inflammatory Bowel Disease (IBD), Pancreatic Exocrine Insufficiency (PEI), colon cancer and H. pylori infection.

The need of an independent system for the execution of fecal specimen analysis, with a higher throughput and greater automation, has become evident. Eurospital makes up to this need by offering, together with an exhaustive portfolio of turbidimetric tests for the quantitative determination of gastrointestinal markers from stool specimens, also an independent benchtop turbidimetric instrument, the **Eu-Turbo Analyzer**.

As per the pre-analytical process, Eurospital allows to safely and easily prepare the fecal extracts with **EasyCal**, a ready-to-use device, which tube can be inserted directly into the **Eu-Turbo Analyzer** after the quick extraction protocol. **Eu-Turbo Analyzer** will perform the determination of the desired analytical markers and provide the quantitative results in about 10 minutes.

**Eu-Turbo Analyzer**, together with the Eurospital turbidimetric tests **Calprest Turbo**, **Elaprest Turbo**, **FOB-Test Turbo** and **Helori Turbo**, provide the laboratory user with a standalone solution for the rapid and safe analysis of fecal specimens for the quantitative determination of gastrointestinal markers such as calprotectin, pancreatic elastase, FOB and H. pylori antigen.

## Eurospital Turbo: a comprehensive panel of tests for the analysis of the fecal specimen

Test	<b>Calprest® Turbo</b>	<b>Elaprest Turbo</b>	<b>FOB-Test Turbo</b>	<b>Helori Turbo</b>
Test reference number	9300	9298	9297	9296
Number of tests per kit*	200	100	100	100
Analyzed marker	Calprotectin	Pancreatic elastase	Haemoglobin	Helicobacter pylori
Measuring range	0 - 1,500 µg/g 0 - 8,000 µg/g (with 1:10 sample dilution)	0 - 400 µg/g	0 - 1,000 ng/ml	0 - 40 ng/ml
Calibrator	Human recombinant calprotectin	Human recombinant pancreatic elastase E1	Human haemoglobin	Recombinant H.pylori antigen
Compatible fecal extraction device	<b>EasyCal Turbo</b>	<b>EasyCal Turbo</b>	<b>EasyCal FOB</b>	<b>EasyCal Helori</b>
Extraction device reference number	9302	9302	9293	9294
Extraction devices per kit	100	100	100	100
System certification (test + device)	CE IVD	CE IVD	CE IVD	CE IVD
Sensitivity (Positive % agreement)**	97.1%	100%	100%	83.8%
Specificity (Negative % agreement)**	87.9%	93%	97.5%	98.4%
Total % agreement**	92.2%	95%	98%	93%

\*The number of tests may vary depending on the analytical instrument used

\*\*Clinical performances were evaluated by a method comparison study performed between the Eurospital turbidimetric test and a predicate

## Calprest® Turbo

REF. 9300



CALPROTECTIN

Calprest Turbo determines human **calprotectin** from fecal specimens as an aid for the pathologists to discriminate **IBD** patients (Inflammatory Bowel Disease) from **IBS** subjects (Irritable Bowel Syndrome). Thanks to its wide determination range, Calprest Turbo can be used for both the identification of the IBD patient and the subsequent monitoring of the clinical course.

Fecal extraction device: **EasyCal Turbo** (ref. 9302)

CALPROTECTIN CONCENTRATION	INTERPRETATION
< 50 µg/g	Subject without intestinal inflammation
50 - 120 µg/g	Borderline subject
> 120 µg/g	Subject with intestinal inflammation

## Elaprest Turbo

REF. 9298



PANCREATIC ELASTASE

Elaprest Turbo determines human pancreatic elastase from fecal samples in order to help pathologists in the identification of patients with Pancreatic Exocrine Insufficiency (**PEI**) from subjects with similar symptoms attributable to other possible pathologies. Elaprest Turbo specifically determines **human pancreatic elastase 1 (E1)**, not detecting the enzyme of other species, therefore allowing the correct monitoring of the disease during the pharmacological treatment of PEI patients.

Fecal extraction device: **EasyCal Turbo** (ref. 9302)

PANCREATIC ELASTASE CONCENTRATION	INTERPRETATION
> 200 µg/g	Subject with normal pancreatic function
100 - 200 µg/g	Borderline subject with mild PEI
< 100 µg/g	Subject with PEI

## FOB-Test Turbo

REF. 9297



HAEMOGLOBIN

FOB-Test Turbo allows the quantitative determination of human **haemoglobin** from fecal samples that can be linked to the bleeding derived from specific **Lesions of the colorectal intestinal tract**. Haemoglobin in feces can be used as a marker of colorectal cancer, therefore directing the patient to further clinical investigations in order to assess the specific clinical condition.

Fecal extraction device: **EasyCal FOB** (ref. 9293)

HUMAN HAEMOGLOBIN CONCENTRATION	INTERPRETATION
< 50 ng/ml	Subject with no colorectal bleeding
50 - 200 ng/ml	Subject with mild colorectal bleeding
> 200 ng/ml	Subject with high colorectal bleeding

## Helori Turbo

REF. 9296



HELICOBACTER PYLORI

Helori Turbo allows the quantitative determination of the **Helicobacter pylori antigen** from human fecal samples, helping the pathologists in the detection of **chronic infections derived from this bacteria**. In more severe cases, the prolongation of the inflammatory state can lead to the onset of malignant tumors. Helori Turbo allows a quick and non-invasive determination of the presence of H. pylori directing the patient to further clinical investigations or therapeutic treatments.

Fecal extraction device: **EasyCal Helori** (ref. 9294)

H.PYLORI ANTIGEN CONCENTRATION	INTERPRETATION
< 0.8 ng/ml	Subject with no H.pylori antigen
0.8 - 1 ng/ml	Borderline subject
> 1 ng/ml	Subject with high H.pylori antigen levels

# 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 fecal markers** like calprotectin, pancreatic elastase, haemoglobin and Helicobacter pylori antigen.

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 after 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**.



MADE IN ITALY

## Main features

- Benchtop: 49 cm x 60 cm x 62 cm x 38 kg
- Capacitive liquid level detector
- Needle shock sensor
- Wash station for reusable cuvettes
- Removable reagents trays
- Removable samples tray with 60 numbered positions
- EasyCal tube can be positioned directly inside the samples tray
- Separated racks for controls and calibrators
- Rotor with 80 washable cuvettes positions
- Pipetting volumes:
  - Sample 2 - 300  $\mu$ l
  - Reagent 5 - 350  $\mu$ l
  - Precision: 1.5 CV% at 2  $\mu$ l, 1 CV% at 4  $\mu$ L mixing
- Automatic pre-dilution up to 1:100
- Refrigerated chamber for reagent onboard stability up to expiry date
- Random / urgent test run
- 125 tests / hour
- No carry-over
- Daily start-up automatically run: self-test, reader's optics offset, cuvettes' wash and check
- Sampling needle automatically washed after each operation
- PC connected via USB port
- Ethernet LAN connection

# EasyCal<sup>®</sup> Family

## 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. Each EasyCal variant is associated with a specific analytical test and allows the **extraction** and **preservation** of one or more diagnostic markers. EasyCal devices consist of a test tube pre-filled with the extraction solution, a grey flexible rod and a 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 allows **reproducible processing** by retaining the excess stool specimen present on the stick, therefore allowing to extract the markers from a very precise amount of specimen.

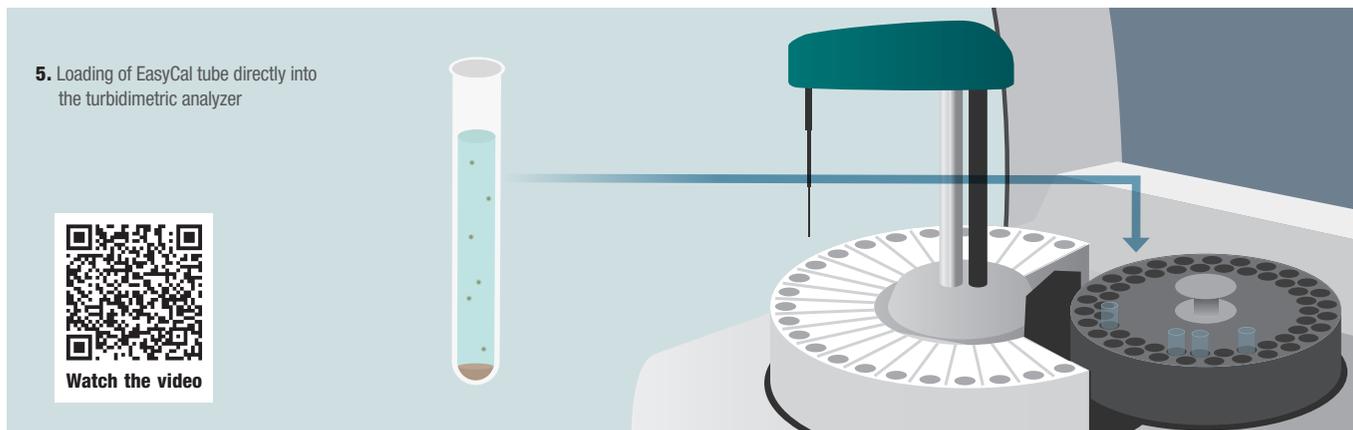
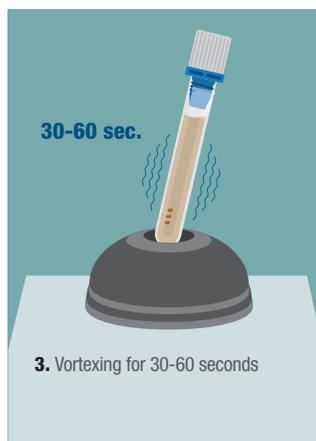
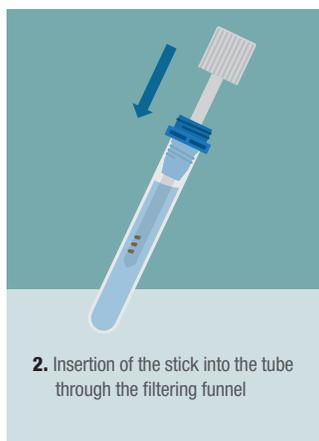
The extraction protocol consists of just a few simple steps, providing users with an analyzable fecal extract in just a few minutes. EasyCal tubes containing the fecal extract can be then loaded directly into the turbidimetric analytical instrument, without the need to further transfer the supernatant to a different tube.

### EasyCal Family unique features

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

EasyCal Family	Associated analytical kit
<b>EasyCal Turbo</b> (Ref. 9302)	<b>Calprest Turbo</b> (Ref. 9300) <b>Elaprest Turbo</b> (Ref. 9298)
<b>EasyCal FOB</b> (Ref. 9293)	<b>FOB-Test Turbo</b> (Ref. 9297)
<b>EasyCal Helori</b> (Ref. 9294)	<b>Helori Turbo</b> (Ref. 9296)

### Easy and fast extraction protocol





More information and scientific references on:  
[www.calprotectintest.com](http://www.calprotectintest.com)

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