General Information

Intended use:

FOB Turbilatex is a latex turbidimetric assay for the quantitative detection of human haemoglobin (hHb) 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 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.

Reagents:

Materials provided by CerTest BIOTEC:

Reagents	Quantity	Code
Turbidimetric reagents (R1 & R2) 200 Det/kit	R1: 2 vials, 2x22 mL R2: 1 vial, 1x13 mL	TL-022FB01 TL-022FB02
Auxiliary Reagents		
Calibration kit	Calibrator: 6 vials, 6x1 mL.	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, 2x 1 mL/vial.	TL-022FB08 TL-022FB09
Sample dilutions vials	1x2 mL/vial 1x2.4 mL/vial	MST-0018MU 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 (4±2°C) prior to testing. If not immediately tested, freeze the stored samples at -20 °C maximum 6 months. In this case, the sample will be totally thawed, and brought to room temperature before testing. Homogenize stool samples as thoroughly as possible prior to preparation.

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 Biolis 24i/50i (Tokio Boeki) analyzer manual and instructions for use provided with the kit.

Loading of reagents:

Load reagents according to the Biolis 24i/50i (Tokio Boeki) analyzer manual.

Calibration curve establishment:

A 6 point calibration curve can be established in Biolis 24i/50i (Tokio Boeki) 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 faecal 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 faecal extract. If the control values are out of range, follow next procedures: 1) Repeat QC control measurement, 2) Repeat calibration measurement.

Results:

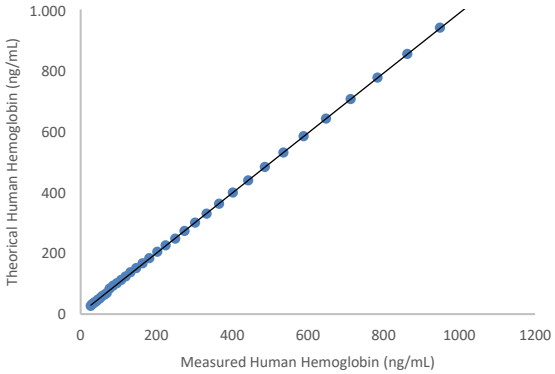
The results are evaluated automatically by the analyser and presented in ng hHb/mL.

Performance characteristics

The following results have been obtained during the validation of FOB Turbilatex on the Biolis 24i/50i (Tokio Boeki) analyzer.

Linearity:

FOB Turbilatex on Biolis 24i/50i (Tokio Boeki) analyzer using calibrator kit is linear in the calibration range of 0-1000 ng hHb/mL.



Measuring range:

FOB Turbilatex assay measuring range is 10-1000 ng hHb/mL on the Biolis 24i/50i (Tokio Boeki) analyser. Samples higher concentrated than 1000 ng hHb/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 10 µg hHb/mL. Samples with Haemoglobin concentration of 10 µg/mL give a typical positive result >1000 ng hHb/mL.

Detection limit

Limit of detection (LOD): 8 ng hHb/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): 10 ng hHb/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%.

Precision

FOB Turbilatex was tested with three different controls levels.

	Low (20 ng/mL)	Medium (80 ng/mL)	High (250 ng/mL)
N	20	20	20
Mean (ng/g)	19.8	81.1	247.8
SD (ng/g)	1.6	4.2	8.4
CV (%)	8	5	3

Method comparison

Results obtained with FOB Turbilatex on the analyser Biolis 24i (Tokyo Boeki) were compared with those obtained with EIKEN FOB Latex.

	Sensitivity	Specificity
FOB Turbilatex vs FOB Latex®	**96%**	**>99%**

Shipping damage

Please notify your distributor, it 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

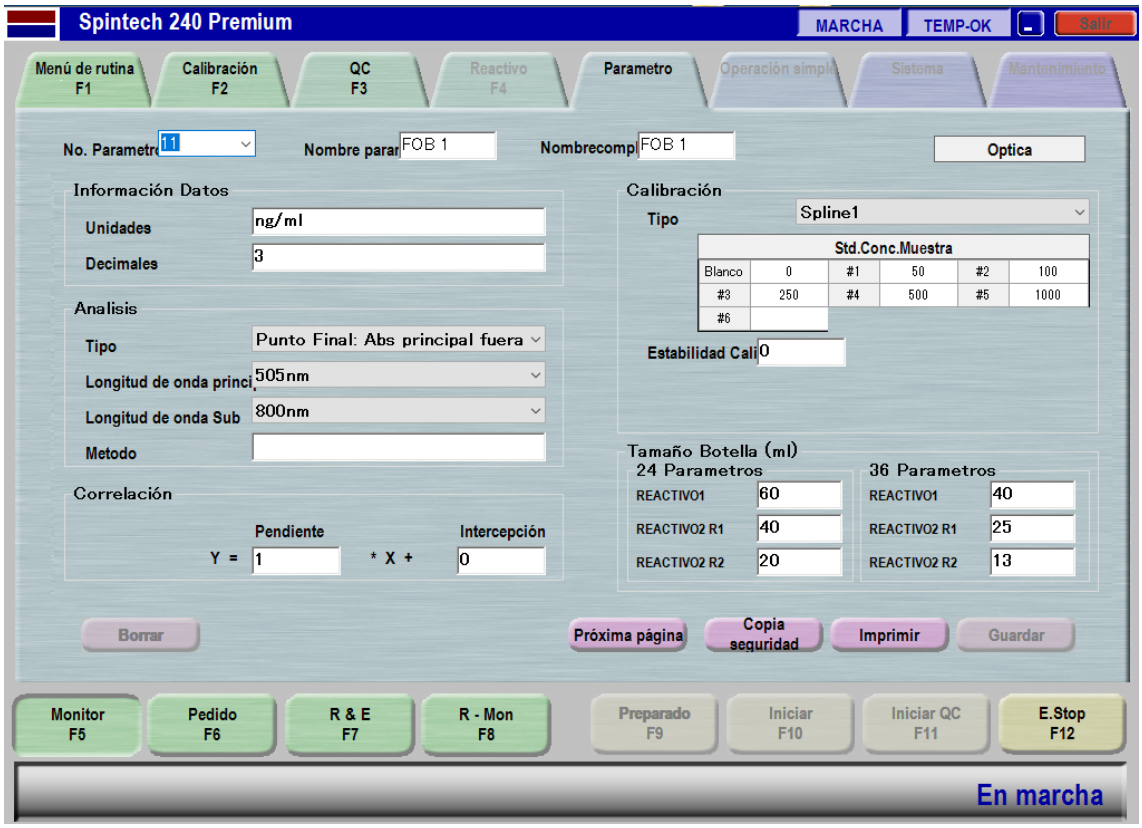
Pol. Industrial Río Gállego II,Calle J, Nº 1, 50840,
San Mateo de Gállego, Zaragoza (SPAIN)
www.certest.es

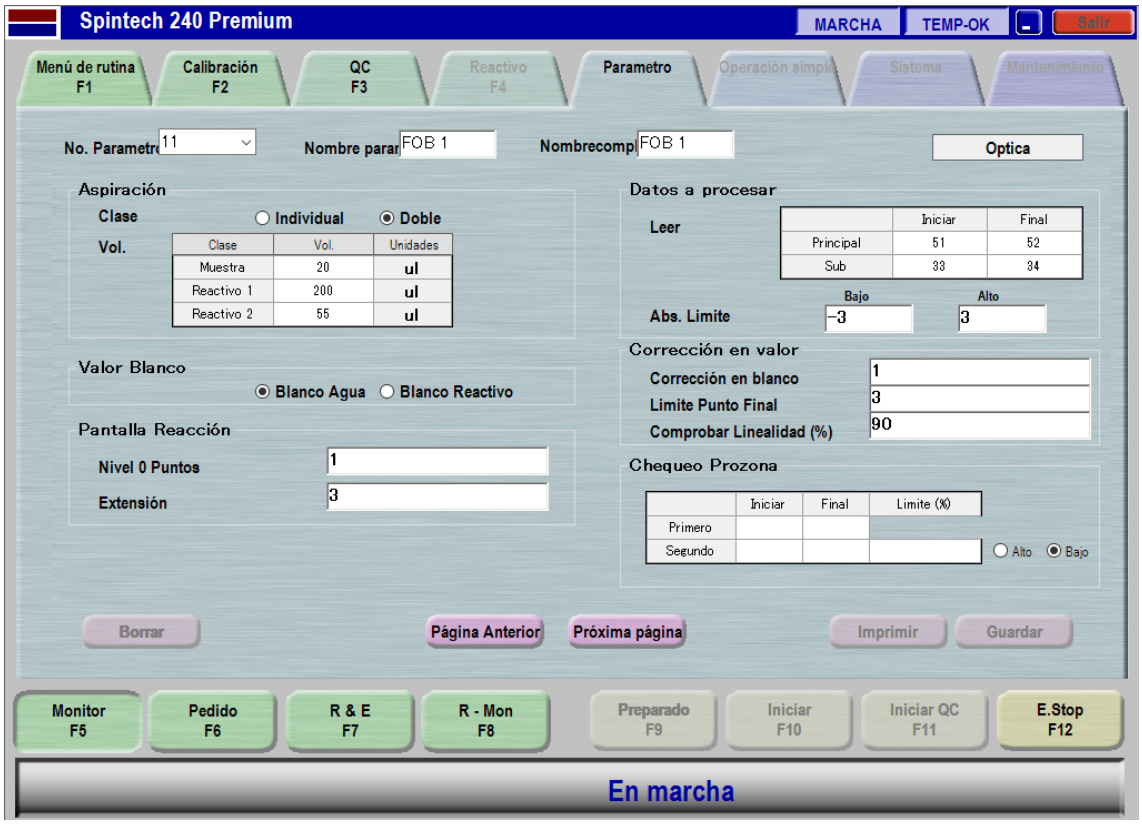
NOTES

Please refer to the instruction for use for the detailed information about the test on the following:
Synthesis; Principle; Precautions; Reagents; Specimen collection; Interpretation of results.

Biolis 24i/50i, Tokyo Boeki / Application parameters

ASSAY PARAMETERS	
Std. No	6
R1	200 µL
Sample	20 µL
R2	55 µL
Others	N/A s
Reaction mode	Endpoint
Primary wavelength	505 nm
Secondary wavelength	800 nm
Direction	Increase
Reagent blank lecture	33-34 cycle
Final lecture	51-52 cycle
Reaction time	10 min
Linear range	0-1000 ng/ml
CALIBRATION	
Calibration Method	Linear
Calibration set	5 calibrators + Blank
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)
STEPS	
Addition R1	
Addition Sample	
Incubation	
Addition R2	
Blank Lecture	Cycle 33-34
Incubation (time between lecture)	
Final lecture	Cycle 51-52


Spintech 240 Premium
MARCHA
TEMP-OK
Salir
Menú de rutina F1
Calibración F2
QC F3
Reactivo F4
Parametro
Operación simple
Sistema
Mantenimiento
No. Parametr
11
Nombre parar
FOB 1
Nombrecompl
FOB 1
Optica
Información Datos
Unidades
ng/ml
Decimales
3
Analisis
Tipo
Punto Final: Abs principal fuera
Longitud de onda princi
505nm
Longitud de onda Sub
800nm
Metodo
Correlación
Pendiente
Intercepción
Y =
1
* X +
0
Calibración
Tipo
Spline1
Std.Conc.Muestra
Blanco
0
#1
50
#2
100
#3
250
#4
500
#5
1000
#6
Estabilidad Cali
0
Tamaño Botella (ml)
24 Parametros
REACTIVO1
60
REACTIVO2 R1
40
REACTIVO2 R2
20
36 Parametros
REACTIVO1
40
REACTIVO2 R1
25
REACTIVO2 R2
13
Borrar
Próxima página
Copia seguridad
Imprimir
Guardar
Monitor F5
Pedido F6
R & E F7
R - Mon F8
Preparado F9
Iniciar F10
Iniciar QC F11
E.Stop F12
En marcha


Spintech 240 Premium
MARCHA
TEMP-OK
Salir
Menú de rutina F1
Calibración F2
QC F3
Reactivo F4
Parametro
Operación simple
Sistema
Mantenimiento
No. Parametr
11
Nombre parar
FOB 1
Nombrecompl
FOB 1
Optica
Aspiración
Clase
Individual
Doble
Vol.
Clase
Vol.
Unidades
Muestra
20
ul
Reactivo 1
200
ul
Reactivo 2
55
ul
Valor Blanco
Blanco Agua
Blanco Reactivo
Pantalla Reacción
Nivel 0 Puntos
1
Extensión
3
Datos a procesar
Leer
Iniciar
Final
Principal
51
52
Sub
33
34
Bajo
Alto
Abs. Limite
-3
3
Corrección en valor
Corrección en blanco
1
Limite Punto Final
3
Comprobar Linealidad (%)
90
Chequeo Prozona
Iniciar
Final
Limite (%)
Primero
Segundo
Alto
Bajo
Borrar
Página Anterior
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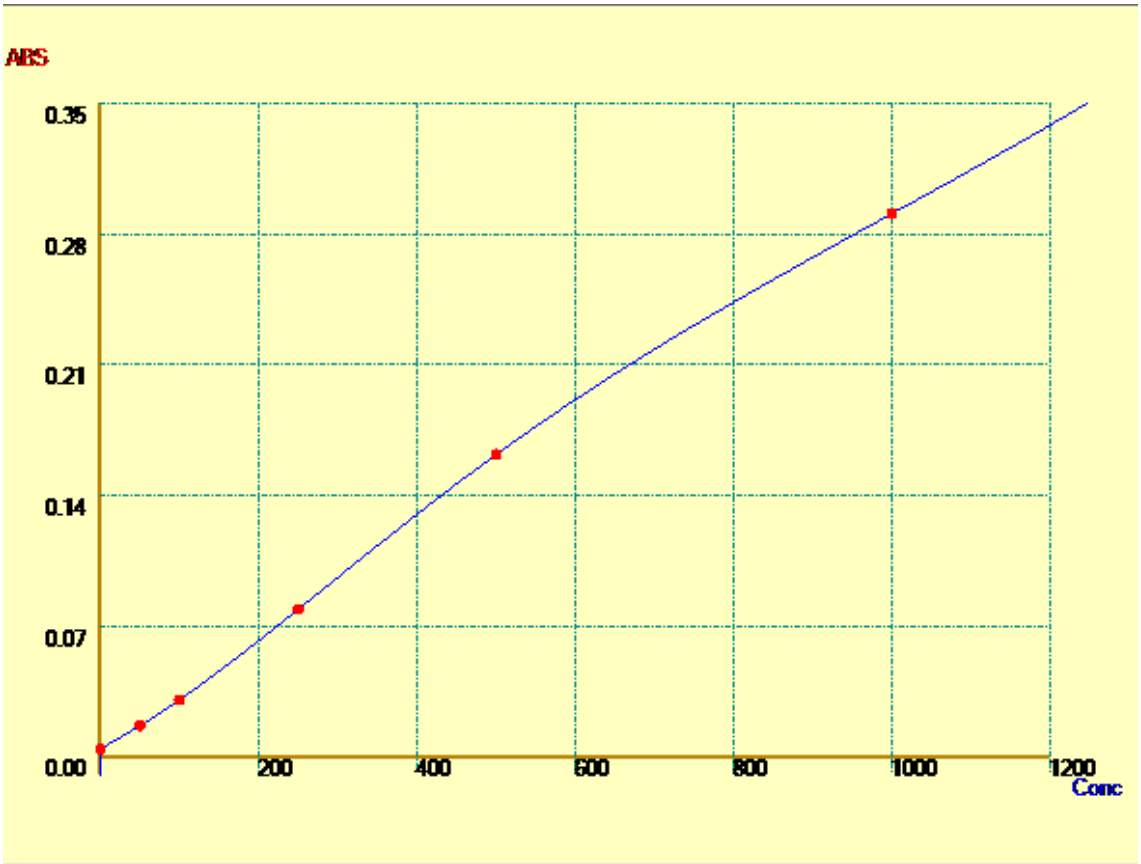
En marcha


ABS
0.35
0.28
0.21
0.14
0.07
0.00
200
400
600
800
1000
1200
Conc