

# Turbilatex<sup>®</sup> Immunodiagnostic





**High precision and reliability** in antigen measurement



**Fully automated workflow** with no need for manual interpretation



**Compatible with any instrument** (maximum adaptability)



Objective **quantitative results** easy to interpret

## Turbidimetry







The turbidimetric assay is based on **the agglutination reaction between antibody-coated latex particles and antigen in solution** measured in any kind of clinical chemistry analyser used in the lab.

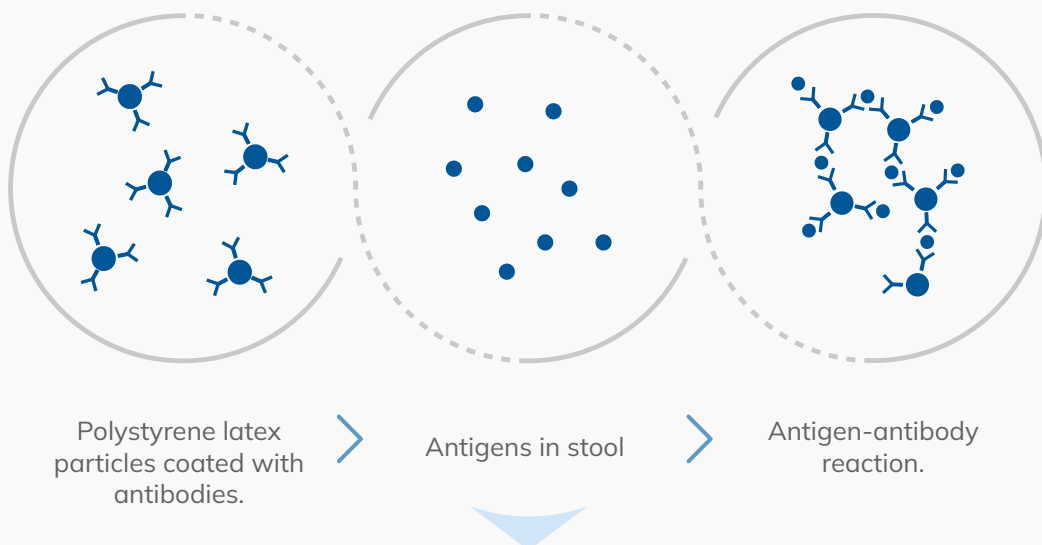
It's a **quantitative** immundiagnostic method. The Turbilatex® reagents allows a **high-sensitivity** detection method to be obtained, detecting and quantifying antigens present in the faecal eces.

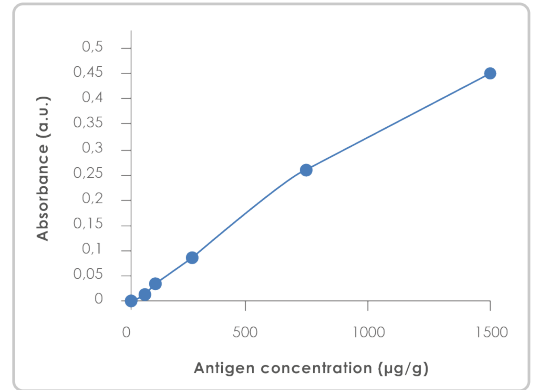
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The intended use for Turbilatex® products is to detect and quantify the antigen present in human stool samples.

	<b>FOB</b>	<b>6</b>
	<b>Calprotectin</b>	<b>7</b>
	<b>Pancreatic elastase</b>	<b>8</b>
	<b>Transferrin</b>	<b>9</b>

## Turbidimetric technique





Example of calibration curve for Calprotectin assay.

## Equipment needed: Biochemistry analyzer

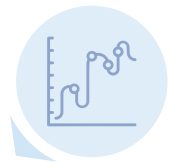
Space and instrument maintenance are key aspects in laboratories. To meet these needs, Certest, develops **Turbilatex®** products designed for integration into different analytical platforms used in laboratories worldwide.



**Not necessary to interpret results**



**Open-system reagents**  
Suitable for various analyzers.



**Quantitative 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.
- **The shelf life** of the reagents, calibrators and controls is **15 months** from the date of manufacture when **stored at 2–8 °C**.
- Wide measuring range, possibility of diluting the sample.

## Available application sheets

Manufacturer	Model
Abbott	Alinity c-series
	Architect c4000/c8000/c16000
Awareness	Chemwell-T
Beckman Coulter	AU480/AU680
	DxC 700AU
Binding Site	Optilite
Biobase	BK Mini/BK 600
Biosystems	A15
	A25
	BA 400
Diasys Diagnostic Systems GmbH	Respons 910
Diconex	InCCA/InCCA bit
Elitech	Selectra PRO S; Selectra PRO M
Erba	XL-180 & XL-200
Furuno	CA800
Diconex	InCCA/InCCA bit
Elitech	Selectra PRO S; Selectra PRO M
Erba	XL-180/XL-200
Furuno	CA800
Mindray	BS-200/200E
	BS-230
	BS-240
	BS-380
	BS-480
	BS-600

Manufacturer	Model
Ortho Clinical Diagnostics	Vitros 5600
Roche	Cobas c111
	Cobas c303
	Cobas c311
	Cobas c501
	Cobas c501/c502/c503
	Cobas c702/Integra 400 Plus
Siemens	ADVIA 1800
	ADVIA 2400
	ATELLICA
Snibe	Bioassays 240PLUS
Tecom	TC220
Thermo Fisher Scientific	Indiko
Tokyo Boeki	Biolis 24i/50i
	Biolis 30i
Horiba	Pentra C400
Wiener	CB350i

Refer the application sheets available for your analyzer.



## FOB Turbilatex® Combo

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, faecal occult blood tests (FOB) are able to offer clinical evidence for the early diagnosis of bowel cancer in its different stages or states.

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

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

References	Description
TL-022FB100ED	FOB Turbilatex® Combo (kit 100 det.) <sup>(3)</sup>
TL-022FB200ED	FOB Turbilatex® Combo (kit 200 det.) <sup>(3)</sup>
TL-022FB400ED	FOB Turbilatex® Combo (kit 400 det.) <sup>(3)</sup>
TL-022FB800ED	FOB Turbilatex® Combo (kit 800 det.) <sup>(3)</sup>
MST-0019UR	Universal Turbilatex® Sample Vial

<sup>(3)</sup> The number of determinations may vary depending on the analyzer used. Optimized value for Biolis 24i.



### Product specifications

FOB Turbilatex® Combo	
Sensitivity (%)	87,5% <sup>(1)</sup>
Specificity (%)	97,9% <sup>(1)</sup>
Cut-off value (in dilution)	100 ng/mL
Cut-off value (in faeces)	10 µg/g
Main interferences	None <sup>(2)</sup>

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

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

<sup>(2)</sup> Found in the analyses performed.



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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.

# Calprotectin Turbilatex® Combo

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 faeces. The protein has a high resistance to degradation, making it stable in the faecal 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.

**Calprotectin Turbilatex® Combo** is a non-invasive immunological assay which quantifies the calprotectin present in human faeces. 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</b> (kit 100 det.) <sup>(3)</sup>
TL-022CP200ED	<b>Calprotectin Turbilatex® Combo</b> (kit 200 det.) <sup>(3)</sup>
TL-022CP400ED	<b>Calprotectin Turbilatex® Combo</b> (kit 400 det.) <sup>(3)</sup>
TL-022CP800ED	<b>Calprotectin Turbilatex® Combo</b> (kit 800 det.) <sup>(3)</sup>
MST-0019UR	<b>Universal Turbilatex® Sample Vial</b>

<sup>(3)</sup> The number of determinations may vary depending on the analyzer used. Optimized value for Biolis 24i.



## Product specifications

Calprotectin Turbilatex® Combo	
<b>Sensitivity (%)</b>	96,8 <sup>(1)</sup>
<b>Specificity (%)</b>	91,4 <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 <sup>(2)</sup>

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

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

<sup>(2)</sup> Found in the analyses performed.



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

# Pancreatic Elastase Turbilatex® Combo

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

**Pancreatic Elastase Turbilatex® Combo** 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.

References	Description
TL-022EL100ED	<b>Pancreatic Elastase Turbilatex® Combo</b> (kit 100 det.) <sup>(3)</sup>
TL-022EL200ED	<b>Pancreatic Elastase Turbilatex® Combo</b> (kit 200 det.) <sup>(3)</sup>
TL-022EL400ED	<b>Pancreatic Elastase Turbilatex® Combo</b> (kit 400 det.) <sup>(3)</sup>
TL-022EL800ED	<b>Pancreatic Elastase Turbilatex® Combo</b> (kit 800 det.) <sup>(3)</sup>
MST-0019UR	<b>Universal Turbilatex® Sample Vial</b>

<sup>(3)</sup> The number of determinations may vary depending on the analyzer used. Optimized value for Biolis 24i.



## Product specifications

Pancreatic Elastase Turbilatex® Combo	
<b>Sensitivity (%)</b>	89,1% <sup>(1)</sup>
<b>Specificity (%)</b>	98,4% <sup>(1)</sup>
<b>Cut-off value (in dilution)</b>	2 µg/mL
<b>Cut-off value (in faeces)</b>	200 µg/g
<b>Main interferences</b>	None <sup>(2)</sup>

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

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

<sup>(2)</sup> Found in the analyses performed.



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

# Transferrin Turbilatex® Combo

Transferrin, like haemoglobin, is an iron-binding protein of the free iron in blood. Its presence in faeces 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®.

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

## Product specifications

Transferrin Turbilatex® Combo	
Sensitivity (%)	94,7 <sup>(1)</sup>
Specificity (%)	> 99 <sup>(1)</sup>
Cut-off value (in dilution)	10 ng/mL
Cut-off value (in faeces)	1 µg/g
Main interferences	None <sup>(2)</sup>

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

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

<sup>(2)</sup> Found in the analyses performed.

References	Description
TL-022TF100ED	<b>Transferrin Turbilatex® Combo</b> (kit 100 det.) <sup>(3)</sup>
TL-022TF200ED	<b>Transferrin Turbilatex® Combo</b> (kit 200 det.) <sup>(3)</sup>
MST-0019UR	<b>Universal Turbilatex® Sample Vial</b>

<sup>(3)</sup> The number of determinations may vary depending on the analyzer used. Optimized value for Biolis 24i.



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*The detection and quantification of faecal transferrinis.*

## 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, Pancreatic elastase and Transferrin 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-0019UR	Universal Sample Vial (100)

**1**  
sampling



**4**  
assays

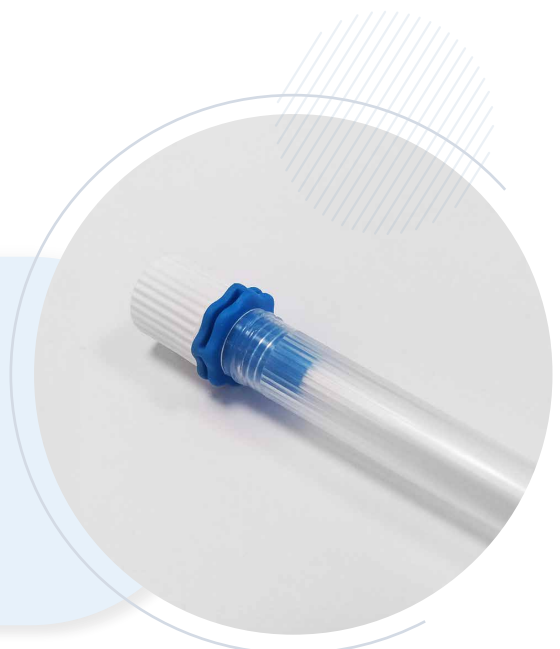


## Specimen collection

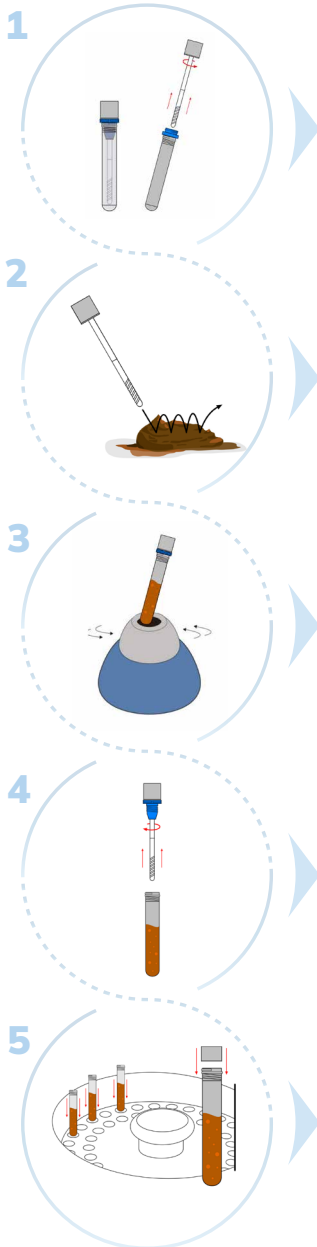
Additionally, a sample collection device (MST-0019U) is provided, common to all Turbilatex® assays, which guarantees minimal manipulation of the sample and can be inserted directly into the equipment.



- **Quick and easy** sample collection, improving laboratory workflow.
- It only takes **10 minutes of analysis**.
- **No additional processing is required** after sample extraction.



## 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**, and introduce in to the vial through the blue reducer.
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 **1,000 & 3,000 x g** for 10 minutes or allow it to stand upright for at least 15 minutes in order to deposit the particulate matter at the bottom.
4. **Remove the white cap and the blue reducer**, turning in the opposite direction.
5. Introduce the sample vials into the **analysis equipment**. When the measurement is finished, remove the vials and close them with the additional white cap.

Once the sampling process has been completed, diluted samples can be stored **refrigerated (2-8°C)** up to **14 days** prior to analysis



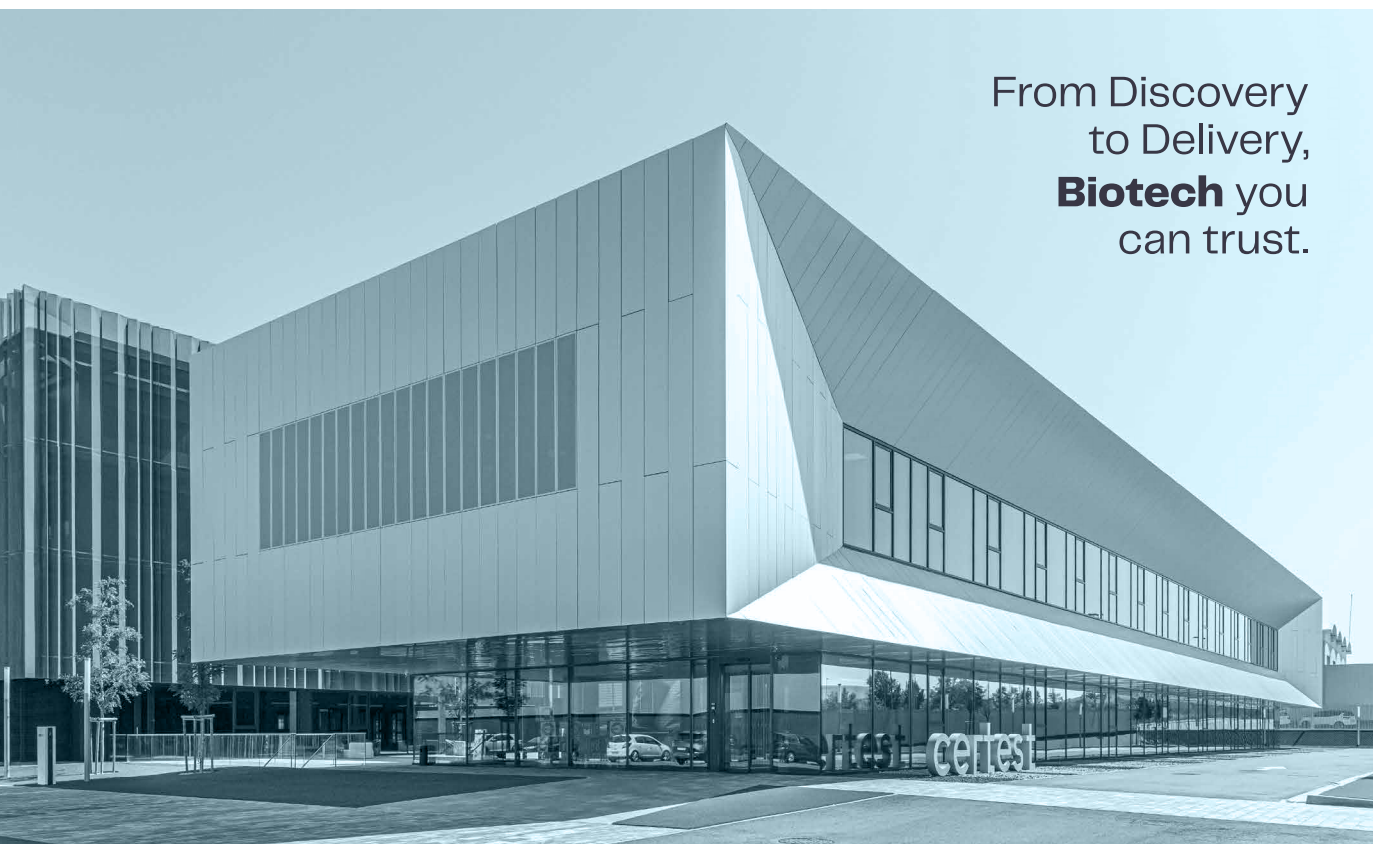
# Enhancing automated immuno- diagnostics

High precision  
and reliability

Simple and efficient  
process

Maximum  
adaptability

Quantitative  
solution



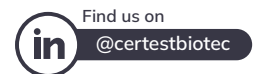
From Discovery  
to Delivery,  
**Biotech** you  
can trust.

**certest**

IMMUNODIAGNOSTIC

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