AMYLASE CNPG3

Kinetic method

6 x 10 ml CL05-60
6 x 25 ml CL05-150

INTENDED USE

Kit for quantitative determination of α-Amylase (EC 3.2.1.1.) in serum and plasma.

CLINICAL MEANING

Amylase is an enzyme produced by pancreas: it helps with the digestion of plant-derived sugars (starch) found in food. Measuring amylase levels is especially useful to verify the correct function of pancreas or to diagnose the presence of inflammation (acute pancreatitis) and other issues of this organ.

PRINCIPLE

α-amylase hydrolizes 2-chloro-4-nitrophenyl-α-D-maltotrioside (CNPG3) into 2-chloro-4-nitrophenyl-α-D-maltoside (CNPG2), maltotriose (G3), glucose and 2-chloronitrophenol. The absorbance change in unit time measured at 405 nm is proportional to the enzyme activity in the sample.

SAMPLE

Serum, heparinized plasma. Do not use other anticoagulants like EDTA, citrate and oxalate as they inhibit the enzyme. Avoid hemolyzed samples.
STABILITY: more than 1 week at 20-25°C and several months at 2-8°C.

REAGENTS

Only for in Vitro diagnostics. Liquid mono-reagent ready to use.

Package content	CL05-60	CL05-150
REAGENT 1 MES buffer (pH 6,0) 75 mmol/L, CNPG3 1,7 mmol/L, sodium chloride 250 mmol/L, calcium acetate 4,5 mmol/L, potassium thiocyanate 0,65 mol/L, sodium azide 15 mmol/L	6 x 10 ml	6 x 25 ml

Stability: the reagent is ready to use. Store at 2-8°C and protect from light to keep the reagent stable up to the expiration date on the label. Do not freeze. Once opened the reagent is stable for 2 months at 2-8°C, if contamination is avoided. Keep bottles closed when not in use.

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:	increasing kinetic
Reaction Time:	3 minutes
Sample/Reagents Ratio:	1/40

Bring the reagents necessary for the test to the chosen temperature for the analysis.
NOTE: saliva and sweat contain 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 in cuvette:

Sample	25 µl
Reagent	1,0 ml

Stir and incubate at 37°C for 1 minute. Read initial absorbance, repeat reading at constant intervals of 1 minute for 3 minutes. Calculate the average value of the absorbance variations per minute (ΔA/min).

Reaction volumes can be proportionally varied without any change.

CALCULATION

Calculate the enzymatic activity in the sample using the following formula:
α-amylase [U/L] = ΔA/min x 3178

REFERENCE VALUES

Serum / plasma: 25 ÷ 98 U/L

Each laboratory should define its own reference values for this method.

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 multi-parametric calibrator of human origin is available.

PERFORMANCE CHARACTERISTICS

Sensitivity: the sensitivity of the method is 2 U/L.

Linearity: up to 2000 U/L (at 37°C).
For higher values, dilute the sample 1:10 with saline solution and multiply the result by 10.

Precision

Within run (n=10)	Average [U/L]	SD	CV %
Sample 1	77,8	1,3	1,7
Sample 2	199,4	5,46	2,7

Between run (n=20)	Average [U/L]	SD	CV %
Sample 1	76,6	2,03	2,7
Sample 2	196	5,39	2,75

Interferences: up to 30 mg/dl of bilirubin does not interfere. Lipids do not interfere up to 2000 mg/dl of triglycerides. Up to 100 mg/dl do of haemoglobin does not interfere.
Correlation against a reference method: the correlation of the FAR method X against a reference method Y gives this equation:
n=95

Y = 0,9832 x – 0,0883 mg/dl r = 0,999

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 behaviour in laboratory.

DISPOSAL

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

REFERENCES

1 Kaufman R.A., Tietz N.W., Clin. Chem. 26: 846, (1980)
2 Young D.S., Pestaner L.C., Gibberman V., Clin. Chem. 21: 1D, (1975)
3 Kaplan LA, Pesce AJ: "Clinical Chemistry", Mosby Ed. 1989
4 NCCLS Document, "Procedures for the collection of arterial blood specimens", Approved Standard, 3rd Ed. (1999).
5 EU-Dir 1999/11 Commission Directive of 8 March 1999 adapting to technical progress the principles of good laboratory practice as specified in Council Directive 87/18/EEC

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KEY SYMBOLS

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

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