Pancreatic AMYLASE EPS

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Blocked Method

R1: 4 x 25 ml + R2: 1 x 25 ml CL40-125

INTENDED USE

Kit for the determination of pancreatic α-amylase in serum, plasma and urine.

CLINICAL MEANING

The test is performed to diagnose an acute pancreatitis or the exacerbation of a chronic pancreatitis; to differentiate pancreatitis from other forms of abdominal pain; to evaluate a possible pancreatic damage following abdominal trauma.

PRINCIPLE

α-amylase enzyme hydrolyzes blocked p-nitrophenyl-maltoheptaoside (blocked EPS) in glucose and p-nitrophenyl-oligosaccharides polymers. α-glucosidase enzyme hydrolyzes the latter ones into glucose and p-nitrophenol. As the salivary isoenzyme is inhiboted by two monoclonal antibodies, the absorbance increase at 405 nm defines the pancreatic α-amylase activity in the sample.

SAMPLE

EDTA or heparinized serum or plasma.
Urine, diluted 1:3.
STABILITY: 7 days at 2-8°C.

REAGENTS

Only for in Vitro diagnostics. Liquid reagents ready to use.

Kit components:	**CL40-125**
REAGENT 1 Good buffer pH 7.1, α-glucosidase > 2 KU/L, Monoclonal Antibodies	4 x 25 ml
REAGENT 2 Good buffer pH 7.1, EPS 1.6 mmol/L	1 x 25 ml

STABILITY: stored at 2-8°C and away from light, reagents are stable up to the expiration date on the label.

NECESSARY ITEMS – NOT PROVIDED

Usual laboratory equipment: UV/VIS Spectrophotometer with temperature control; automatic micropipettes; Optical glass cuvettes or, alternatively, disposable ones in optical polystyrene; Saline solution.

MANUAL ASSAY PROCEDURE

Wavelength:	405 nm
Optical path:	1 cm
Reading:	against air or distilled water
Temperature:	37°C
Method:	kinetic
Sample/Reagent:	1/50/12.5

BI-REAGENT PROCEDURE

Let the necessary reagents reach 15-25°C.

NOTE: saliva and sweat contains amylase, hence avoid any contamination with these biological liquids. Do not pipette by mouth and avoid any reagent contact with skin. Use perfectly clean and rinsed material, disposable is recommended.

Pipette into cuvettes:

	Serum/ Plasma	Urine
Reagent 1	1.0 ml	1,0 ml
Sample	20 µl	10 µl

Mix, incubate for 5 minutes at the 37°C, then add:

Reagent 2	250 µl	250 µl

Mix, read absorbance after 2 minutes (37°C) and start timer.
Read absorbance after 1, 2 and 3 minutes.

CALCULATION

Calculate the absorbance reading average per minute (ΔA/min) and define the enzymatic activity value of the sample using the following formula:

Pancreatic α-amylase [U/L] = ΔA/min x 5670

REFERENCE VALUES

	Women	Men
Siero/Plasma	<53 U/L	<53 U/L
Urine	<319 U/L	<356 U/L

Each laboratory should define its own reference values.

QUALITY CONTROL – CALIBRATION

All Clinical Chemistry laboratories should implement a quality control program. Control serums of human origin are available for this purpose on request:

PRE-NORM serums with normal values
PRE-PATH serums with pathological values

If the method requires it, a multiparameter calibrator of human origin is available. Contact FAR for further information.

PERFORMANCE CHARACTERISTICS

Sensitivity: 3 U/L.
Linearity: up to 1500 U/L.
For higher values, dilute the sample with saline solution and multiply the result by the dilution factor.
Precision:

Within run (n=10)	Average [U/L]	SD	CV %
Sample 1	34	0,286	0,84
Sample 2	89	0,83	0,93

Between run (n=20)	Average [U/L]	SD	CV %
Sample 1	36	0,654	1,81
Sample 2	83	1,85	2,23

Interferences: up to 30 mg/dl of ascorbic acid does not interfere. Up to 40 mg/dl of bilirubin does not interfere. Lipemia up to 1000 mg/dl of triglycerides does not interfere. Hemoglobin interferes even at low concentrations.
Correlation against a reference method: the correlation of FAR method (x) against a reference method (y) gave the following results (on 95 samples):
n = 95

$y = 1{,}03x - 8.7612$ $r^2 = 0.995$

DISPOSAL

The product must be used for professional analysis only. The product must be disposed of according to national/international laws.

WARNINGS AND PRECAUTIONS

The reagents may contain non-reactive components and various preservatives. Contact with the skin and ingestion should be avoided. Use the normal precautions expected with correct behavior in laboratory.

REFERENCES

1. Dupuy G. et al. (Clin. Chem. 33/4, 524-8:1987)
2. Lent R.W. et Karmen A. (Clin Chem.32/6, 1132-3; 1986).

MANUFACTURER

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KEY SYMBOLS

IVD	In Vitro diagnostic medical device
LOT	batch number
REF	catalog number
	temperature limits
	use by
	caution
	consult accompanying documents

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