General Information

Intended use:

FOB Turbilatex® Combo is a latex turbidimetric assay **for the quantitative detection of haemoglobin (faecal occult blood) in human stool samples**.

This assay is simple and widely applicable. This product is optimized for several automated analyser.

For professional *in vitro* diagnostic use only.

Reagents:

Materials provided by CerTest Biotec:

Reagents	Code
Turbidimetric reagents (R1 & R2)	TL-022FB01 TL-022FB02
Auxiliary Reagents	
Calibration kit	TL-022FB70, TL-022FB71 TL-022FB72 TL-022FB73 TL-022FB74 TL-022FB75
Controls kit	TL-022FB08 TL-022FB09
Sample dilutions vials	MST-0019U

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® Combo** stool collection tubes for sample collections described the instructions for use.

Assay procedure

FOB Turbilatex® Combo can be performed on every open chemistry analyser. Please follow the subsequent instructions in order 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.

Application parameter set up:

Specific analyzers settings for **FOB Turbilatex® Combo** must be programmed onto the analyzer, see below. For instructions, consult the Selectra PRO S; Selectra PRO M (Elitech) analyzer manual and instructions for use provided with the kit.

Loading of reagents:

Load reagents according to the Selectra PRO S; Selectra PRO M (Elitech) analyzer manual.

Calibration curve establishment:

A 6-points calibration curve can be established in Selectra PRO S; Selectra PRO M (Elitech) analyzer. For instructions consult analyzer manual.

Calibration stability:

Calibrate the system at least once a week 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® Combo 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 **FOB Turbilatex® Combo** on the Selectra PRO S; Selectra PRO M (Elitech) analyzer.

Linearity:

FOB Turbilatex® Combo using calibrator kit is linear in the calibration range of 40-1000 ng/mL.

Measuring range:

FOB Turbilatex® Combo assay measuring range is 34.60-1953 ng hHb/mL. Samples more concentrated than 1000 ng hHb/mL must be diluted for proper quantification by the user, using additional sample buffer.

Prozone effect:

Studies have been made up to a concentration of 1 mg of hHb/mL of stool and no false negative results have been observed. Studies using higher concentrations have not been carried out.

Samples with concentrations up to 1953 ng hHb/mL can be measured without inhibitory prozone effect.

Detection limit:

Limit of detection (LOD): 32.33 ng hHb/mL.

Limit of quantification (LOQ): 34.60 ng hHb/mL. The lower limit of quantification is defined as the lowest actual amount of analysis that can be reliably detected. The Upper Limit of Quantification, it has not been determined since the LOQ experiment has proved that there is good quantification up to the 1000 ng hHb/mL point, which is the maximum point of the **FOB Turbilatex® Combo** calibration curve. This point can be quantified with a coefficient of variation lower than the %CV goal (13%).

Precision:

Within-laboratory and repeatability were determined according to CLSI EP05 using a standardised study design of 80 replicates per sample were evaluated (5 days x 4 runs x 4 replicates) and with an acceptance criterion of 20% CV.

Sample	N	Mean (ng/mL)	Repeatability		Total	
			Sd	CV%	Sd	CV%
1	80	50.37	4.83	9.6%	5.62	11.15%
2	80	124.40	13.57	10.8%	18.62	14.87%
3	80	232.78	3.46	1.5%	11.46	4.92%
4	80	320.80	3.97	1.2%	18.44	5.75%
5	80	403.55	6.57	1.6%	43.52	10.78%
6	80	561.96	8.78	1.6%	13.16	2.34%
7	80	992.05	50.49	5.1%	51.22	5.16%

Similarly, following the CLSI EP05 recommendations for reproducibility analysis, 80 replicates per sample were evaluated with three lots (5 days x 4 runs x 4 replicates) and with an acceptance criterion of 20% CV.

Sample	N	Mean (ng/mL)	Repeatability		Within lot		Reproducibility	
			Sd	CV%	Sd	CV%	Sd	CV%
1	80	49.466	4.067	8.2%	7.111	14.4%	7.111	14.4%
2	80	124.443	8.666	7.0%	16.788	13.5%	17.241	13.9%
3	80	238.002	9.261	3.9%	15.706	6.6%	15.868	6.7%
4	80	323.423	2.936	0.9%	17.057	5.3%	17.372	5.4%
5	80	411.280	4.693	1.1%	39.011	9.5%	39.180	9.5%
6	80	590.760	6.462	1.1%	29.908	5.1%	48.175	8.2%
7	80	1011.871	33.099	3.3%	43.607	4.3%	45.049	4.5%

Method comparison

An evaluation was performed comparing **FOB Turbilatex® Combo** against another commercially available turbidimetric assay, which was considered as a gold standard. This evaluation has undergone with cut-off 10 µg of hHb/g of stool:

FOB Turbilatex® vs Evaluation criteria		
	Mean Value	95% confidence interval
Sensitivity	87.5%	71.0-96.5%
Specificity	97.9%	88.7-99.9%
PPV	96.6%	82.2-99.9%
NPV	92.0%	80.8-97.8%
LR+	41.13	5.890-287.2
LR-	0.128	0.051-0.320

Shipping damage

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

Symbols key

IVD	For *in vitro* diagnostic use only		Keep dry
	Consult instructions for use		Temperature limitation
REF	Catalogue number	LOT	Lot number
	Use by		Manufacturer
Σ n	Contains sufficient for <n> test	DIL	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

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.

(*) Analytical performance data were obtained with the Biolis 24 i(Tokyo Boeki) analyser.

Selectra PRO S; Selectra PRO M, Elitech/ Application parameters

ASSAY PARAMETERS	
Std. No	6
R1	220 µL
Sample	20 µL
R2	60 µL
Others	N/A
Reaction mode	End point
Primary wavelength	505 nm
Secondary wavelength	None
Direction	Increase
Reagent blank lecture (cycle)	8 s
Final lecture (cycle)	317 s
Reaction time	close to 10 min
Linear range	40-1000 ng/mL
CALIBRATION	
Calibration Method	Linear
Calibration set	5 calibrators + Blank
Blank	Calibrator 0 (0 ng/mL)
Calibrator 1	Calibrator 1 (50 ng/mL)
Calibrator 2	Calibrator 2 (100 ng/mL)
Calibrator 3	Calibrator 3 (250 ng/mL)
Calibrator 4	Calibrator 4 (500 ng/mL)
Calibrator 5	Calibrator 5 (1000 ng/mL)
STEPS	
Addition R1	-2.25 min
Addition Sample	
Incubation R1+S	120-180 s
Addition R2	2.9 min
Blank Lecture	8 s
Incubation reaction	close to 300 sec
Final lecture	317 s