

**Turbilatex**

A quantitative immundiagnostic method

FOB | Calprotectin | Transferrin | Pancreatic elastase | H. pylori | CRP | HS-CRP








**certest**  
IMMUNODIAGNOSTIC



## Turbidimetric method

The turbidimetric assay is based on the agglutination reaction between antibody-coated latex particles and the antigen in solution. The **Turbilatex®** reagents permit a high-sensitivity detection method to be obtained.

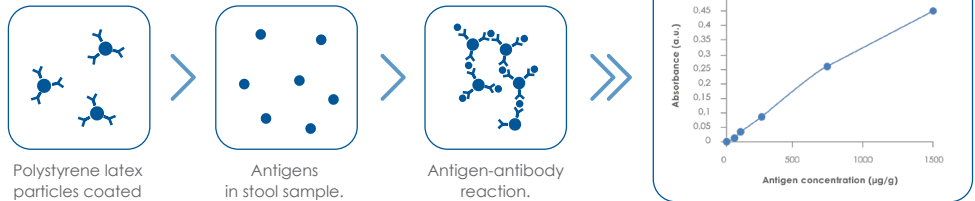
### Faecal products:

-  **FOB**
-  **Calprotectin**
-  **Transferrin**
-  **Pancreatic elastase**
-  **H. pylori**

### Serum products:

-  **C-Reactive Protein**
-  **High Sensitivity C-Reactive Protein**

### • Turbidimetric technique:



Example of calibration curve for Calprotectin assay.

“ The intended use for Turbilatex® products is to detect and quantify the antigen present in human stool samples and serum samples.

### • Equipment needed: Biochemistry analyzer

Space and the maintenance of the instruments are always a problem.

Trying to minimize it, Certest develops **Turbilatex®** products suitable with any analyzer to reach any lab all over the world.

### Advantages:

- **Fully automated**, computer controlled system.
- **Open-system reagents**: Suitable for use in any analyzer.
- **Not necessary to interpret results.**



### Advantages:

- It provides a reliable and **quantitative measure** of the concentration of these biomarkers in stool.
- All reagents are liquid and **ready-to-use** (minimal handling).
- Non-invasive, quick and easy to use test (**10 minutes**).
- The half-life of the product: calibrators, controls and reagents is **12-15 months**.
- **Calibration is stable for 30 days**.
- **The stability of the reagents on board is 3 months**.
- Wide measuring range, possibility of diluting the sample.

# Calprotectin Turbilatex®

**Inflammatory bowel disease (IBD) has different clinical forms which may affect the whole digestive tract, but more often the colon and rectum.** Its importance lies in the levels of chronicity, the frequency of relapses, hospital admissions and a not insignificant risk of bowel cancer.

In addition, the incidence of the disease is clearly rising all over the world. Therefore, the use of a rapid, simple and non-invasive diagnostic tool is of great interest for the physician.

Calprotectin is a protein present in the neutrophils, which appears in high concentrations in any tissue which is experiencing an inflammatory process. In the case of patients with inflammatory bowel disease, this protein can be detected in patient feces. The protein has a high resistance to degradation, making it stable in the fecal content.

Numerous studies support the use of this marker as a diagnostic and monitoring tool for inflammatory bowel disease and severe illnesses, such as Ulcerative Colitis (UC), Crohn's disease and indeterminate colitis. It has also been considered as an initial screening method for patients with chronic diarrhea.

**Certest Calprotectin Turbilatex®** is a non-invasive immunological assay which quantifies the calprotectin present in human feces. This simple test is able to provide quick, reliable information about the condition of the patient's inflammatory process.

References	Description
TL-022CP100ED	<b>Calprotectin Turbilatex Combo kit</b> 100 det.
TL-022CP200ED	<b>Calprotectin Turbilatex Combo kit</b> 200 det.
TL-022CP400ED	<b>Calprotectin Turbilatex Combo kit</b> 400 det.
TL-022CP800ED	<b>Calprotectin Turbilatex Combo kit</b> 800 det.
MST-0019U	<b>Universal Turbilatex</b> Sample Collection Tube



## Product specifications

Calprotectin Turbilatex®	
<b>Sensitivity (%)</b>	94 <sup>(1)</sup>
<b>Specificity (%)</b>	> 99 <sup>(1)</sup>
<b>Cut-off value (in dilution)</b>	500 ng/mL
<b>Cut-off value (in faeces)</b>	50 µg/g
<b>Main interferences</b>	None

*(Cut-off value can be modified according to laboratory needs.)*

<sup>(1)</sup> Results obtained against a similar reference product in the market



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Quantification of fecal calprotectin is one of the most widely used parameters in the analysis of inflammatory processes which affect the distal gastrointestinal tract.

## FOB Turbilatex®

**Bowel cancer is the second leading cause of death in the western world after cardiovascular disease.** Among the different types of tumors, bowel cancer is the most frequently occurring in the adult population, considering both genders.

Colonic lesions considered preneoplastic (polyps) and invasive new vessel growth may bleed, even in the early stages of their development. Consequently, fecal occult blood tests (FOBT) are able to offer clinical evidence for the early diagnosis of bowel cancer in its different stages or states.

The FOB Turbilatex® reagents detect and quantify human hemoglobin, a protein present in blood which may be found in low concentration in patients' feces. This protein is sensitive to degradation in the gastrointestinal system, and therefore its use is limited to the detection of bleeding from the colon.

**Certest FOB Turbilatex®** is a non-invasive immunological test which can be used in a simple and effective manner in bowel cancer screening.

### Product specifications

FOB Turbilatex®	
<b>Sensitivity (%)</b>	96 <sup>(1)</sup>
<b>Specificity (%)</b>	> 99 <sup>(1)</sup>
<b>Cut-off value</b> (in dilution)	50 ng/mL
<b>Cut-off value</b> (in faeces)	5 µg/g
<b>Main interferences</b>	None

*(Cut-off value can be modified according to laboratory needs.)*

<sup>(1)</sup> Results obtained against a similar reference product in the market

References	Description
TL-022FB100ED	<b>FOB Turbilatex</b> Combo kit 100 det.
TL-022FB200ED	<b>FOB Turbilatex</b> Combo kit 200 det.
TL-022FB400ED	<b>FOB Turbilatex</b> Combo kit 400 det.
TL-022FB800ED	<b>FOB Turbilatex</b> Combo kit 800 det.
MST-0019U	<b>Universal Turbilatex</b> Sample Collection Tube



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Bowel cancer screening is a useful preventive measure for the diagnosis of preneoplastic lesions (polyps) and for the detection of invasive neoplasms in early stages.



# Pancreatic elastase Turbilatex®

**Pancreatic elastase** is produced in the acinar cells of the pancreas. A reduced level of this protein in the gastrointestinal tract is related to pancreatic insufficiency. It typically occurs as a result of progressive pancreatic damage, because of several pathological conditions.

Human pancreatic elastase 1 (E1) remains undegraded during intestinal tract, which makes pancreatic elastase a perfect biomarker.

**Pancreatic elastase Turbilatex®** is a non-invasive in vitro diagnostic method used to monitorize pancreatic function, revealing pancreatic insufficiency in the patient.

**Pancreatic elastase Turbilatex®** is based on specific and stable monoclonal antibodies that provide the required specificity and sensibility. Moreover, as all **Turbilatex®** products are customer friendly and liquid and ready to be used.

## Product specifications

Pancreatic elastase Turbilatex®	
<b>Sensitivity (%)</b>	95 <sup>(1)</sup>
<b>Specificity (%)</b>	> 99 <sup>(1)</sup>
<b>Cut-off value</b> (in dilution)	2 µg/mL
<b>Cut-off value</b> (in faeces)	200 µg/g
<b>Main interferences</b>	None

*(Cut-off value can be modified according to laboratory needs.)*

<sup>(1)</sup> Results obtained against a similar reference product in the market

References	Description
TL-022EL100ED	<b>Pancreatic elastase</b> Combo kit 100 det.
TL-022EL200ED	<b>Pancreatic elastase</b> Combo kit 200 det.
TL-022EL400ED	<b>Pancreatic elastase</b> Combo kit 400 det.
TL-022EL800ED	<b>Pancreatic elastase</b> Combo kit 800 det.
MST-0019U	<b>Universal Turbilatex</b> Sample Collection Tube



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Pancreatic Elastase concentration in faeces monitorizes exocrine pancreatic function, revealing insufficiency caused by pathological conditions of pancreas.

## Transferrin Turbilatex®

Transferrin, like hemoglobin, is an iron-binding protein of the free iron in blood. Its presence in feces can be linked with bleeding of the upper or lower intestinal tract, **as it remains stable after its passage through the gastrointestinal tract. This makes it the perfect complementary analyte in the detection of occult digestive bleeding.**

This is the reason why Certest has designed the **Transferrin Turbilatex®** turbidimetric assay, which detects and quantifies human transferrin in the same sample collection vial as **FOB Turbilatex®**.

**Certest Transferrin Turbilatex®** is a non-invasive immunological test which can be used as a complement in the detection of FOBT. Together with **FOB Turbilatex®**, it is a sensitive specific tool for the detection of neoplasms in the colon.

### Product specifications

Transferrin Turbilatex®	
<b>Sensitivity (%)</b>	95 <sup>(1)</sup>
<b>Specificity (%)</b>	> 99 <sup>(1)</sup>
<b>Cut-off value (in dilution)</b>	10 ng/mL
<b>Cut-off value (in faeces)</b>	1 µg/g
<b>Main interferences</b>	None

*(Cut-off value can be modified according to laboratory needs.)*

<sup>(1)</sup> Results obtained against a similar reference product in the market

References	Description
TL-022TF100ED	<b>Transferrin Turbilatex Combo kit 100 det.</b>
TL-022TF200ED	<b>Transferrin Turbilatex Combo kit 200 det.</b>
MST-0019U	<b>Universal Turbilatex Sample Collection Tube</b>



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The detection and quantification of fecal transferrin is a complementary tool in the early diagnosis of bowel cancer.



## Universal diluent

We want to make your lab work easier.

Thinking in reducing our customer's bench work, **Turbilatex®** has developed an universal sample buffer to perform all its **Tumoral Turbilatex®** panel.



**FOB, Calprotectin, Transferrin and Pancreatic elastase Turbilatex®** Kits use the same diluent to perform the turbidimetric assay. It simplifies the work in the laboratory and makes it easier to use and test the assay.

Reference	Description
MST-0019U	<b>Universal Sample Collection Tube (100)</b>

One sampling >> 4 assays

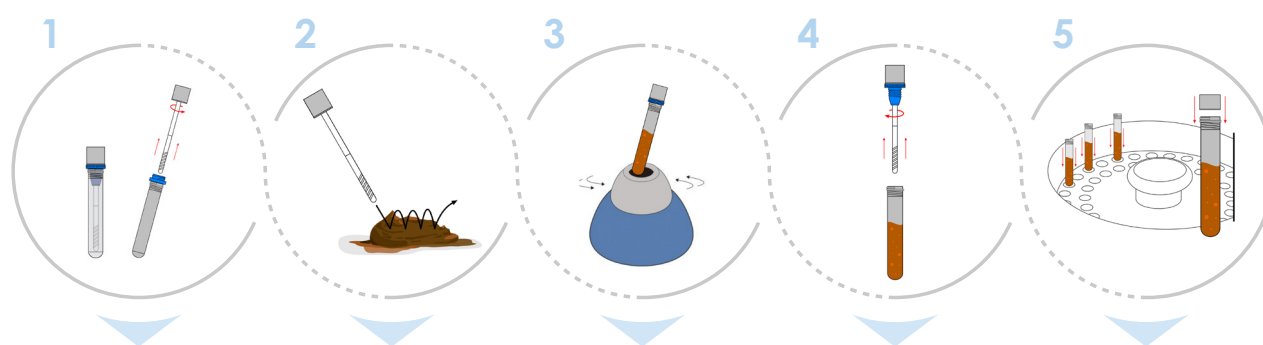
## Specimen collection:

Additionally, a sample collection device (MST-0019U & MST-0020P) is provided, common to all **Turbilatex®** assays, which guarantees minimal manipulation of the sample and can be inserted directly into the equipment.



- **Quick** and **easy** sample collection, improving laboratory workflow.
- It takes only **5 minutes**.
- It does not require incubation times or processing prior to analysis.

### • Specimen collection and preparation.



1. Take the sample dilution vial. Remove the stick by turning the thread of the white cap in the opposite direction.
2. Introduce the stick in up to 4 different points of the sample.
3. Shake the sample dilution vial, which contains diluent and sample, in order to obtain a good dispersion. Use a vortex for 1 minute. Once the sample is dissolved, centrifuge the tube between 2,000-3,000 rpm for 1 minute to deposit the particulate matter at the bottom.
4. Remove the white cap and the blue spacer, turning in the opposite direction.
5. Introduce the sample vials into the analysis equipment. Fit the additional cap.

Once the sampling process has been carried out, samples can be stored **cold (2-8°C)** up to **7 days** before being analyzed.

## H. pylori Turbilatex®

*Helicobacter pylori* (*H. pylori*) is a bacteria in helical bacillus shape, found in the human gastric epithelium in more than 50% of the global population.

There is significant correlation between the presence of this bacteria in the stomach and certain gastrointestinal diseases, including gastritis, gastroduodenal peptic ulcers, gastric carcinoma and mucosa-associated lymphoid tissue (MALT) lymphoma. In particular, the presence of *H. pylori* in the stomach is indicated as a fundamental etiological factor of gastric cancer.

**Certest has developed the first turbidimetric test for the detection and quantification of an antigen present in feces when *H. pylori* colonizes the stomach.**

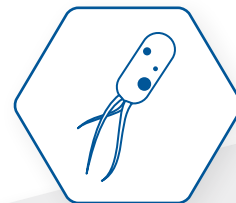
With Certest **H. pylori Turbilatex®** it is possible to perform a rapid, simple screening which determines the presence or absence of the bacteria in the patient's stomach.

### Product specifications

H. pylori Turbilatex®	
<b>Sensitivity (%)</b>	88 <sup>(1)</sup>
<b>Specificity (%)</b>	> 98 <sup>(1)</sup>
<b>Límite de Sensitivity</b>	0.5 ng/mL
<b>Main interferences</b>	None

<sup>(1)</sup> Results obtained against a similar reference product in the market

References	Description
TL-022HP100ED	<b>H. pylori</b> Turbilatex Combo kit 100 det.
TL-022HP200ED	<b>H. pylori</b> Turbilatex Combo kit 200 det.
MST-0020P	<b>H. pylori</b> Turbilatex Sample Collection Tube



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The bacteria *Helicobacter pylori* is involved in more than 90% of duodenal ulcers, and up to 80% of gastric cancers.



# C-Reactive Protein Turbilatex® Combo

C-reactive protein, synthesised in the liver, is a circulating plasma protein that increases in levels in response to an inflammatory process and is therefore known as an acute phase protein.

It has been established that inflammation is a fundamental process in the pathogenesis of atherosclerosis in all its stages, initiation, growth and complication of atherosclerotic plaque, considered as an inflammatory response to damage.

C-reactive protein (CRP) is involved in innate immunity as the first defence system against infection.

It is an early indicator of infection or inflammation because its levels begin to rise in the blood shortly after the onset of infection or inflammation, before the onset of other symptoms such as fever or pain, and can increase up to 50,000-fold in acute inflammatory states.

**Certest C-Reactive Protein Turbilatex®** is a marker with which we can monitor acute infections, because the first response of our body to an infection will be inflammation.

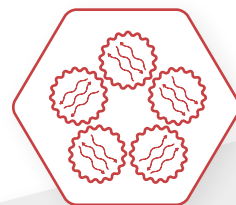
## Product specifications

C-Reactive Protein Turbilatex®	
<b>Sensitivity (%)</b>	93 <sup>(1)</sup>
<b>Specificity (%)</b>	98 <sup>(1)</sup>
<b>Límite de Sensitivity</b>	10 µg/mL
<b>Range of detection</b>	3 ug/ml to 150 ug/ml
<b>Main interferences</b>	None

*(Cut-off value can be modified according to laboratory needs.)*

<sup>(1)</sup> Results obtained against a similar reference product in the market

References	Description
TL-022CR200ED	<b>C-Reactive Protein Turbilatex Combo kit</b> 200 det.
TL-022CR800ED	<b>C-Reactive Protein Turbilatex Combo kit</b> 800 det.



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*C-reactive protein  
is an indicator  
of an inflammation  
or acute infection.*

# High Sensitivity C-Reactive Protein Turbilatex® Combo

Cardiovascular accidents are the leading cause of death in developed countries.

The concentration of high-sensitivity C-reactive protein (Hs-CRP) increases the risk of myocardial infarction and cerebrovascular disease.

Useful in the early diagnosis of cardiovascular accidents, one of the main causes of death in developed countries.

**Certest High Sensitivity C-Reactive Protein Turbilatex®** will detect an increased risk of myocardial infarction and cerebrovascular disease due to the inflammation that our organism generates in front of an atherogenic pathology.

## Product specifications

High Sensitivity C-Reactive Protein Turbilatex®	
<b>Sensitivity (%)</b>	100 <sup>(1)</sup>
<b>Specificity (%)</b>	91 <sup>(1)</sup>
<b>Sensitivity Limit</b>	5 µg/mL
<b>Range of detection</b>	1 µg/ml to 20 µg/ml
<b>Main interferences</b>	None

*(Cut-off value can be modified according to laboratory needs.)*

<sup>(1)</sup> Results obtained against a similar reference product in the market

References	Description
TL-022HS200ED	<b>High Sensitivity CRP Turbilatex Combo</b> kit 200 det.
TL-022HS800ED	<b>High Sensitivity CRP Turbilatex Combo</b> kit 800 det.



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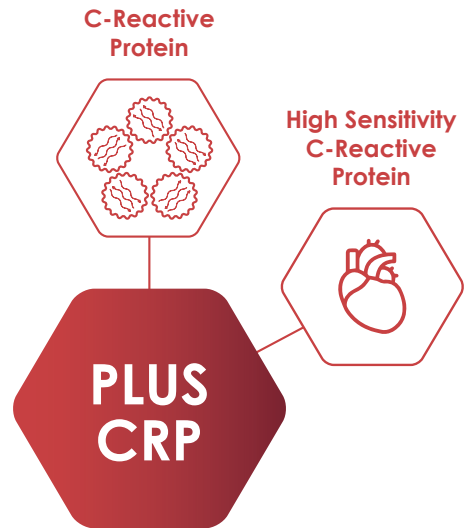
Early detection of C-reactive protein helps to detect the risk of myocardial infarction at a very early stage.

# PLUS C-Reactive Protein Turbilatex® Combo

This test offers the possibility to calibrate in both CRP detection ranges with the same reagents using the specific calibrators for each.

**PLUS C-Reactive Protein Turbilatex® detects Hs-CRP and CRP in one kit, containing the components to perform both parameters.**

References	Description
TL-022CRP200ED	<b>Plus CRP</b> Turbilatex Combo kit 200 det.
TL-022CRP800ED	<b>Plus CRP</b> Turbilatex Combo kit 800 det.



The image shows a row of six vials on a white surface. From left to right: a white vial labeled "CRP TURBILATEX CALIBRATOR", a yellow vial labeled "CRP TURBILATEX CALIBRATOR", a blue vial labeled "CRP TURBILATEX CONTROL", a yellow vial labeled "CRP TURBILATEX CONTROL", an orange vial labeled "CRP TURBILATEX CALIBRATOR", and a pink vial labeled "CRP TURBILATEX CALIBRATOR". To the right, a larger white vial is partially visible, labeled "CRP TURBILATEX REAGENT".

- Performs calibrations of the two ranges of **C-reactive Protein, High Sensitivity and normal.**
- Provides results to differentiate the diagnosis between **risk of AMI or infections and inflammatory reactions.**
- Same reagents** differ according to the calibration in which you measure.
- High Sensitivity** to differentiate specifically between the **two ranges.**



## Turbilatex products offer:

- **High quality and reliability.**  
Concentration of the specific antigen will be determined with high accuracy.
- **Usefulness.**  
The high level of automation of the Turbilatex assay allows for optimal throughput.
- **Clearness.**  
The simplicity of the reaction implies low technical manipulation and easy interpretation by clinical technicians.
- **Easy sampling.**  
It is a complete system from sampling to results, starting and finishing with the patient.
- **Automatism.**  
User interpretation is not needed.
- **Adaptable.**  
Turbilatex reagents work with any equipment.

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