

BioMed- AMYLASE SL



Kinetic method

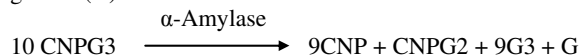
REF: AMY126060 (10 x 6 ml)

INTENDED FOR USE:

For the quantitative determination of α -Amylase in serum, plasma and urine

PRINCIPLE :

α -Amylase hydrolyzes the 2-chloro-p-nitrophenyl- α -D-maltotrioside (CNPG3) to release 2-chloro-nitrophenol and form 2-chloro-p-nitrophenyl- α -D-maltoside (CNPG2), maltotriose(G3) and glucose(G).



The rate of increase in absorbance is measured at 405nm and is proportional to the α -Amylase activity in the sample.

SPECIMEN COLLECTION:

Serum, plasma with heparin.

Urine24/h: Urine must be diluted at 1:3 with physiological solution.

Note: Amylase is contained in saliva and sweat so avoid pipetting with mouth ; avoid sample and reagent contamination using gloves.

Do not utilize hemolyzed sample.

α -Amylase activity in serum or plasma is stable for one week at +2/8°C, and one month at -20°C.

Shake and bring the samples at room temperature (+15/25°C) before using.

REAGENTS COMPOSITION:

Reagent (A) Zn	Good's Buffer	100mmol/L
Liquid	CNPG3	3.1mmol/L
Vol. = 2x50mL	Sodium Chloride	300mmol/L
	Calcium Acetate	6mmol/L
	Potassium thiocyanate	<10%

PACKAGE : Collection and Storage .

Store at +2/8°C .

Stable until the expiration date reported upon the package.

After the unsealing and the taking of the reagent , it is advised to close up the bottle immediately in order to avoid evaporation , direct light exposure and bacteric contamination .

PRECAUTION & WARNING:

Avoid pipette with mouth.

The preparation, according to current regulation, is classified as not dangerous.

The total concentration of non active components (preservatives, detergents, stabilizers) is below the minimum required for citation. Anyway handle with care, avoid ingestion, avoid contact with eyes, skin and mucous membranes. The samples must be handle as potentially infected from HIV or Hepatitis material.

REAGENT PREPARATION & STABILITY :

Before using, the liquid reagent must be at room temperature (+15-25°C).

The Reagent is limp and colourless.

Stability is indicated on the label

REQUIRED MATERIALS NOT PROVIDED :

General Laboratory Equipment and instrumentations.

PROCEDURE :

Wavelength 405 nm
Optical path : 1 cm light path
Temperature : 37°C
Reading : Against distilled water
Assay type : Increasing Kinetic
Sample/reagent Ratio: 1/50

Procedure : Pipetting in tubes :

	SAMPLE	
Reagent (A)	1000	μ L
Sample	20	μ L

Adjust the instrument to zero with distilled water.

Mix and transfer in cuvette; incubate for 1min at 37°C.(T.0 sec); read sample extinction at time 0 sec and after 60/120/180 sec.

Calculate $\Delta E/\text{min}$. at 405nm.

Volumes can be proportionally modified.

This methodology describes the manual procedure to use the kit.

For automated procedure, ask for specific application

CALCULATION :

α -Amylase (U/L) = $\Delta E/\text{min} \times 3805$

Factor is referred to a temperature of 37°C.

EXPECTED VALUES AT +37°C :

Serum and plasma:	25 – 110 U/L	=====
Urine:	< a 480U/L	=====

the above mentioned values are to be considered as a reference.

It is strongly recommended that each laboratory establish its own normal range according to its geographic area , according to IFCC protocol .

WASTE DISPOSAL :

Do not dispose in the environment owing to potassium thiocyanate.

The disposal of the product must be in accordance with local regulation concerning waste disposal.

QUALITY CONTROL :

It is recommended to execute the quality control at every kit utilization to verify that values are within the reference range indicated by the methodology.

REFERENCES :

- 1)Henry, R.J., Chiamori, N., Clin. Chem., 6:434, (1960)
- 2)Winn-Deen et Al., Clin. Chem. 24-10 (1989)
- 3)Lorentz, K., Clin. Chem. Clin. Biochem. 17,499 (1979)
- 4)Vassault,A. et al. Ann.Biol.Clin.,44,686,(1986).
- 5)Tietz,N.W.,Fundamentals of Clinical Chemistry, Philadelphia, W.B.Saunders Company,p.627 (1982).

PERFORMANCE : (COBAS MIRA ANALYZER)

MEASURE INTERVAL INEARTITY :	2.5 - 2000 U/L
DETECTION LIMIT (2DS):	2.5 U/L
SENSITIVITY:	1 U/L= 0.00072ΔE/min

INTER-ASSAY PRECISION: n=20

LOW LEVEL	M=106 U/L	C.V.=1.81%
HIGH LEVEL	M=418 U/L	C.V.=1.33%

INTER-ASSAY PRECISION: n=20

LOW LEVEL	M= 109 U/L	C.V.=2.1%
HIGH LEVEL	M= 421 U/L	C.V.=1.3%
INTER.ANALYZED	32-2112U/L	
CORRELATION	r = 0.97	n=10
LIN. REGRESSION	y= 0.983 x- 3.4	n=10

INTERFERENCE: (In Accordance With Raccomandation SFBC)






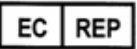



Interferences are negligible up to :			
Glucose	500mg/dL	Bilirubin	39mg/dL
Triglicerides	1500mg/dL	Hemoglobin	500mg/dL

LIMITATIONS:

The presence of macro amylase in the specimen can cause a measured hyper amylasemia, which could lead to a false diagnosis of acute pancreatitis.

However, no clinical symptoms are usually associated with macro amylasemia.⁵

For concentration higher than 2000U/L , repeat the measure on a sample diluted 1:2 with saline solution e multiply the results × 2. For a thorough evaluation of the interfering substances, consult: Young, D.S.,et al.,Clin.Chem. 21:1D (1975)

	Consult Instructions for Use
	Caution, consult accompanying Documents
	In Vitro Diagnostic Medical Device
	Temperature limitation
	Manufacturer
	Authorized Representative in the European Community
	Catalogue number
	Batch code
	Use by

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