

CerTest
BIOTEC

CerTest Turbilatex



A quantitative immunological latex method

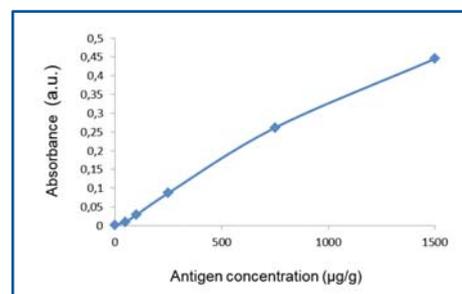
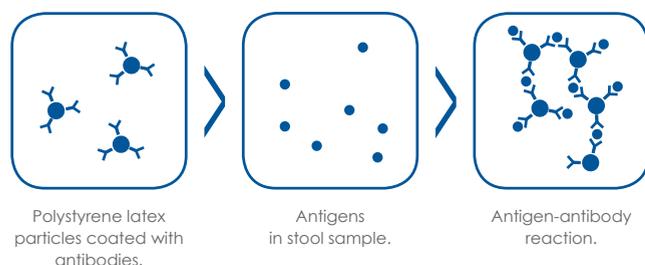
FOB | Calprotectin | Transferrin | *H. pylori*

Turbidimetric technique.

A latex turbidimetric assay

The turbidimetric assay is based on the agglutination reaction between latex particles coated with antibody and the antigen in solution.

Turbilatex® reagents are developed to obtain a high sensitivity detection method.



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.

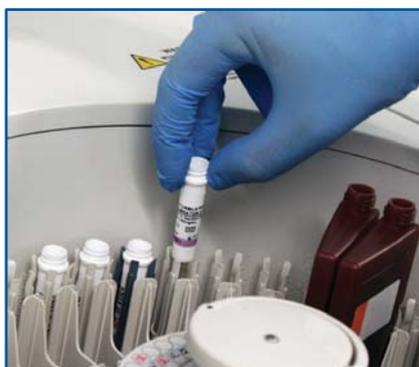
Equipment needed: Biochemistry analyzer.

Space and instruments maintenance 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:

- Completely **automated system** computer-controlled.
- **Open-system reagents:** Suitable with any analyzer.
- **No result interpretation** is needed.



Our provided kits:

1. Tumoral Panel:

FOB Turbilatex® | Calprotectin Turbilatex® | Transferrin Turbilatex®

2. Infectious Panel:

H. pylori Turbilatex®



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 work with any equipment.

_FOB Turbilatex®

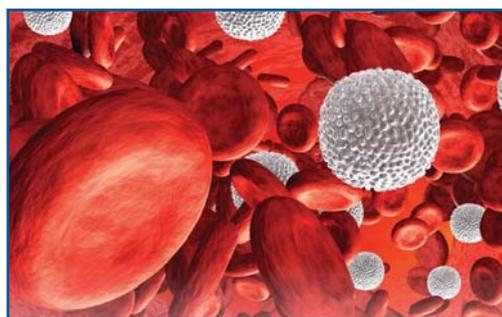
Colorectal cancer is the second leading cause of illness and death in Western world. The screening with faecal occult blood tests is based on the concept that important colonic neoplasm, such as early-stage cancer and large adenomatous polyps, will bleed, for which may be detected by an occult blood test. Colorectal cancer is also associated with local acute inflammatory reaction being visualized, in some cases, by white cell neutrophil scanning.

Haemoglobin is the iron-containing oxygen-transport in the blood cells of all vertebrates that may be leaked into gastrointestinal tract and then discharged with the feces in gastrointestinal bleeding diseases.

When gastrointestinal blood is lost, the stool will contain a combination of intact or nearly intact haemoglobin, intact heme and heme-derived porphyrins in amounts that depend on the site and amount of bleeding and the transit time through the gut.

CerTest FOB Turbilatex® detects intact or nearly intact human haemoglobin, being a very specific technique for detecting loss of blood from lower intestine.

CerTest FOB Turbilatex® is a quantitative assay, which offers a simple, a highly sensitive and non-invasive screening assay to make a presumptive diagnosis of gastrointestinal bleeding.



The screening of **Faecal Occult Blood tests (FOB)** are applied to early diagnose colonic neoplasma, such as early-stage cancer and large adenomatous polyps.

Product specifications

| FOB Turbilatex® | |
|------------------------------------|---------------------|
| Sensitivity (%) | 96 ⁽¹⁾ |
| Specificity (%) | > 99 ⁽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



| 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-022FB03E | FOB Turbilatex Sample diluent |

_Calprotectin Turbilatex®

Calprotectin is a neutrophil cytosolic protein with antimicrobial properties, present at increased concentration in stool samples during bowel inflammation. The resistance of the protein to degradation keeps it stable in faeces for up to 7 days at room temperature, making it an ideal analyte.

Calprotectin is released by activation of leukocytes, giving increased levels in plasma, cerebral spinal fluid, synovial fluid, urine or stools as a consequence of disease in the relevant organ(s). **As it is non-invasive marker of inflammation, determination of calprotectin can be useful in the diagnosis of Ulcerative Colitis (UC) and Crohn's Disease (CD).**

Calprotectin has been proven as an excellent surrogate marker in the diagnosis of Intestinal Bowel Diseases (IBD) and helps therefore to reliably select patients for further invasive diagnostic procedures.

CerTest Calprotectin Turbilatex® is a quantitative assay for the determination of human calprotectin in stool samples. It offers a simple, highly sensitivity and non-invasive screening assay to determine intestinal inflammatory activity, monitor treatment response and predict risk of relapse.



Measurement of faecal **Calprotectin** would represent a surrogate marker of neutrophil influx into the bowel lumen and in turn, act as a marker of intestinal inflammation.

Product specifications

| Calprotectin Turbilatex® | |
|------------------------------------|---------------------|
| 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



| References | Description |
|---------------|---|
| TL-022CP100ED | Calprotectin Turbilatex Combo kit 100 det. |
| TL-022CP200ED | Calprotectin Turbilatex Combo kit 200 det. |
| TL-022CP03E | Calprotectin Turbilatex Sample diluent |

_Transferrin Turbilatex®

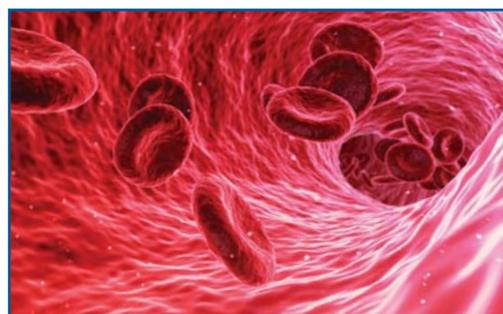
Colorectal cancer is the second most significant cause of illness and death in the Western world. Blood in stool is an important symptom of colon neoplasm, the cancer in its initial stage and intestinal adenomatous polyps.

Transferrin is an iron binding protein derived from blood and akin to haemoglobin, which can be released into the gastrointestinal tract and eliminated through faeces in illnesses associated with gastrointestinal bleeding.

Transferrin is very stable in stool, **making transferrin an ideal marker for detecting the loss of blood from both the upper and lower intestine (gastrointestinal bleeding)**. Haemoglobin is unstable in stool samples and it is only used to detect lower intestine bleeding. The detection of transferrin in stool provides an alternative method for the diagnosis of illnesses associated with bleeding from the digestive tract.

CerTest Transferrin Turbilatex® is a quantitative assay for the quantitative detection of transferrin in human stool samples. It offers a simple, highly sensitive and non-invasive screening assay to make a presumptive diagnosis of gastrointestinal bleeding.

Sharing the sample diluent, a stool sample can be analyzed with both tests, **FOB** and **Transferrin Turbilatex®** to ensure a proper and accurate diagnosis of gastrointestinal bleeding.



The detection of **faecal transferrin** provides an alternative way of diagnosing the disease in the upper digestive tract.

Product specifications

| Transferrin Turbilatex® | |
|------------------------------------|---------------------|
| 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. |
| TL-022FB03E | Transferrin Turbilatex Sample diluent ⁽²⁾ |

⁽²⁾ **FOB** and **Transferrin Turbilatex®** use the same Sample Diluent.

H. pylori Turbilatex®

Helicobacter pylori (*H. pylori*) is a spiral-shaped bacterium that is found in the gastric mucous layer or adherent to the epithelial lining of the stomach.

H. pylori causes more than 90% of duodenal ulcers and up to 80% of gastric ulcers.

The importance of *Helicobacter pylori* testing has increased due to the strong correlation between the presence of bacteria and confirmed gastrointestinal diseases (stomach and duodenum) like gastritis, peptic ulcer disease and gastric carcinoma.

Patients suffering from gastro-duodenal ulcer may develop complications such as upper gastrointestinal bleeding or perforation.

CerTest *H. pylori* Turbilatex® is a quantitative assay for the determination of *H. pylori* in stool samples. It offers a simple, highly sensitivity and non-invasive screening assay to determine low-level inflammation of the stomach lining, duodenal and gastric ulcers and stomach cancer.



H. pylori in the specimen causes a particular antigen-antibody reaction with Anti-*H. pylori* Monoclonal antibody sensitized latex and produce turbidity proportional to the amount of *H. pylori* in the specimen.

Product specifications

| <i>H. pylori</i> Turbilatex® | |
|------------------------------|---------------------|
| Sensitivity (%) | 88 ⁽¹⁾ |
| Specificity (%) | > 98 ⁽¹⁾ |
| Sensitivity limit | 0.5 ng/mL |
| Main interferences | None |

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



| References | Description |
|---------------|--|
| TL-022HP100ED | <i>H. pylori</i> Turbilatex Combo kit 100 det. |
| TL-022HP200ED | <i>H. pylori</i> Turbilatex Combo kit 200 det. |
| TL-022HP03E | <i>H. pylori</i> Turbilatex Sample diluent |



Turbilatex

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One step ahead



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