General Information

Intended use:

Pancreatic Elastase Turbilatex® Combo is a latex turbidimetric assay **only for the quantitative detection of Pancreatic Elastase 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-022EL01 TL-022EL02
Auxiliary Reagents	
Calibration kit	TL-022EL70, TL-022EL71 TL-022EL72 TL-022EL73 TL-022EL74 TL-022EL75
Controls kit	TL-022EL08 TL-022EL09
Sample dilutions vials	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 7 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

Pancreatic Elastase 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 **Pancreatic Elastase Turbilatex® Combo** must be programmed onto the analyzer, see below. For instructions, consult the Cobas c303 (Roche) analyzer manual and instructions for use provided with the kit.

Loading of reagents:

Load reagents according to the Cobas c303 (Roche) analyzer manual.

Calibration curve establishment:

A 6-points calibration curve can be established in Cobas c303 (Roche) 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:

Pancreatic Elastase 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:

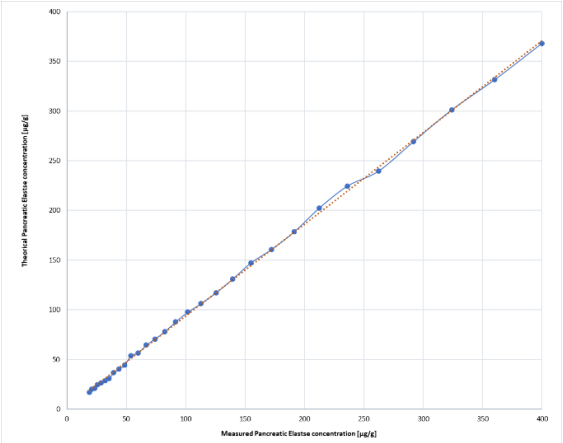
The results are evaluated automatically by the analyzer and presented in µg hEL/g of stool.

Performance characteristics (*)

The following results have been obtained during the validation of **Pancreatic Elastase Turbilatex® Combo** on the Cobas c303 (Roche) analyzer.

Linearity:

Pancreatic Elastase Turbilatex® Combo using calibrator kit is linear in the calibration range of 18.8-400 µg hEL/g of stool.



Measuring range:

Pancreatic Elastase Turbilatex® Combo assay measuring range is 5.3-625 µg hEL/g of stool. Samples more concentrated than 400 µg hEL/g of stool 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 µg hEL/g of stool and no false negative results have been observed. Studies using higher concentrations have not been carried out. Samples with concentrations up to 625 µg hEL/g of stool can be measured without inhibitory prozone effect.

Detection limit:

Limit of detection (LOD): 1.07 µg hEL/g of stool. The lower limit of detection of **Pancreatic Elastase Turbilatex® Combo** was determined on 20 samples and 2 sample replicates as the mean value +2· SD.

Limit of quantification (LOQ): 5.3 µg hEL/g of stool. 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:

Pancreatic Elastase Turbilatex was tested with three different controls levels.

	Low (25 µg/g)	Medium (100 µg/g)	High (400 µg/g)
N	20	20	20
Mean (µg/g)	25.0	101.9	390.6
SD (µg/g)	0.8	1.7	9.4
CV (%)	3	2	2

Method comparison

The following tables provide information on the summary of the evaluations that have been carried out on the product **Pancreatic Elastase Turbilatex® Combo** with a cut-off of 200 µg of hEL/g of stool:

Pancreatic Elastase Turbilatex® vs Evaluation criteria		
	Mean Value	**95% confidence interval**
Sensitivity	89.1%	77.8-95.9%
Specificity	98.4%	94.4-99.8%
PPV	96.1%	86.5-99.5%
NPV	95.4%	90.2-98.3%
LR+	56.13	14.15-222.7
LR-	0.111	0.052-0.236

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.

Cobas c303, Roche/ Application parameters

ASSAY PARAMETERS	
Std. No	6
R1	220 µL
Sample	8 µL
R2	20 µL
Others	Stirring=3
Reaction mode	2-Point End point
Primary wavelength	480 nm
Secondary wavelength	800 nm
Direction	Increase
Reagent blank lecture (cycle)	9 cycle
Final lecture (cycle)	32 cycle
Reaction time	close to 10 min
Linear range	18.8-400 µg/g
CALIBRATION	
Calibration Method	Spline
Calibration set	5 calibrators + Blank
Blank	Calibrator 0 (0 µg/g)
Calibrator 1	Calibrator 1 (25 µg/g)
Calibrator 2	Calibrator 2 (50 µg/g)
Calibrator 3	Calibrator 3 (100 µg/g)
Calibrator 4	Calibrator 4 (200 µg/g)
Calibrator 5	Calibrator 5 (400 µg/g)
STEPS	
Addition R1	
Addition Sample	
Incubation R1+S	120-180 s
Addition R2	
Blank Lecture	9 cycle
Incubation reaction	close to 300 sec
Final lecture	32 cycle