

## General Information

### Intended use:

FOB Turbilatex is a latex turbidimetric assay for **the quantitative detection of human haemoglobin (hHb) (faecal occult blood) 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 S.L.:

| Reagents  | Quantity  | Code  |
|---|---|---|
| Turbidimetric reagents (R1 & R2)<br>200 Det/kit | R1: 2 vials, 2x22 mL<br>R2: 1 vial, 1x13 mL                                   | TL-022FB01<br>TL-022FB02  |
| <b>Auxiliary Reagents</b>                       |   |   |
| Calibration kit                                 | Calibrator: 6 vials,<br>6x1 mL.   | TL-022FB70,<br>TL-022FB71<br>TL-022FB72<br>TL-022FB73<br>TL-022FB74<br>TL-022FB75 |
| Controls kit                                    | Control C1,<br>2 vials, 2x1 mL/vial.<br>Control C2,<br>2 vials, 2x 1 mL/vial. | TL-022FB08<br>TL-022FB09  |
| Sample dilutions vials                          | 1x2 mL/vial<br>1x2.4 mL/vial  | MST-0018MU<br>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 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 BS-200 (Mindray) analyzer manual and instructions for use provided with the kit.

### Loading of reagents:

Load reagents according to the BS-200 (Mindray) analyzer manual.

### Calibration curve establishment:

A 6 point calibration curve can be established in BS-200 (Mindray) 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 labels 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:

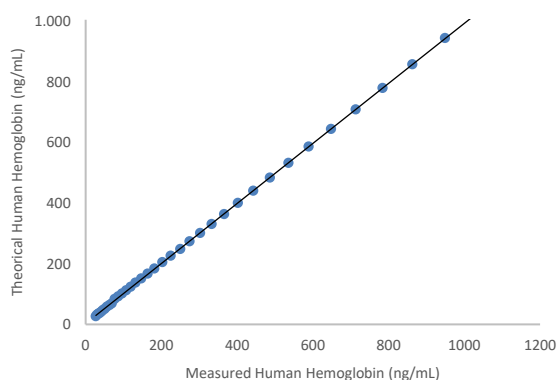
The results are evaluated automatically by the analyzer and presented in ng hHb/mL.

## Performance characteristics

The following results have been obtained during the validation of FOB Turbilatex on the BS-200 (Mindray) analyzer.

### Linearity:

FOB Turbilatex on BS-200 (Mindray) 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 BS-200 (Mindray) 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 prozone effect (hook effect) was observed up to 10 ng hHb/mL. Samples with Haemoglobin concentration of 10 ng/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% on the BS-200 (Mindray) analyzer.

(\* Data obtained by the analyser Biolis 24i (Tokyo Boeki)

### Precision

FOB Turbilatex was tested with three different controls levels.

|                    | Low<br>(50 ng/mL) | Medium<br>(100 ng/mL) | High<br>(500 ng/mL) |
|--------------------|-------------------|-----------------------|---------------------|
| <b>N</b>           | 20                | 20                    | 20                  |
| <b>Mean (ng/g)</b> | 46.3              | 97.7                  | 495.3               |
| <b>SD (ng/g)</b>   | 4.2               | 7.5                   | 15.9                |
| <b>CV (%)</b>      | 9                 | 8                     | 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    |
|-------------------------------------|-------------|----------------|
| <b>FOB Turbilatex vs FOB Latex®</b> | <b>96%</b>  | <b>&gt;99%</b> |

### Symbols key

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

### Shipping damage

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

### NOTES

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

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

### Manufacturer

#### CERTEST BIOTEC

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

The parameters optimized for BS200 might be applied for BS200E and BS240.

**BS-200 (Mindray) /Application parameters**

| <b>ASSAY PARAMETERS</b> |                           |
|-------------------------|---------------------------|
| Std. No                 | 6                         |
| R1                      | 200 µL                    |
| Sample                  | 20 µL                     |
| R2                      | 55 µL                     |
| Others                  | NA                        |
| Reaction mode           | Endpoint                  |
| Primary wavelength      | 505 nm                    |
| Secondary wavelength    | 800 nm                    |
| Direction               | Increase                  |
| Reagent blank lecture   | 1 cycle                   |
| Final lecture           | 20 cycle                  |
| Reaction time           | 10 min                    |
| Linear range            | 0-1000 ng/ml              |
| <b>CALIBRATION</b>      |                           |
| 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) |
| <b>STEPS</b>            |                           |
| Addition R1             |                           |
| Addition Sample         |                           |
| Incubation              |                           |
| Addition R2             |                           |
| Blank Lecture           | Cycle 1                   |
| Incubation              |                           |
| Final lecture           | Cycle 20                  |

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FOB Turbilatex CP Turbilatex

| Parámetros | Referenc       | Calibración       | CC               |
|------------|----------------|-------------------|------------------|
| Test       | FOB Turbilatex | R1                | 200              |
| Nº         | 1              | R2                | 55               |
| Nomb comp  |                | Volum muestra     | 20               |
| Nº estánd  |                | Blanc R1          |                  |
| Tipo reac  | Pto fin        | Blan react mez    |                  |
| Onda prim  | 505nm          | Interv lineali    |                  |
| Onda secu  | 800nm          | Límite lineali    |                  |
| Dirección  | Aumentar       | Límit sustrato    |                  |
| Tiem reac  | 0              | Factor            |                  |
| Tiem incu  | 14             | Compensar         | Pend 1 Interse 0 |
| Unidad     | ng/mL          | Comprobación pro: | q1 q2 q3 q4      |
| Precisión  | 0.1            | CP                | Abs              |

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