

Eurospital Rapid Tests



CALPROTECTIN

PANCREATIC ELASTASE

TDM

Rapid tests and dedicated reader as a complete solution
for the identification of gastrointestinal disorders
and the assessment of the biological therapy

Introduction

Eurospital has developed a novel **all-in-one** rapid test reader that extends the analysis of fecal specimens beyond the sole determination of **calprotectin** with **CalFast NeXT** for the identification and monitoring of patients affected by Inflammatory Bowel Disease (IBD).

The portfolio of Eurospital rapid tests is now implemented with **ElaFast**, a rapid test for the determination of fecal **pancreatic elastase**, aimed as an aid in the identification and monitoring of patients with Pancreatic Exocrine Insufficiency (PEI).

The new **Eu-Fast Reader** has been further designed to analyze and report the new **TDM** (Therapeutic Drug Monitoring) rapid tests, Eurospital solution for the assessment and monitoring of the clinical treatment of IBD patients with **Infliximab** and **Adalimumab** biological drugs. This makes Eu-Fast Reader the perfect IVD device for both the identification of gastrointestinal patients and the precise monitoring of IBD patients' clinical course for the fine tuning of the therapeutic approach.

Eu-Fast Reader

REF. 9190NT

Eu-Fast Reader is the new all-in-one portable instrument for the quantitative reading of Eurospital rapid tests, characterized by an **intuitive software interface** and an integrated **touchscreen display**.

Eu-Fast Reader has been designed as an **independent solution**, ready to use, with no need of other external devices to operate. Eu-Fast Reader is equipped with an integrated external camera for a handy reading of 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, avoid 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

Main features

- Touchscreen display for simplified operativity
- Intuitive operating system for quick and easy use
- Double sided cassette slide for higher test cassette compatibility
- Last generation internal videocamera for high resolution reading
- Built-in barcode reader for simplified test lot recording
- Wi-Fi connectivity for improved data transfer
- Windows Enterprise OS for optimized system stability

Rapid identification of patients with gastrointestinal disorders

CalFast NeXT

REF. 9191NT



CALPROTECTIN

CalFast NeXT is the rapid immunochromatographic test for the quantitative determination of **calprotectin from fecal specimens**. Calprotectin is a 36 kDa protein produced by polymorphonuclear cells, having proapoptotic, bacteriostatic and antimycotic properties. Calprotectin is secreted in the site of leisure in order to exert its biological functions. Due to its functional meaning and to its resistance to degradation, calprotectin has recently become a pivotal player as a **marker of inflammation** since its concentration is proportional to the inflammatory state.

CalFast NeXT is a valid aid for the differential diagnosis of chronic **Inflammatory Bowel Disease (IBD)** from **Irritable Bowel Syndrome (IBS)**, providing a rapid and easy solution for fecal calprotectin determination, thus giving a clear idea about the inflammation status of the intestinal mucosa. CalFast NeXT allows not only the **identification of IBD patients**, but thanks to its extensive measuring range up to **2,100 µg/g**, it also permits a **precise monitoring** of the IBD clinical course.

ElaFast

REF. 9191EP



PANCREATIC ELASTASE

ElaFast is the rapid immunochromatographic test for the quantitative determination of human **pancreatic elastase from fecal specimens**. Pancreatic elastase is one of the enzymes synthesized and secreted by the pancreas which, thanks to its proteolytic activity, promotes the digestion of ingested food during its passage through the gastrointestinal tract. Quantifying pancreatic elastase from fecal specimens permits the **evaluation of the exocrine functionality of the pancreas** with a non-invasive approach.

ElaFast helps clinicians with the correct identification of patients with **Pancreatic Exocrine Insufficiency (PEI)** and their differentiation from those with similar symptoms however attributable to other possible pathologies such as Crohn's Disease and Ulcerative Colitis. ElaFast specifically detects human pancreatic elastase 1 (E1), not identifying the enzyme of other species, thus allowing the **precise monitoring of the disease** even during the pharmacological treatment of the patient with PEI.

CalFast NeXT and ElaFast: rapid determination of gastrointestinal patients

The dedicated **Eu-Fast Reader** uses a lot-specific standard curve to calculate the concentration of the fecal calprotectin analyzed with **CalFast NeXT**. CalFast NeXT has a measuring range now extended to **2,100 µg/g**, allowing both the **identification** of IBD patients, as well as the **monitoring** of their clinical course.

ElaFast is the quick solution for the **quantitative** determination of pancreatic elastase from fecal specimens. Thanks to the Eu-Fast Reader, clinicians can rapidly identify patients affected by Pancreatic Exocrine Insufficiency, for a non-invasive evaluation of the pancreatic exocrine function.

Interpretation of results

Calprotectin and pancreatic elastase cut-off values from fecal specimens for the identification of IBD and PEI patients:



TDM: Therapeutic Drug Monitoring

Biological therapies making use of **monoclonal antibodies** have recently revolutionized the management of chronic inflammatory diseases such as IBD. The role of proinflammatory cytokines, like Tumour Necrosis Factor alpha (TNF α), in the development of the chronic inflammatory state, is well established. The introduction of specific **TNF α inhibitors**, such as monoclonal antibody drugs Infliximab (IFX) and Adalimumab (ADM), plays a pivotal role in the **clinical management of IBD patients**, enabling long standing remissions and positive changes of the IBD course in a significant percentage of patients.

For the optimization of biological drugs' activity, it's crucial to regularly check drug's blood concentration. The key point of this kind of assessment is the **trough level concentration** (TL), defined as the drug's blood concentration just before the subsequent drug infusion. Drug's blood concentration may vary among different patients due to intra- and inter-individual variability in pharmacokinetics and pharmacodynamics, thus the need for a reliable system able to rapidly assess the use of the most efficient drug and monitor the drug's blood level.

Eurospital made TDM fast and easy thanks to IFX-Fast and ADM-Fast, two new immunochromatographic tests adapted for the Eu-Fast Reader. Eu-Fast Reader, in association with CalFast NeXT and TDM-Fast kits, represent Eurospital's complete solution for the **identification** of IBD patient and the **monitoring** of the patient's clinical treatment.

Monitoring the clinical treatment of IBD patients

IFX-Fast

REF. 9191TI



INFLIXIMAB

IFX-Fast kit is a lateral flow immunochromatographic assay for the quantitative detection of **Infliximab** (IFX, Remicade®) in human serum and plasma. Infliximab is a chimeric therapeutic **monoclonal antibody** targeting the proinflammatory cytokine **TNF α** . Infliximab has revolutionized the treatment of chronic inflammatory diseases like Inflammatory Bowel Disease (IBD) by inducing deep remission and improving patient's quality of life. Infliximab is administered as an intravenous infusion with weight-based dosing (5mg/kg) and a regimen that includes an induction phase followed by maintenance treatment in responder patients. A target **therapeutic trough concentration** window of **3-7 μ g/ml** is recommended.

IFX-Fast kit is intended for professional use only as an aid for therapeutic drug monitoring in order to easily verify drug's bloodstream concentrations and quickly assess any changes in the dosage regimen. IFX-Fast test **quantitative results** can be displayed with Eu-Fast Reader in less than **20 minutes**.

ADM-Fast

REF. 9191TA



ADALIMUMAB

ADM-Fast is a lateral flow immunochromatographic assay for the quantitative detection of **Adalimumab** (ADM, Humira®) in human serum and plasma. Adalimumab is a fully human **monoclonal antibody** targeting the proinflammatory cytokine **TNF α** . The drug is used to treat chronic inflammatory diseases such as Inflammatory Bowel Disease (IBD) since triggers long-term remission and improves patient's quality of life. Adalimumab is administered by subcutaneous injections and a regimen that includes an induction phase followed by maintenance treatment in responder patients. For Adalimumab, a target **therapeutic trough concentration** window of **5-10 μ g/ml** has been recommended.

ADM-Fast kit is intended for professional use only as an aid for therapeutic drug monitoring in order to easily verify drug's bloodstream concentrations and quickly assess any changes in the dosage regimen. ADM-Fast test **quantitative results** can be displayed with Eu-Fast Reader in less than **20 minutes**.

EasyCal[®]

THE COLLECTION DEVICE FOR PRE-ANALYTICAL PROCESSING OF FECAL SPECIMEN

EasyCal is a **ready-to-use** disposable *in vitro* diagnostic device for the pre-analytical processing of fecal specimens. EasyCal devices, CE-IVD marked, consist of a test tube pre-filled with the extraction solution, a white flexible rod and a coloured funnel.

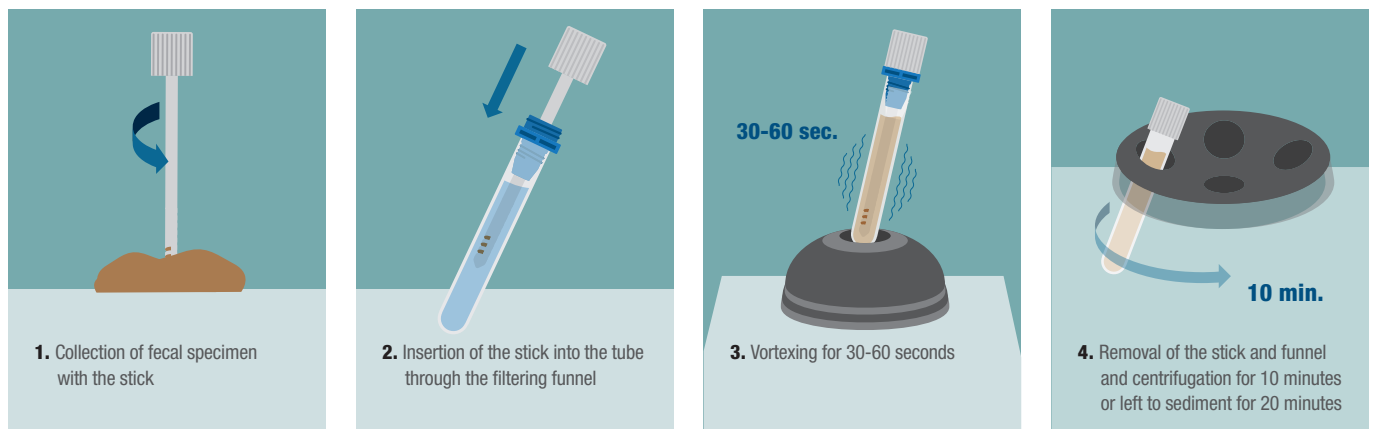
The diagonal grooves on the lower part of the stick have been designed to collect a precise amount of feces, of **any consistency**, from the most liquid to the most solid. The funnel allows **reproducible processing** by retaining the excess stool specimen present on the stick, therefore allowing to 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. Fecal extracts shall then be diluted and analyzed with the specific lateral flow test cassette for the quantitative determination of the relative diagnostic marker.

EasyCal 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

Easy and fast extraction protocol



Rapid test set up and analysis for a reliable quantitative determination

Concentration of analyzed markers (calprotectin and pancreatic elastase) is determined with the dedicated **Eu-Fast Reader** after a 20 minutes incubation time of the previously diluted fecal extract, pipetted into the test cassette.





More information and scientific references 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