

## General Information

### Intended use:

Pancreatic Elastase Turbilatex is a latex turbidimetric assay only for the quantitative detection of Pancreatic elastase E1 in human stool samples.

This assay is simple and widely applicable. This product is optimized for several automated analyser.

Test results should exclusively be used to evaluate exocrine pancreatic function in stool samples.

For professional *in vitro* diagnostic use only.

Pancreatic Elastase 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)	R1: 2 vials, 2x24 mL	TL-022EL01
200 Def/kit	R2: 1 vial, 1x6 mL	TL-022EL02
<b>Auxiliary Reagents</b>		
Calibration kit	Calibrator: 6 vials, 6x1 mL.	TL-022EL70, TL-022EL71 TL-022EL72 TL-022EL73 TL-022EL74 TL-022EL75
Controls kit	Control C1, 2 vials, 2x1 mL/vial. Control C2, 2 vials, 2x 1 mL/vial.	TL-022EL08 TL-022EL09
Sample diluent kit	4 vials, 4x125 mL/vial	TL-022UN03E
Sample dilutions vials	1x2.4 mL/vial 1x2 mL/vial	MST-0019U MST-0018MU

### 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 7 days prior to testing. For longer storage, maximum 6 months, the specimen must be kept frozen at -20°C. In this case, the sample will be totally thawed, and brought to room temperature (15-30°C) before testing. Freezing and thawing cycles are not recommended. Homogenise stool samples as thoroughly as possible prior to preparation.

Use Pancreatic Elastase Turbilatex sample collection vials for sample collections described the instructions for use.

## Assay procedure

### Application parameter set up:

Specific analyzers settings for Pancreatic Elastase Turbilatex must be programmed onto the analyzer, see below. For instructions, consult the Cobas c501 (Roche) analyzer manual and instructions for use provided with the kit.

### Loading of reagents:

Load reagents according to the Cobas c501 (Roche) analyzer manual.

### Calibration curve establishment:

A 6 point calibration curve can be established in Cobas c501 (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 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:

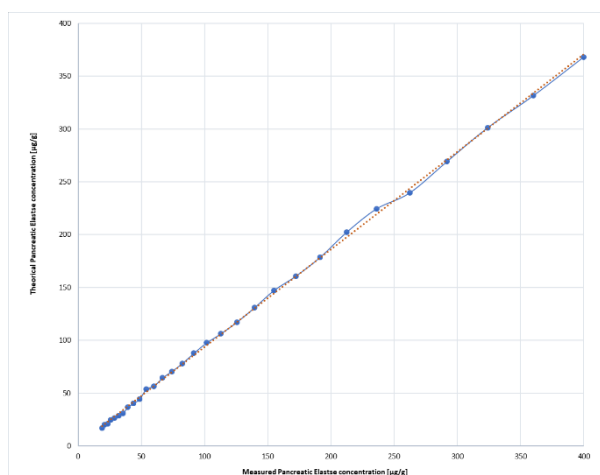
The results are evaluated automatically by the analyzer and presented in µg hEL/g of stool.

## Performance characteristics

The following results have been obtained during the validation of Pancreatic Elastase Turbilatex on the Cobas c501 (Roche) analyzer.

### Linearity:

Pancreatic Elastase Turbilatex on Cobas c501 (Roche) analyzer using calibrator kit is linear in the calibration range of 0-400 µg hEL/g of stool.



### Measuring range:

Pancreatic Elastase Turbilatex assay measuring range is 5.3-10000 µg hEL/g of stool on Cobas c501 analyzer. Samples higher concentrated than 400 µg hEL/g of stool 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 10000 µg hEL/g of stool. Samples with Pancreatic Elastase concentration of 10000 µg hEL/g of stool give a typical positive result >400 µg hEL/g.

### Detection limit

**Limit of detection (LOD): 1.07 µg hEL/g of stool \***. The lower limit of detection of Pancreatic Elastase Turbilatex 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% on the Cobas c501 (Roche) analyzer.

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

### Precision

Pancreatic Elastase Turbilatex was tested with three different controls levels.

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

### Method comparison

Results obtained with Pancreatic Elastase Turbilatex on the Cobas c501 (Roche) analyzer were compared with a commercial immunoassay (Schebo® Pancreatic Elastase 1).

	<b>Sensitivity</b>	<b>Specificity</b>
<b>Schebo® Pancreatic Elastase 1</b>	<b>100%</b>	<b>93%</b>

### Shipping damage

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

### Symbols key

	For in vitro diagnostic use only		Keep dry
	Consult instructions for use		Temperature limitation
	Catalogue number		Lot number
	Use by		Manufacturer
	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.**

**Cobas c501 (Roche)/Application parameters**

<b>ASSAY PARAMETERS</b>	
Std. No	6
R1	220 µL
Sample	8 µL
R2	20 µL
Others	NA
Reaction mode	2 point end
Primary wavelength	480 nm
Secondary wavelength	800 nm
Direction	Increase
Reagent blank lecture (cycle)	12
Final lectura (cycle)	47
Reaction time	10 min
Linear range	0-400 µg/g
<b>CALIBRATION</b>	
Calibration Method	Spline
Calibration set	5 calibrators + Blank
Blank	Calibrator 1 (0 µg/g)
Calibrator 1	Calibrator 2 (25 µg/g)
Calibrator 2	Calibrator 3 (50 µg/g)
Calibrator 3	Calibrator 4 (100 µg/g)
Calibrator 4	Calibrator 5 (200 µg/g)
Calibrator 5	Calibrator 6 (400 µg/g)
<b>STEPS</b>	
Addition R1	
Addition Sample	
Incubation	
Addition R2	
Blank Lecture	Cycle 12
Incubation	
Final lecture	Cycle 47