

## General Information

### Intended use:

FOB Turbilatex is a latex turbidimetric assay for the quantitative detection of human haemoglobin in human stool samples.

This assay is simple and widely applicable. Test results aid in a presumptive diagnosis of faecal occult blood (gastrointestinal bleeding).

For professional *in vitro* diagnostic use only.

FOB Turbilatex can be performed on every open chemistry analyser. Please follow the subsequent instructions to assure performance characteristics as describes in the instructions for use. This instruction has been validated by CerTest BIOTEC S.L Laboratories.

Additionally, please read the “Instructions for use” for instructions on operating and programming user defined test.

### Reagents:

Materials provided by CerTest BIOTEC S.L.:

Reagents	Quantity	Cat. reference
Turbidimetric reagents (R1 & R2) 200 Det/kit	R1: 2 vials, 2x22 mL. R2: 1 vial, 1x13 mL.	TL-022FB01 TL-022FB02
Auxiliary Reagents	Quantity	Cat. reference
Calibration kit	Calibrator: 6 vials, 6x1mL.	TL-022FB70, TL-022FB71, TL-022FB72, TL-022FB73, TL-022FB74, TL-022FB75
Controls kit	Control C1, 2 vials, 2x1 mL/vial. Control C2, 2 vials, 2x1 mL/vial.	TL-022FB08 TL-022FB09
Sample diluent kit	4 vials, 4x125 mL/vial	TL-022FB03E
Sample dilutions vials	1x2 mL/vial 1x2 mL/vial	MST-0005MF MST-0009F

### Preparation of reagents:

R1 and R2 are ready to use.

Calibrators are ready to use.

Controls are ready to use

### Storage and stability

Kit components must be stored at temperature indicated on the label. Do not freeze.

Reagents are stable up to the expiration date printed on the label, always considering that reagent containers must be properly closed to avoid any contamination, must be kept away from the sunlight and conserved at temperature indicated on the label of each reagent.

### Specimen:

Collect enough quantity of human stool samples. These samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-8°C) for 3 days prior to testing. Homogenise stool samples as thoroughly as possible prior to preparation.

The sample dilution vial with diluted sample can be stored for 7 days in the refrigerator (2-8°C) prior to testing.

Use FOB Turbilatex stool collection tubes for sample collections described the instructions for use.

## Assay procedure

### Application parameter set up:

Specific analyzers settings for FOB Turbilatex must be programmed onto the analyzer, see below. For instructions, consult the AU680 (Beckman Coulter) analyzer manual and instructions for use provided with the kit.

### Loading of reagents:

Load reagents according to the AU680 (Beckman Coulter) analyzer manual.

### Calibration curve establishment:

A 6 points calibration curve can be established in AU680 (Beckman Coulter) analyzer. For instructions consult analyzer manual.

### Calibration stability:

Calibrate the system at least once a month is extremely recommended. Recalibrate the system when reagent lot is change or when the controls are out of the assigned range given in the control label and CoA.

### QC controls:

FOB Turbilatex controls C1 and C2 must be assayed each day before running patient fecal sample extract to validate the calibration curve. The controls have assigned value ranges indicated on the label and certificate of analysis supplied. The control measurements must be within the indicated value range to obtain valid results for patient fecal extract. If the control values are out of range, follow next procedures: 1) Repeat QC control measurement, 2) Repeat calibration measurement.

### Results:

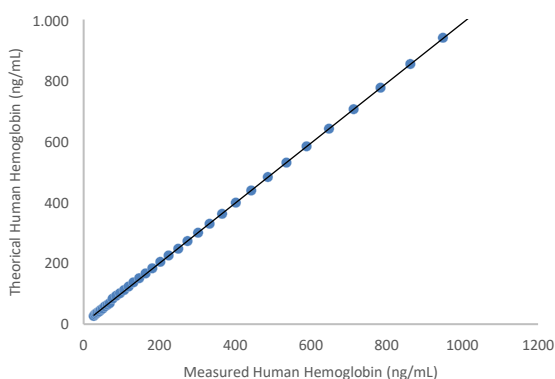
The results are evaluated automatically by the analyzer and presented in ng/mL.

## Performance characteristics

The following results have been obtained during the validation of Calprotectin Turbilatex on the AU680 (Beckman Coulter) analyzer.

### Linearity:

FOB Turbilatex on AU680 (Beckman Coulter) instrument using calibrator kit is linear in the calibration range of 0-1000 ng/mL.



### Measuring range:

FOB Turbilatex assay measuring range is 20-1000 ng/mL on the AU680 (Beckman Coulter) analyser. Samples higher concentrated than 1000 ng/mL must be diluted for proper quantification by the user, using additional sample buffer.

### Prozone effect

Using the reported parameters, no hook effect was observed up to 8000 ng/mL. Samples with Haemoglobin concentration of 16000 ng/mL give a typical positive result >500 ng/mL.

### Detection limit

**Limit of detection (LOD): 9 ng/mL.** The lower limit of detection of FOB Turbilatex was determined on 20 samples and 2 sample replicates as the mean value + 2·SD.

**Limit of quantification (LOQ): 20 ng/mL.** The lower limit of quantification is defined as the lowest actual amount of analysis that can be reliably detected; imprecision is < 20% as CV% on the AU680 (Beckman Coulter) instrument.

### Precision

FOB Turbilatex was tested with three different controls levels.

	Low (50 ng/mL)	Medium (100 ng/mL)	High (500 ng/mL)
<b>N</b>	20	20	20
<b>Mean (ng/mL)</b>	49	98,5	501
<b>SD (ng/mL)</b>	3,3	4,5	9,4
<b>CV (%)</b>	6,7%	4,6%	1,9%

## Method comparison












Results obtained with FOB Turbilatex on the AU680 (Beckman Coulter) instrument were compared with those obtained with EIKEN FOB Latex.

	Sensitivity	Specificity
<b>FOB Turbilatex vs EIKEN FOB Latex</b>	96%	>99%

## Shipping damage

Please notify your distributor, if this product was received damaged.

## Symbols key

	For <i>in vitro</i> diagnostic use only		Keep dry
	Consult instructions for use		Temperature limitation
	Catalogue number		Lot number
	Use by		Manufacturer
	Contains sufficient for <n> test		Sample diluent
	Keep out of the sunlight		

## Manufacturer

### CERTEST BIOTEC

Pol. Industrial Río Gállego II, Calle J, Nº 1, 50840,  
 San Mateo de Gállego, Zaragoza (SPAIN)  
[www.certest.es](http://www.certest.es)

## NOTES

Please refer to the instructions for use for the detailed information about the test on the following:

**Synthesis; Principle; Precautions; Reagents; Specimen collection; Interpretation of results.**

**Application Note**  
**FOB Turbilatex, AU680, Beckman Coulter**  
 (AN-Fb-AU680.EN rev 2019.05.27)

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### AU680, Beckman Coulter / Application parameters

<b>ASSAY PARAMETERS</b>	
Std. No	6
R1	100 µL
Sample	25 µL
R2	15 µL
Others	NA
Reaction mode	Endpoint
Primary wavelength	480 nm
Secondary wavelength	800 nm
Direction	Increase
Reagent blank lecture	11 cycle
Final lecture	27 cycle
Reaction time	10 min
Linear range	0-1000 ng/ml
<b>CALIBRATION</b>	
Calibration Method	Polygonal
Calibration set	6 calibrators
Blank	Calibrator 1 (0 ng/ml)
Calibrator 1	Calibrator 2 (50 ng/ml)
Calibrator 2	Calibrator 3 (100 ng/ml)
Calibrator 3	Calibrator 4 (250 ng/ml)
Calibrator 4	Calibrator 5 (500 ng/ml)
Calibrator 5	Calibrator 6 (1000 ng/ml)
<b>STEPS</b>	
Addition R1	
Addition Sample	
Incubation	5 min
Addition R2	
Blank Lecture	
Incubation	5 min
Final lecture	

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**Parameters** **Specific Test Parameters**

General LTH ISE HbA1c Calculated Tests Range

Test Name: 116.FOB Type: Serum Operation: Yes

Sample Volume: 25.0 uL Dilution: 0 uL OD Limit: Min.OD: -2.0000 Max.OD: 3.0000

Pre-Dilution Rate: 1

Reagent Volume R1(R1-1): 100 uL Dilution: 0 uL Reagent OD Limit: First Low: -2.0000 High: 3.0000

R2(R2-1): 15 uL Dilution: 0 uL Last Low: -2.0000 High: 3.0000

Common Reagent Type: None Name: Dynamic Range: Low: -999999.9 High: 999999.9

Wave Length Pri.: 480 nm Sec.: 800 nm Correlation Factor A: 1 B: 0

Method: FIXED Factor for Maker A: 1 B: 0

Reaction Slope: + Onboard Stability Period: Day Hour

Measuring Point-1 First: 11 Last: 27

Measuring Point-2 First: Last:

Linearity Limit: %

Lag Time Check:

Edit List Display Print

**Calibration** **Calibration Monitor**

Status RB History RB Detail Calibration History Calibration Detail

Test Name: 116.FOB Type: Serum

Date/Time: 9/13/2018 01:54 PM Passed

Reagent Lot No. Bottle No.

R1(R1-1)

R2(R2-1)

Cal Expiration Date:

Reagent Blank: 9/13/2018 01:51 PM

Cal Type: 6AB

Measure Type: Rack

Formula: Polygonal

Factor:  
 A0 = 3.0581E003  
 B0 = -2.2000E-003  
 A1 = 3.0581E003

Cal No.	CONC	OD
1	1	0
2	2	0.0144
3	3	0.0338
4	4	0.0998
5	5	0.1477
6	6	0.1696

Comment:

Lot to Lot Calibration RB/CAL Selection Data Select Comment Graph Scale Print

