Application Note

Pancreatic Elastase Turbilatex, Architect c1000/c2000/c4000/c16000, Abbott

(AN-EL-Architect. EN rev2020.06.22)

For *in vitro* diagnostic device
ENGLISH

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) 200 Det/kit	R1: 2 vials, 2x17 mL R2: 1 vial, 1x32 mL	TL-022EL01 TL-022EL02
Auxiliary Reagents		
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 dilutions vials	1x2 mL/vial	MST-0021E MST-0022ME

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.

Performance characteristics

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 (2-8ºC) for 7 days prior to testing. For longer storage, maximum 6 months, the specimen must be kept frozen at -20ºC. In this case, the sample will be totally thawed, and brought to room temperature (15-30ºC) 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 Architect c1000/c2000/c4000/c16000 (Abbott) analyzer manual and instructions for use provided with the kit.

Loading of reagents:
Load reagents according to the Architect c1000/c2000/c4000/c16000 (Abbott) analyzer manual.

Calibration curve establishment:
A 6 point calibration curve can be established in Architect c1000/c2000/c4000/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:
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.

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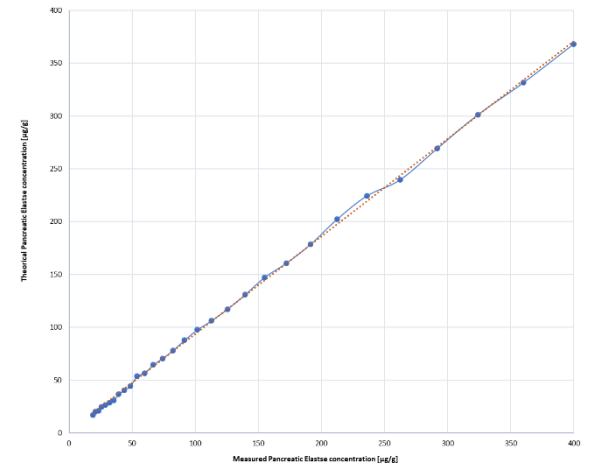
The following results have been obtained during the validation of Pancreatic Elastase Turbilatex on the Architect c1000/c2000/c4000/c16000 (Abbott) analyzer.

Linearity:
Pancreatic Elastase Turbilatex on Architect c1000/c2000/c4000/c16000 (Abbott) 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 3.2-1250 µg hEL/g of stool on Architect c1000/c2000/c4000/c16000 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 1250 µg hEL/g of stool. Samples with Pancreatic Elastase concentration of 1250 µg hEL/g of stool give a typical positive result >400 µg hEL/mL.

Detection limit
Limit of detection (LOD): 1.5 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): 3.2 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 Architect c1000/c2000/c4000/c16000 (Abbott) analyzer.

Precision
Pancreatic Elastase Turbilatex was tested with three different controls levels.

	Low (50 µg/g)	Medium (100 µg/g)	High (400 µg/g)
N	20	20	20
Mean (µg/g)	47.2	106.1	408.5
SD (µg/g)	2.4	4.6	13.9
CV (%)	5.1	4.3	3.4

Method comparison

Results obtained with Pancreatic Elastase Turbilatex on the Architect c1000/c2000/c4000/c16000 (Abbott) analyzer were compared with a commercial immunoassay (Pancreatic Elastase 1 Quick®, Schebo).

	Sensitivity	Specificity
Pancreatic Elastase 1 Quick®	95%	>99%

Shipping damage

Please notify your distributor, it 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 instruction for use for the detailed information about the test on the following:
Synthesis; Principle; Precautions; Reagents; Specimen collection; Interpretation of results.

Architect c1000/c2000/c4000/c16000 (Abbott)/Application parameters

ASSAY PARAMETERS	
Std. No	6
R1	100 µL
Sample	4 µL
R2	90 µL
Others	NA
Reaction mode	End point
Primary wavelength	450 nm
Secondary wavelength	None
Direction	Increase
Self blank	19 cycle
Final Lecture	30-32 cycle
Reaction time	10 min
Linear range	0-400 µg/g
CALIBRATION	
Calibration Method	Linear
Calibration set	6 calibrators
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)
STEPS	
Addition R1	
Addition Sample	
Incubation	5 min
Addition R2	
Blank Lecture	
Incubation	5 min
Final lecture	