ALPHA-AMYLASE

Kinetics determination of α-amylase in serum and plasma

TEST SUMMARY

α-amylase hydrolizes the 2-chloro-4-nitrophenyl-α-D-maltotrioside (CNP-G3) to release 2-chloro-4-nitrophenol (CNP) and form 2 –chloro-4-nitrophenyl-α-D-maltoside (CNP-G2), maltotriose (G3) and glucose (G). The rate of CNP formation, can be spectrophotometrically measured at 405 nm to give a measurement of α-amilase in serum.

SAMPLES

Serum not hemolized, plasma (heparinate only) or urine.
Stability: 1 week at 2-8°C or 1 months at -20°C.

REAGENTS

Sole Reagent: CNP-G3 2.3 mM, NaCl 350 mM, calcium acetate 6 mM, potassium thyocianate 600 mM, Good buffer pH 6.0 100 mM, preservatives and stabilizers.

MATERIAL REQUIRED BUT NOT SUPPLIED

Normal laboratory equipment. Spectrophotometer UV/VIS with thermostatation. Automatic Micropipette. Cuvette in optical glass or monouse in optical polystyrene. Physiologic solution.

PRECAUTIONS

Reagent may contain not reactive and conservative components. It is opportune to avoid contacts with the skin and do not swallow.
Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

REAGENTS PREPARATION

Reagent is supplied in liquid form ready to use.
Stability: until expiration date on label stored at 2-8°C away from direct light source.
Stability after firs opening: ≥ 60 days at 2-8°C.

PROCEDURE

Kind of analysis:	Kinetics (increasing)
Delay:	60 sec.
Reading time:	1,2,3 minutes
Wavelength:	405 nm
Temperature:	37°C
Lightpath:	1 cm
Zero:	Distilled Water

REAGENTS	CUVETTE
Sole Reagent	1 ml
Preincubate at 37 °C at least for 5 minutes	
Sample	25 µl

CALCULATION

Activity in U/l ΔA/min x 3178

Activity in µkat/l U/l x 0.0167

EXPECTED VALUES

Serum-plasma: < 96 U/l (< 1.60 µkat/l)
Spontaneous urine: < 480 U/l (< 8.00 µkat/l)

Every laboratory should establish own reference intervals in accordance with own population.

NOTES

- If the results are incompatible with clinical presentation, they have to be evaluated within a total clinical study.
- Only for IVD use.

CALIBRATION/QUALITY CONTROL

It is suggested to perform an internal quality control. For this purpose the following control sera on human base are available on request:

QN 0050 CH **10 x 5 ml**
Control Sera normal values

QP 0050 CH **10 x 5 ml**
Control Sera pathological values

TEST PERFORMANCE

Precision
The analysis underline intra-assay CV ≤ 1.5% and inter-assay CV ≤ 2.5%.

Sensitivity/limit of detection
The method is able to discriminate until 2,5 U/l.

Linearity
The method is linear up to 1500 U/l.
If ΔA/min of 0.500 is exceeded, it is suggested to dilute the sample 1+9 with saline and to repeat the test, multiplying the results by 10.

Methods comparison
A comparison with a commercial available product gave the following results:

α-amylase LTA = x
α-amylase competitor = y

y = 0,9348x + 3,9668 r = 0,9795

Interferences
No interference was observed by the presence of :

hemoglobin	≤ 500 mg/dl
bilirubin	≤ 39 mg/dl
lipids	≤ 1500 mg/dl

WASTE DISPOSAL

Product is intended for professional laboratories. Waste products must be handled as per relevant security cards and local regulations.

PACKAGING

CODE CC00300 **(200 TESTS)**
Sole Reagent 4 x 50 ml (liquid)

REFERENCES

Ranson, JHC. Curr Prob Surg 1979; 16:1.
Salt WB II, Schenker S. Medicine 1976; 55:269.
Stefanini P; Ermini M; Carboni M. J Am Surg 1965; 110:866.
Henry RJ, Chiarori N. Clin Chem 1960; 6:434.
Kaufman RA; Telz NW. Clin Chem 1980; 28:846.
Blair HE. U.S. Patent No. 4.649,108.
Chavez RG et al. U.S. Patent 4,963,479.
Demetriou J et al. Clinical Chemistry 1974 ; Principles and Techniques, 2nd Ed, Harper & Row.
Young OS, Pestaner LC, Gibberman V. Clin Chem 1975; 21:10.

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SYMBOLS

IVD	Only for IVD use
LOT	Lot of manufacturing
REF	Code number
	Storage temperature interval
	Expiration date
	Warning, read enclosed documents
	Read the directions
	Biological risk

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