

# **General Information**

# Intended use:

Transferrin Turbilatex<sup>®</sup> 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	Code	
Turbidimetric reagents (R1 & R2)	TL-022TF01	
	TL-022TF02	
Auxiliary Reagents		
	TL-022TF70,	
	TL-022TF71	
	TL-022TF72	
Calibration kit	TL-022TF73	
	TL-022TF74	
	TL-022TF75	
Controls kit	TL-022TF08	
	TL-022TF09	
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 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

F-549 rev01 Page 1 of **3**  testing. Homogenize stool samples as thoroughly as possible prior to preparation.

Use **Transferrin Turbilatex**<sup>®</sup> **Combo** stool collection tubes for sample collections described the instructions for use.

### Assay procedure

**Transferrin Turbilatex**<sup>®</sup> **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**<sup>®</sup> **Combo** must be programmed onto the analyzer, see below. For instructions, consult the Architect c4000/c8000/c16000 (Abbott) analyzer manual and instructions for use provided with the kit.

#### Loading of reagents:

Load reagents according to the Architect c4000/c8000/c16000 (Abbott) analyzer manual.

#### Calibration curve establishment:

A 6-points calibration curve can be established in Architect c4000/c8000/c16000 (Abbott) 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**<sup>®</sup> **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.

# Tranferrin Turbilatex Combo, Architect c4000/c8000/c16000, Abbott (AN-TF-Architect c4000/c8000/c16000 .EN rev 2025.02.20)



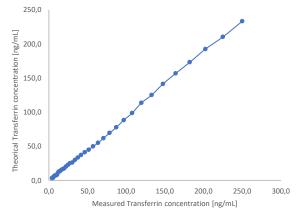
# Performance characteristics (\*)

The following results have been obtained during the validation

of **Transferrin Turbilatex® Combo** on the Architect c4000/c8000/c16000 (Abbott) 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**<sup>®</sup> **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**<sup>®</sup> **Combo** was tested with three different controls levels.

	Low (15 ng/mL)	Medium (80 ng/mL)	High (200 ng/mL)
Ν	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**<sup>®</sup> **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		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	Ť	Keep dry
Ĩ	Consult instructions for use	X	Temperature limitation
REF	Catalogue number	LOT	Lot number
	Use by	***	Manufacturer
∑ n	Contains sufficient for <n> test</n>	DIL	Sample diluent
紊	Keep out of the sunlight		

### CERTEST BIOTEC

Manufacturer

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.



# Architect c4000/c8000/c16000 (Abbott)/ Application parameters

Sample10 µlR230 µL + 4.2 µL (4% over suction + 3 µL dead volumeOthersDispense type 2Reaction modeEnd poinPrimary wavelength500 nmSecondary wavelengthIncrease	Std. No	
R2     30 µL + 4.2 µL (4% over suction + 3 µL dead volume       Others     Dispense type 7       Reaction mode     End poin       Primary wavelength     S00 nm       Secondary wavelength     Nom       Direction     Increase       Reagent blank lecture (cycle)     19 cycle       Final lecture (cycle)     30-32 cycle       Reaction time     close to 10 min       Linear range     3.7-250 ng/ml       Calibration Method     Linear       Calibration set     5 calibrators + Blank       Blank     Calibrator 0 (ng/mL       Calibrator 1     Calibrator 0 (ng/mL       Calibrator 2     Calibrator 1 (10 ng/mL       Calibrator 3     Calibrator 3 (50 ng/mL       Calibrator 4     Calibrator 3 (50 ng/mL       Calibrator 5     Calibrator 5 (250 ng/mL       Calibrator 5     Calibrator 5 (250 ng/mL       Calibrator 5     Calibrator 5 (250 ng/mL       STEPS     Steps       Addition R1     Lincubation R1+S       Addition R2     Incubation R1+S       Blank Lecture     Cycle 19       Incubation reaction     close to 300 set	R1	120 μL +7.8 μL (4% over suction+ 3 μL dead volume
OthersDispense type 1Reaction modeEnd poinPrimary wavelength500 nmSecondary wavelengthNomeDirectionIncreaseReagent blank lecture (cycle)19 cycleFinal lecture (cycle)30-32 cycleReaction timeclose to 10 minLinear range3.7-250 ng/mlCalibration MethodLinearCalibration set5 calibrators + BlanlBlankCalibrator 0 (on g/mLCalibrator 1Calibrator 0 (on g/mLCalibrator 2Calibrator 1 (10 ng/mLCalibrator 3Calibrator 3 (50 ng/mLCalibrator 4Calibrator 3 (50 ng/mLCalibrator 5Calibrator 3 (50 ng/mLCalibrator 5Calibrator 4 (100 ng/mLCalibrator 5Calibrator 5 (250 ng/mLCalibrator 6120-180 fAddition R1120-180 fAddition R2120-180 fBlank LectureCycle 15Incubation reactionclose to 300 set	Sample	10 µl
Reaction modeEnd poinPrimary wavelength500 nmSecondary wavelengthNomeDirectionIncreaseReagent blank lecture (cycle)19 cycleFinal lecture (cycle)30-32 cycleReaction timeclose to 10 mirLinear range3.7-250 ng/mlCALIBRATIONCalibrator setCalibration set5 calibrators + BlandBlankCalibrator 0 (0 ng/mLCalibrator 1Calibrator 0 (25 ng/mLCalibrator 2Calibrator 3 (50 ng/mLCalibrator 3Calibrator 3 (50 ng/mLCalibrator 4Calibrator 3 (50 ng/mLCalibrator 5Calibrator 3 (50 ng/mLCalibrator 5Calibrator 3 (50 ng/mLCalibrator 7Calibrator 3 (50 ng/mLCalibrator 8120-180 ng/mLCalibrator 9120-180 ng/mLAddition 81120-180 ng/mLAddition R2120-180 ng/mLBlank LectureCycle 19Incubation reactionclose 0 300 set	R2	30 μL + 4.2 μL (4% over suction+ 3 μL dead volume
Primary wavelength500 mSecondary wavelength500 mDirectionIncreaseReagent blank lecture (cycle)19 cycleFinal lecture (cycle)30-32 cycleReaction timeclose to 10 mirLinear range3.7-250 ng/mlCALIBRATIONClaibrator 1Calibration MethodLineaCalibrator set5 calibrators + BlanlBlankCalibrator 0 (ng/mLCalibrator 1Calibrator 0 (ng/mLCalibrator 2Calibrator 1 (10 ng/mLCalibrator 3Calibrator 2 (25 ng/mLCalibrator 4Calibrator 3 (50 ng/mLCalibrator 5Calibrator 5 (250 ng/mLSTEPSIncubation R1Addition R1120-180 rAddition R2Calibrator 5 (250 ng/mLBlank LectureCycle 15Incubation R1+S120-180 rCycle 15Cycle 15Incubation R2Cycle 15StepsCycle 15Calibrator 2Cycle 15Cycle 15Cyc	Others	Dispense type 2
Secondary wavelengthNomDirectionIncreaseReagent blank lecture (cycle)30-32 cycleFinal lecture (cycle)30-32 cycleReaction timeclose to 10 mitLinear range3.7-250 ng/mlCALIBRATIONClibration MethodCalibration MethodLinearCalibration set5 calibrators + BlanBlankCalibrator 0 (0 ng/mLCalibrator 1Calibrator 0 (10 ng/mLCalibrator 2Calibrator 1 (10 ng/mLCalibrator 3Calibrator 2 (25 ng/mLCalibrator 4Calibrator 3 (50 ng/mLCalibrator 5Calibrator 5 (250 ng/mLSTEPSIncubation SampleIncubation R1120-180 ng/mLAddition R2Calibrator 5 (250 ng/mLBlank LectureCycle 19Incubation reactioncolos to 30 seCycle 10Cycle 19Calibrator 2Cycle 19Cycle 10Cycle 19Cycle 10Cycle 19Cycle 10Cycle 19Cycle 10Cycle 19Cycle 11Cycle 19Cycle 12Cycle 19Cycle 13Cycle 19Cycle 14Cycle 19Cycle 15Cycle 19 <t< td=""><td>Reaction mode</td><td>End poin</td></t<>	Reaction mode	End poin
DirectionIncreaseReagent blank lecture (cycle)19 cycleFinal lecture (cycle)30-32 cycleReaction timeclose to 10 miLinear range3.7-250 ng/mlCALIBRATIONCalibration MethodCalibration MethodLinearCalibration set5 calibrators + BlaniBlankCalibrator 0 (0 ng/mLCalibrator 1Calibrator 0 (0 ng/mLCalibrator 2Calibrator 1 (10 ng/mLCalibrator 3Calibrator 2 (25 ng/mLCalibrator 4Calibrator 3 (50 ng/mLCalibrator 5Calibrator 5 (250 ng/mLSTEPS120-180Addition R1120-180Addition R2Cycle 19Blank LectureCycle 19Incubation reactionClose to 300 se	Primary wavelength	500 nn
Reagent blank lecture (cycle)19 cycleFinal lecture (cycle)30-32 cycleReaction timeclose to 10 minLinear range3.7-250 ng/mlCALIBRATIONCALIBRATIONCalibration MethodLinearCalibration set5 calibrators + BlanlBlankCalibrator 0 (0 ng/mLCalibrator 1Calibrator 0 (0 ng/mLCalibrator 2Calibrator 1 (10 ng/mLCalibrator 3Calibrator 2 (25 ng/mLCalibrator 4Calibrator 3 (50 ng/mLCalibrator 5Calibrator 5 (250 ng/mLSTEPSStepsAddition R1120-180 (200 gg/mL)Addition R2Calibrator 6 (200 gg/mL)Blank LectureCycle 19Incubation reactionclose to 300 gg/mL)	Secondary wavelength	None
Final lecture (cycle)30-32 cycleReaction timeClose to 10 mirLinear range3.7-250 ng/mlCALIBRATIONCalibrationCalibration MethodLineaCalibration set5 calibrators + BlanlBlankCalibrator 0 (0 ng/mLCalibrator 1Calibrator 0 (10 ng/mLCalibrator 2Calibrator 1 (10 ng/mLCalibrator 3Calibrator 2 (25 ng/mLCalibrator 4Calibrator 3 (50 ng/mLCalibrator 5Calibrator 5 (250 ng/mLSTEPSStepsAddition R1120-180 sAddition R2Calibrator 2 (25 ng/mLBlank LectureCalibrator 3 (20 ng/mLCalibrator 1Calibrator 5 (250 ng/mLCalibrator 5Calibrator 5 (250 ng/mLCalibrator 5Calibrator 5 (250 ng/mLCalibrator 7Calibrator 5 (250 ng/mLCalibrator 8Calibrator 9 (20 ng/mLCalibrator 9Calibrator 9Cal	Direction	Increase
Reaction timeClose to 10 mirLinear range3.7-250 ng/mlCALIBRATIONCalibrationCalibration MethodLinearCalibration set5 calibrators + BlanlBlankCalibrator 0 (0 ng/mLCalibrator 1Calibrator 0 (0 ng/mLCalibrator 2Calibrator 1 (10 ng/mLCalibrator 3Calibrator 2 (25 ng/mLCalibrator 4Calibrator 3 (50 ng/mLCalibrator 5Calibrator 5 (250 ng/mLSTEPSStepsAddition R1120-180 sAddition R2Calibrator 8 (20 ng/mL)Blank LectureCycle 19 (20 ng/mL)Calibrator 9120-180 sCalibrator 9Cycle 19 (20 ng/mL)Calibrator 9Cycle 19 (20 ng/mL) <td>Reagent blank lecture (cycle)</td> <td>19 cycle</td>	Reagent blank lecture (cycle)	19 cycle
Linear range 3.7-250 ng/ml CALIBRATION Calibration Method Linea Calibration set 5 calibrators + Bland Blank Calibrator 0 (0 ng/mL Calibrator 1 (10 ng/mL Calibrator 2 (25 ng/mL Calibrator 3 (50 ng/mL Calibrator 4 (100 ng/mL Calibrator 5 Calibrator 5 (250 ng/mL STEPS Addition R1 Addition R1 Addition R1 Addition R2 Blank Lecture (100 ng/mL Calibrator 6 (20 ng/mL Calibrator 7 (20 ng/mL Calibrator 7 (20 ng/mL Calibrator 7 (20 ng/mL Calibrator 7 (20 ng/mL Calibrator 8 (20 ng/mL Calibrator 9 (20 ng/mL Calibrator	Final lecture (cycle)	30-32 cycle
CALIBRATION Calibration Method Calibration set Elank Calibrator 1 Calibrator 1 Calibrator 2 Calibrator 2 Calibrator 3 Calibrator 3 Calibrator 4 Calibrator 4 Calibrator 5 Cali	Reaction time	close to 10 mi
Calibration MethodLineaCalibration set5 calibrators + BlanBlankCalibrator 0 (0 ng/mLCalibrator 1Calibrator 0 (2 ng/mLCalibrator 2Calibrator 1 (10 ng/mLCalibrator 2Calibrator 2 (25 ng/mLCalibrator 3Calibrator 3 (50 ng/mLCalibrator 4Calibrator 3 (50 ng/mLCalibrator 5Calibrator 5 (250 ng/mLSTEPSCalibrator 5 (250 ng/mLAddition R1120-180Addition R2Calibrator 6 (2 ng/mL)Blank LectureCycle 1:Incubation reactionCalibrator 6 (20 ng/mL)	Linear range	3.7-250 ng/m
Calibration set5 calibrators + BlankBlankCalibrator 0 (0 ng/mL)Calibrator 1Calibrator 0 (0 ng/mL)Calibrator 2Calibrator 1 (10 ng/mL)Calibrator 2Calibrator 2 (25 ng/mL)Calibrator 3Calibrator 3 (50 ng/mL)Calibrator 4Calibrator 3 (50 ng/mL)Calibrator 5Calibrator 4 (100 ng/mL)Calibrator 5Calibrator 5 (250 ng/mL)STEPSAddition R1Addition R1120-180 (100 ng/mL)Addition R2Calibrator 6 (200 ng/mL)Blank LectureCycle 19Incubation reactionClose to 300 se	CALIBRATION	
BlankCalibrator 0 (0 ng/mL)Calibrator 1Calibrator 0 (0 ng/mL)Calibrator 1Calibrator 1 (10 ng/mL)Calibrator 2Calibrator 2 (25 ng/mL)Calibrator 3Calibrator 3 (50 ng/mL)Calibrator 4Calibrator 3 (50 ng/mL)Calibrator 5Calibrator 4 (100 ng/mL)Calibrator 5Calibrator 5 (250 ng/mL)STEPSCalibrator 5 (250 ng/mL)Addition R1120-180 (100 ng/mL)Addition R1+S120-180 (100 ng/mL)Addition R2Calibrator 6 (200 ng/mL)Blank LectureCycle 19 (100 ng/mL)Incubation reactionClose to 300 se	Calibration Method	Linea
Calibrator 1Calibrator 1(10 ng/mLCalibrator 2Calibrator 2(25 ng/mLCalibrator 3Calibrator 2(25 ng/mLCalibrator 4Calibrator 3(50 ng/mLCalibrator 5Calibrator 4(100 ng/mLCalibrator 5Calibrator 5(250 ng/mLSTEPSAddition R1Addition SampleIncubation R1+S120-180Addition R2Cycle 19Blank LectureCycle 19Incubation reactionclose to 300 se	Calibration set	5 calibrators + Blan
Calibrator 2Calibrator 2 (25 ng/mLCalibrator 3Calibrator 2 (25 ng/mLCalibrator 4Calibrator 3 (50 ng/mLCalibrator 4Calibrator 4 (100 ng/mLCalibrator 5Calibrator 5 (250 ng/mLSTEPSSTEPSAddition R1Addition SampleIncubation R1+S120-180Addition R2Calibrator 6 (250 ng/mLBlank LectureCycle 1:Incubation reactionclose to 300 se	Blank	Calibrator 0 (0 ng/mL
Calibrator 3Calibrator 3 (50 ng/mLCalibrator 4Calibrator 4 (100 ng/mLCalibrator 5Calibrator 5 (250 ng/mLSTEPSCalibrator 5 (250 ng/mLAddition R1Addition SampleIncubation R1+S120-180Addition R2Cycle 1Blank LectureCycle 1Incubation reactionclose to 300 se	Calibrator 1	Calibrator 1 (10 ng/mL
Calibrator 4Calibrator 4 (100 ng/mLCalibrator 5Calibrator 5 (250 ng/mLSTEPSCalibrator 5 (250 ng/mLAddition R1Addition SampleIncubation R1+S120-180Addition R2Cycle 19Incubation reactionClose to 300 se	Calibrator 2	Calibrator 2 (25 ng/mL
Calibrator 5Calibrator 5 (250 ng/mLSTEPSAddition R1Addition SampleIncubation R1+SAddition R2Blank LectureIncubation reactionClose to 300 seClose to 300 se	Calibrator 3	Calibrator 3 (50 ng/mL
STEPS       Addition R1       Addition Sample       Incubation R1+S       Addition R2       Blank Lecture       Incubation reaction	Calibrator 4	Calibrator 4 (100 ng/mL
Addition R1Addition SampleIncubation R1+SAddition R2Blank LectureIncubation reactionCycle 19ContractionClose to 300 seContraction	Calibrator 5	Calibrator 5 (250 ng/mL
Addition Sample       Incubation R1+S       Addition R2       Blank Lecture       Incubation reaction	STEPS	
Incubation R1+S 120-180 Addition R2 Blank Lecture Cycle 19 Incubation reaction close to 300 ser	Addition R1	
Addition R2 Blank Lecture Cycle 1 Incubation reaction close to 300 se	Addition Sample	
Blank Lecture Cycle 19 Incubation reaction close to 300 se	Incubation R1+S	120-180
Incubation reaction close to 300 se	Addition R2	
	Blank Lecture	Cycle 1
Final lecture Cycle 30-33	Incubation reaction	close to 300 se
	Final lecture	Cycle 30-3