General Information

Intended use:

Transferrin Turbilatex® Combo is a latex turbidimetric assay **only for the quantitative detection of Transferrin E1 in human stool samples** (not to be used for body fluid as blood, serum, plasma, urine, cerebrospinal fluid, oral fluid, synovial fluid or empyema fluid).

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	Quantity	Code
Turbidimetric reagents (R1 & R2) 200 Det/kit	R1: 2 vials, 2x22 mL R2: 1 vial, 1x13 mL	TL-022TF01 TL-022TF02
Auxiliary Reagents		
Calibration kit	Calibrator: 6 vials, 6x1 mL.	TL-022TF70, TL-022TF71 TL-022TF72 TL-022TF73 TL-022TF74 TL-022TF75
Controls kit	Control C1, 2 vials, 2x1 mL/vial. Control C2, 2 vials, 2x 1 mL/vial.	TL-022TF08 TL-022TF09
Sample dilutions vials	1x2.4 mL/vial	MST-0019U/MST-0019UR

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 solid 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. 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 (15-30°C) before testing. Homogenize stool samples as thoroughly as possible prior to preparation.

Use **Universal Turbilatex® Sample Collection Vial** or **Universal Turbilatex® Sample Vial** for sample collections described the instructions for use.

Assay procedure

Transferrin 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 **Transferrin Turbilatex® Combo** must be programmed onto the analyzer, see below. For instructions, consult the Biolis 30i (Tokyo Boeki) analyzer manual and instructions for use provided with the kit.

Loading of reagents:

Load reagents according to the Biolis 30i (Tokyo Boeki) analyzer manual.

Calibration curve establishment:

A 6-points calibration curve can be established in Biolis 30i (Tokyo 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:

Transferrin 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:

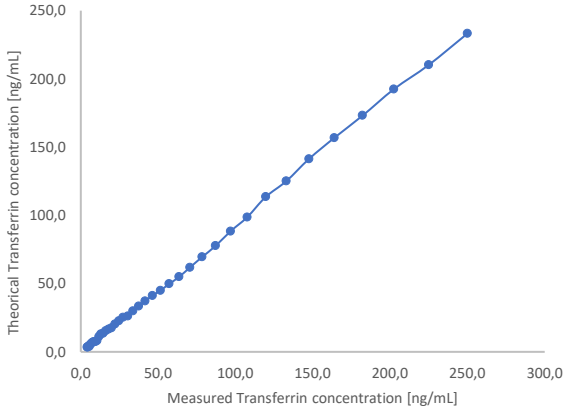
The results are evaluated automatically by the analyzer and presented in ng hTf/mL.

Performance characteristics (*)

The following results have been obtained during the validation of **Transferrin Turbilatex® Combo** on the Biolis 30i (Tokyo Boeki) analyzer.

Linearity:

Transferrin Turbilatex® Combo using calibrator kit is linear in the calibration range of 3.7-250 ng hTf/mL.



Measuring range:

Transferrin Turbilatex® Combo assay measuring range is 2-1250 ng hTf/mL. Samples higher concentrated than 250 ng hTf/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 10000 ng hTf/mL and no false negative results have been observed. Studies using higher concentrations have not been carried out. Samples with concentrations up to 1250 ng hTf/mL can be measured without inhibitory prozone effect.

Detection limit:

Limit of detection (LOD): 1.4 ng hTf/mL. The lower limit of detection of **Transferrin Turbilatex® Combo** was determined on 20 samples and 2 sample replicates as the mean value + 2 SD.

Limit of quantification (LOQ): 2 ng hTf/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:

Transferrin Turbilatex® Combo was tested with three different controls levels.

	Low (15 ng/mL)	Medium (80 ng/mL)	High (200 ng/mL)
N	20	20	20
Mean (µg/g)	15.3	82.1	202.5
SD (µg/g)	1.6	4.8	11.6
CV (%)	10.4	5.8	5.7

Method comparison

Results obtained with **Transferrin Turbilatex® Combo** on the analyser Biolis 24i (Tokyo Boeki) were compared with an immnochromatographic test (CerTest Transferrin, CerTest).

The results were as follows:

Transferrin Turbilatex® vs CerTest Transferrin		
	Mean Value	**95% confidence interval**
Sensitivity	94.7%	82.3-99.4
Specificity	100.0%	90.3-100.0%
PPV	100.0%	89.1-100.0%
NPV	94.1%	80.3-99.3%
LR+	61.77	3.941-968.1
LR-	0.065	0.02-0.216

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.

Biolis 30i (Tokyo Boeki)/ Application parameters

ASSAY PARAMETERS	
Std. No	6
R1	170 µL
Sample	25 µL
R2	46 µL
Others	N/A
Reaction mode	End point
Primary wavelength	505 nm
Secondary wavelength	800 nm
Direction	Increase
Reagent blank lecture (cycle)	33-34 cycle
Final lecture (cycle)	53-54 cycle
Reaction time	close to 10 min
Linear range	3.7-250 ng/mL
CALIBRATION	
Calibration Method	Linear
Calibration set	5 calibrators + Blank
Blank	Calibrator 0 (0 ng/mL)
Calibrator 1	Calibrator 1 (10 ng/mL)
Calibrator 2	Calibrator 2 (25 ng/mL)
Calibrator 3	Calibrator 3 (50 ng/mL)
Calibrator 4	Calibrator 4 (100 ng/mL)
Calibrator 5	Calibrator 5 (250 ng/mL)
STEPS	
Addition R1	6
Addition Sample	8
Incubation R1+S	120-180 s
Addition R2	31
Blank Lecture	Cycle 33-34
Incubation reaction	close to 300 sec
Final lecture	Cycle 53-54