

ALPHA-AMYLASE

Kinetics determination of α -amylase in serum and plasma

TEST SUMMARY

α -amylase hydrolyzes the 2-chloro-4-nitrophenyl- α -D-maltotriose (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 -amylase in serum.

SAMPLES

Serum not hemolyzed, 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 thiocyanate 600 mM, Good buffer pH 6.0 100 mM, preservatives and stabilizers.

MATERIAL REQUIRED BUT NOT SUPPLIED

Normal laboratory equipment. Spectrophotometer UV/VIS with thermostatisation. 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 first 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 μ l

CALCULATION

Activity in U/l $\Delta A/\text{min} \times 3178$

Activity in $\mu\text{kat/l}$ $U/l \times 0.0167$

EXPECTED VALUES

Serum-plasma: < 96 U/l (< 1.60 $\mu\text{kat/l}$)
Spontaneous urine: < 480 U/l (< 8.00 $\mu\text{kat/l}$)

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 $CV \leq 1.5\%$ and inter-assay $CV \leq 2.5\%$.

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 $\Delta A/\text{min}$ 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

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

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