

Turbilatex®

A quantitative immundiagnostic method

FOB | Calprotectin | Transferrin | Pancreatic elastase



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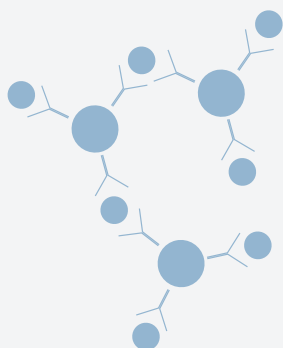
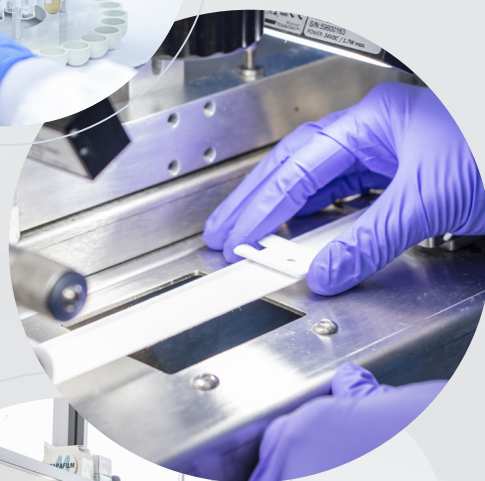
Certest Immunodiagnostic is committed to providing a comprehensive portfolio of diagnostic reagents for detecting infectious diseases and different markers, covering different needs of formats, types of use, throughput, precision, and time from sample to result.

IMMUNOCHROMATOGRAPHY

provides rapid test solutions for aiding the professional of diagnostic with an immediate solution, needing no equipment, and having results usually in less than 15 minutes.

TURBIDIMETRY provides diagnostics solutions for automated and quantitative results and higher throughputs.

CLIA provides a high sensitivity, automated diagnostic solution based on the chemiluminescent amplification of an immunocapture.



TURBIDIMETRY

The turbidimetric assay is based on the agglutination reaction between antibody-coated latex particles and the 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 body.

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.

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



Calprotectin

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FOB

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Pancreatic elastase

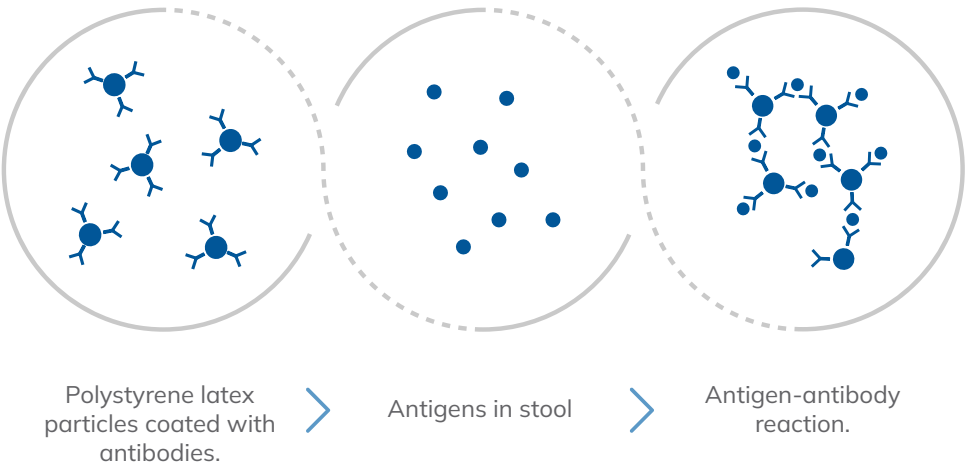
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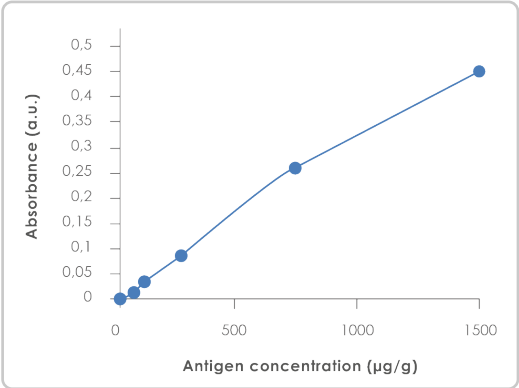


Transferrin

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Turbidimetric technique





Example of calibration curve for Calprotectin assay.

Equipment needed: Biochemistry analyzer

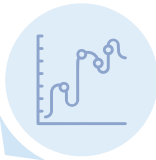
Space and the maintenance of the instruments are always a problem. Trying to minimize it, Certest develops **Turbilatex®** adaptable to various equipment.



Fully automated
Computer controlled system



Open-system reagents
Adaptable to various equipment



Not necessary to interpret results



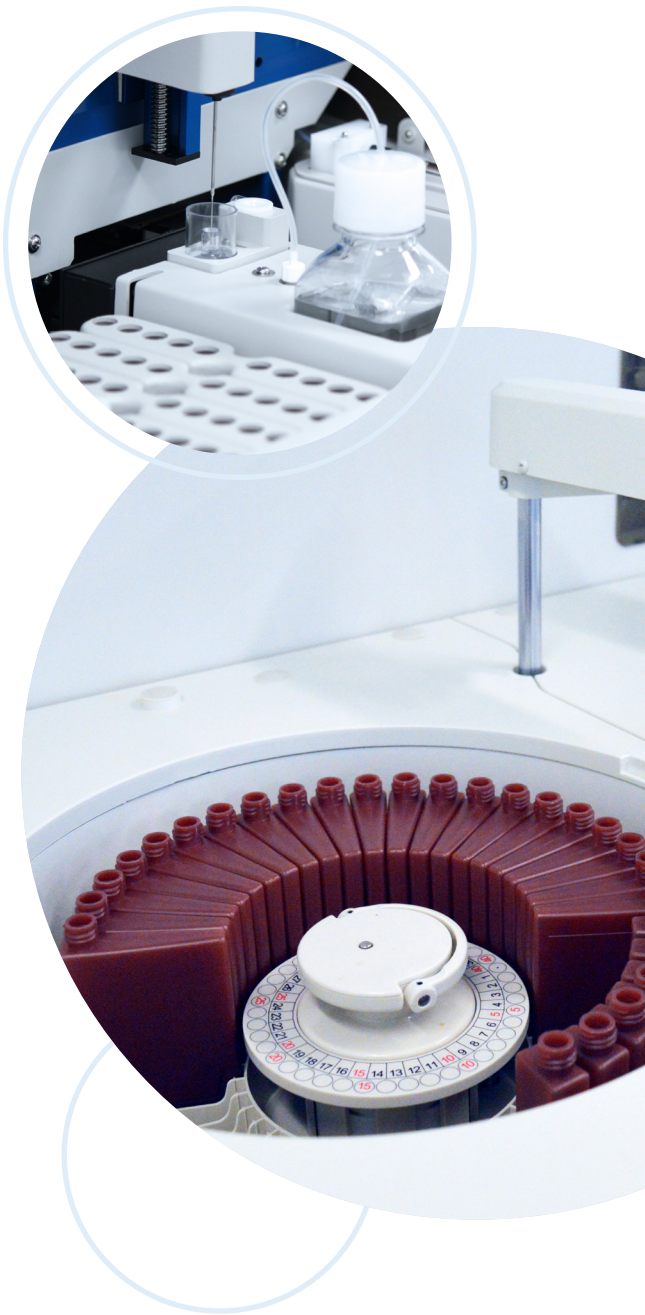
Advantages

- 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.
- The self-life of the product: calibrators, controls and reagents is **15 months at 2-8°C**.
- Wide measuring range, possibility of diluting the sample.

Application Notes

Manufacturer	Model
Abbott	Alinity c-series
	Architect c1000/c4000/ c8000/c16000
Awareness	Chemwell-T
Beckman Coulter	AU680
Binding Site (Thermo Fisher)	Optilite
Biosystems	A15
Diasys Diagnostic Systems GmbH	Respons 910
Diconex	InCCA/InCCA bit
Elitech	Selectra PRO S; Selectra PRO M
Erba	XL-180 & XL-200
Furuno	CA800
Mindray	BS-200/200E
Ortho Clinical Diagnostics	Vitros 5600
Roche	Cobas Integra 400 Plus
	Cobas c111
	Cobas c301
	Cobas c311
	Cobas c501
	Cobas c702
Siemens	ADVIA 1800
	ADVIA 2400
	ATELLICA
Snibe	Bioassays 240PLUS
Tecan	TC220
Thermo Fisher Scien- tific	Indiko
Tokyo Boeki	Biolis i24/i50

*New applications
under LABs requirement.*



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	Calprotectin Turbilatex Combo (kit 100 det.)
TL-022CP200ED	Calprotectin Turbilatex Combo (kit 200 det.)
TL-022CP400ED	Calprotectin Turbilatex Combo (kit 400 det.)
TL-022CP800ED	Calprotectin Turbilatex Combo (kit 800 det.)
MST-0019U	Universal Turbilatex Sample Collection Vial.



Product specifications

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

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

⁽¹⁾ Results obtained against a similar reference product in the market



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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.

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.)
TL-022FB200ED	FOB Turbilatex Combo (kit 200 det.)
TL-022FB400ED	FOB Turbilatex Combo (kit 400 det.)
TL-022FB800ED	FOB Turbilatex Combo (kit 800 det.)
MST-0019U	Universal Turbilatex Sample Collection Vial



Product specifications

FOB Turbilatex Combo	
Sensitivity (%)	96,1%
Specificity (%)	87,8% ⁽¹⁾
Cut-off value (in dilution)	50 ng/mL
Cut-off value (in faeces)	5 µg/g
Main interferences	None

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

⁽¹⁾ Results obtained against a similar reference product in the market



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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 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.

Product specifications

Pancreatic Elastase Turbilatex Combo	
Sensitivity (%)	100%
Specificity (%)	93%
Cut-off value (in dilution)	2 µg/mL
Cut-off value (in faeces)	200 µg/g
Main interferences	None

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

⁽¹⁾ Results obtained against a similar reference product in the market

References	Description
TL-022EL100ED	Pancreatic Elastase Turbilatex Combo (kit 100 det.)
TL-022EL200ED	Pancreatic Elastase Turbilatex Combo (kit 200 det.)
TL-022EL400ED	Pancreatic Elastase Turbilatex Combo (kit 400 det.)
TL-022EL800ED	Pancreatic Elastase Turbilatex Combo (kit 800 det.)
MST-0019U	Universal Turbilatex 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 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 (%)	95 ⁽¹⁾
Specificity (%)	> 99 ⁽¹⁾
Cut-off value (in dilution)	10 ng/mL
Cut-off value (in faeces)	1 µg/g
Main interferences	None

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

⁽¹⁾ Results obtained against a similar reference product in the market

References	Description
TL-022TF100ED	Transferrin Turbilatex Combo (kit 100 det.)
TL-022TF200ED	Transferrin Turbilatex Combo (kit 200 det.)
MST-0019U	Universal Turbilatex Sample Collection Vial



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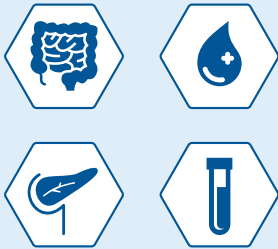
The detection and quantification of faecal transferrinis.



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, 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	Universal Sample Collection Vial (100)

One sampling >> 4 assays

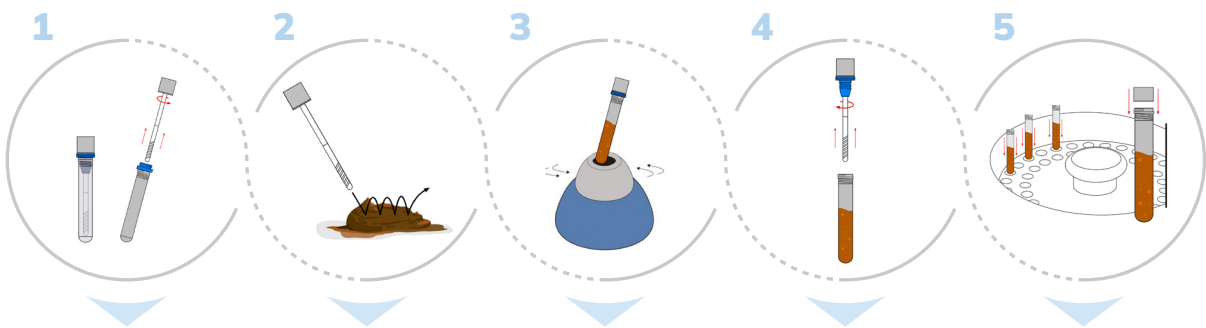
Specimen collection

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 takes only **10 minutes**.
- It does not require incubation times or processing prior to analysis.

Specimen collection and preparation

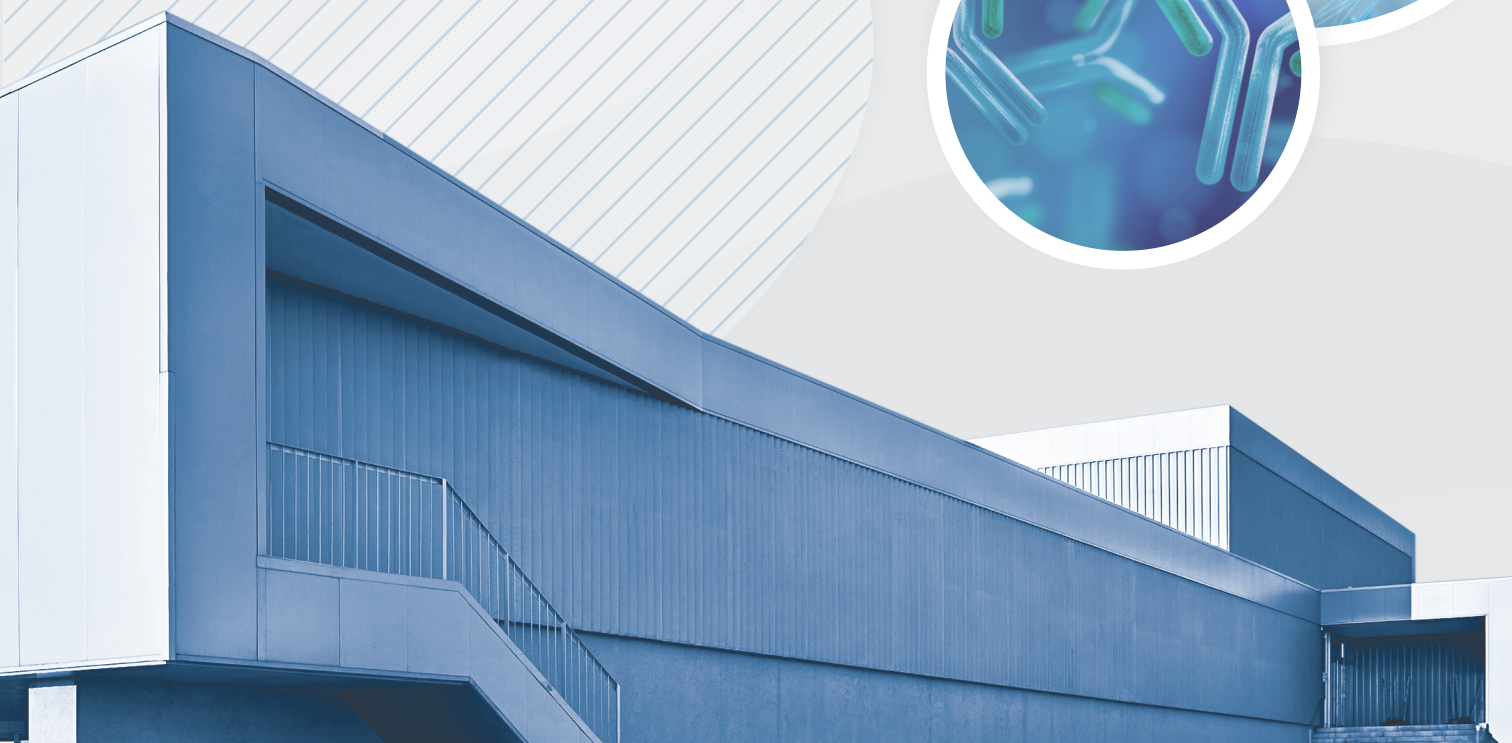
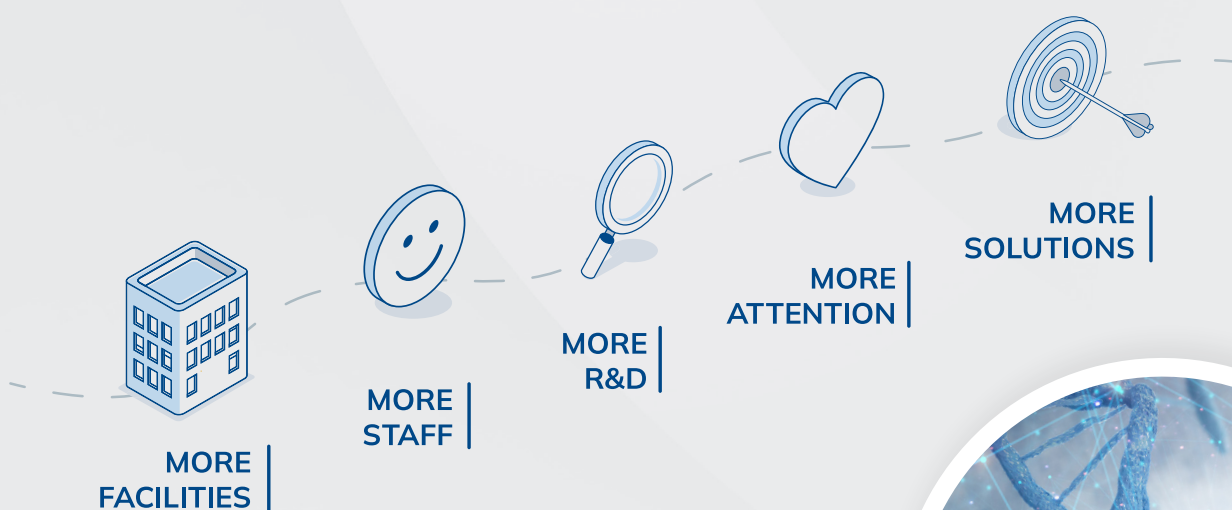


1. Take the sample dilution vial. Remove the stick by turning the thread of the white cap in the opposite direction.
 2. Introduce the stick in up to 4 different points of the sample, and introduce in to the vial through the blue reducer.
 3. Shake the sample dilution vial, which contains diluent and sample, in order to obtain a good dispersion. Use a vortex for 1 minute. Once the sample is dissolved, centrifuge the tube between 1000-3000 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 weasurement is finished, remove the vials and close them with the additional white cap.
- Once the sampling process has been carried out, samples can be stored **cold (2-8°C)** up to **7 days** before being analyzed.



RAW MATERIALS | DIAGNOSTICS | PHARMA

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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

Cleanness

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 are adaptable to any analyzer

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Certest Biotec, S.L.

Pol. Industrial Río Gállego II · Calle J, Nº1
50840, San Mateo de Gállego, Zaragoza (Spain)
Tel. (+34) 976 520 354
salesidx@certest.es · www.certest.es



Find us on

@certestbiotec

TURBILATEX/GEN-0624EN

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