

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 Def/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	1x2.4 mL/vial 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.

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 TC220 (Tecom) analyzer manual and instructions for use provided with the kit.

Loading of reagents:

Load reagents according to the TC220 (Tecom) analyzer manual.

Calibration curve establishment:

A 6 point calibration curve can be established in TC220 (Tecom) 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:

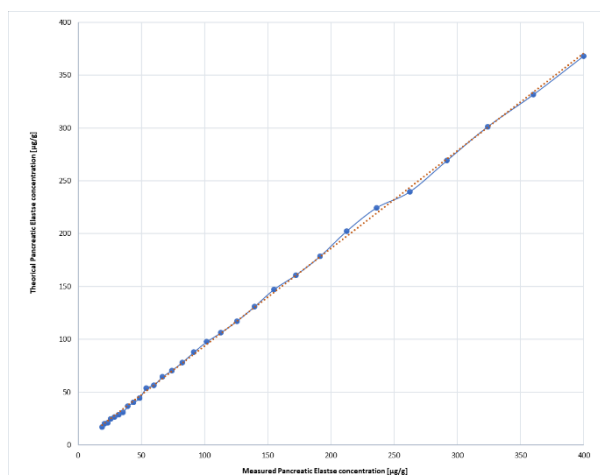
The results are evaluated automatically by the analyzer and presented in µg hEL/g of stool.

Performance characteristics

The following results have been obtained during the validation of Pancreatic Elastase Turbilatex on the Alinity c-series (Abbott) analyzer.

Linearity:

Pancreatic Elastase Turbilatex on TC220 (Tecom) 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 TC220 (Tecom) 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/g.

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 TC220 (Tecom) analyzer.

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

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)	47.3	102	392
SD (µg/g)	2.6	4.4	15
CV (%)	5.5	4.3	3.8

Method comparison

Results obtained with Pancreatic Elastase Turbilatex on the analyser Biolis 24i (Tokyo Boeki) 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, 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.

TC220 (Tecom)/Application parameters

ASSAY PARAMETERS	
Std. No	6
R1	150 µL
Sample	10 µL
R2	15 µL
Others	NA
Reaction mode	Two Points
Primary wavelength	510 nm
Secondary wavelength	None
Direction	Increase
R1 incubation	10 seg after R2 addition
R2 incubation	300 seg after R2 addition
Check time	360 s
Linear range	0-400 µg/g
CALIBRATION	
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)
STEPS	
Addition R1	0 s
Addition Sample	120 s
Incubation	
Addition R2	220 s
Blank Lecture	230 s
Incubation	
Final lecture	530 s

TC Series Automatic Chemistry Analyzer----- Temp. Cubetas:36,94

Test | Informes | QC | AJUSTES | Detener | Salir

Test Bioq. | Otros Parametros | Param. Calculados | Ajuste Perfiles | Secuencia Ensayo | Secuencia Impresion

Item: CALP2, TF, HPylori, FOBh, **ELASTASA**

Simbolo: ELASTASA Nombre: Elastasa pancreatica Cod. de barras Param.Basicos Param.Calibracion

metodo: Two Points 1ª Long.O. 405 2ª long.O. NO Decimal 1 Und. ug/g (Rtvo.1+Rtvo.2)+S

Rtvo.1 Vol.(10-400ul) 150 Incub.Rtvo. 60 Rtvo.1 Pos. 6 Vol. Del envase 20 ml 2ª posicion 0

Rtvo.2 Vol.(0-400ul) 100 Rtvo.2 Pos. 7 Vol. Del envase 20 ml 2ª Posicion 0

S Vol.(1.0-50.0ul) 3,0 Incub.Rtvo. 20 Vel. de Mezcla 0 Tiempos de reaccion 10 Check Time(s) 360

Rango Linealidad 0 — 400 Correccion de resultados 1,0000 X + 0,0000 ratio de Dilucion (2-150) 10

Absorbance Range -5,0 — 10,0 Agotamiento de Sustrato < 10,0 Vol. Muestra (3-70) 15

Lim. de Linealidad 10 Juicio de valor Alto Discrepancia P 10 ctado en la Pendiente = 0 Vol. Total (120-500) 150

Blank read Point offset 0 Ratio de Dilucion 1.9

test blanco Reactivo Blanco de Rtvo. 0,0 — 10,0 Blanco Reactivo 0,3765

Fabricante Certest Biotec No. Lote 200EDEL000 Caducidad 31/01/2021

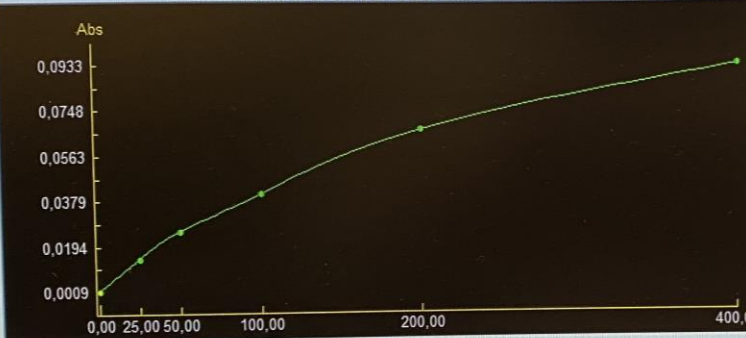
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Informes | QC | AJUSTES | Detener | Salir

Otros Parametros | Param. Calculados | Ajuste Perfiles | Secuencia Ensayo | Secuencia Impresion

Simbolo: ELASTASA Nombre: Elastasa pancreatica Cod. de barras Param.Basicos Param.Calibracion



Nº Std 6 Nº de Rept. 2

Calibracion Spline

Lot 67EL004

Caducidad 31/01/2021

Dilucion

K 0,0 El orden de posicion de los Stds. Deberá ser de MENOR a MAYOR, de lo contrario no se calibrara

R0 0,000872728

a 0,000552106

b -0,000000954

c -0,0000000005

d 0,0 Hª de Calib Recalc.

	1	2	3	4	5	6
Posicion Std	1	2	3	4	5	6
Valor Std	0	25,0	50,0	100,0	200,0	400,0
Absorbancia	0,0009	0,0140	0,0254	0,0406	0,0671	0,0933

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