

α - AMYLASE - L (Single Liquid)

[KINETIC METHOD]

ENZOPAK

Last update 09-2020

Ref. CC3-AMY.03M, 2x10 ml
CC3-AMY.3MU 2x25 ml

INTENDED USE

Reagent kit for quantitative estimation of α -Amylase in serum or plasma

PRODUCT HIGHLIGHTS

- Colorimetric/Spectrophotometric (405 nm) Kinetic Reagent.
- Latest Technology with (GAL- G₂ - CNP) Substrate.
- Stable Reagent.

INTRODUCTION

α -Amylase catalyses the hydrolysis of 1-4 glucosidic linkages of starch and other related polysaccharides to produce maltose and other oligosaccharides. The enzyme is a relatively small molecule which is rapidly cleared by the kidneys and excreted in the urine.

α -Amylase uses Blocked α -(2-Chloro-4-Nitrophenyl) β -1,4-Galactopyranosyl maltoside (GAL-G₂- CNP) as a substrate and does not require coupling of other enzymes and therefore gives a very stable substrate reagent.

α -Amylase gives an excellent correlation to other blocked substrates technology and a linear response to both pancreatic and salivary amylase.

DIAGNOSTIC SIGNIFICANCE

Amylase is mostly measured for the diagnosis of acute pancreatitis wherein serum levels are found to be elevated. In acute pancreatitis α -Amylase starts rising approximately four hours after the onset of pain, reaches peak at 24 hours and remains elevated for 3 to 7 days. High levels of amylase are also associated with other disorders, like biliary tract diseases, severe glomerular dysfunction and salivary gland disorders and ruptured ectopic pregnancy.

PRINCIPLE

α -Amylase uses a chromogenic substrate Gal-G₂- CNP which, by the reaction of α -Amylase breaks down to release 2-Chloro-4-Nitrophenol (CNP).



The release of 2-Chloro-4-Nitrophenol (CNP) is measured at 405 nm and is proportional to α -Amylase activity.

PRESENTATION

	No. of Bottles	
	2 x 10 ml.	2x25 ml.
Amylase-L (Substrate)	2	2

FINAL REAGENT COMPOSITION

Active Ingredients	Concentration
• Buffer	100 mmol/L
• Calcium Acetate	3 mmol/L
• CNPG-3	2 mmol/L

pH 6.0 \pm 0.1 at 25°C

Also contains non-reactive fillers and Stabilizers.

PRECAUTION

Amylase is for *IN-VITRO* diagnostic use only.

Reagent contains Sodium Azide. DO NOT INGEST.

REAGENT STORAGE AND STABILITY

α -Amylase reagents are stable until the expiry date stated on the label when stored at 2-8°C. Opened vial is stable for 4 weeks at 2-8°C.

SPECIMEN COLLECTION

Serum or heparinised plasma are suitable. EDTA, Oxalate or Citrate inhibit the amylase activity, hence cannot be used. Amylase activity in serum samples remain stable for 20 days at 2-8°C.

REACTION PARAMETERS

- Type of Reaction : Kinetic/increasing OD
- Wavelength : 405 nm
- Flowcell Temperature : 37°C
- Delay Time : 60 Seconds
- Interval Time : 30 Seconds
- No. of readings : 4
- Sample Volume : 50 μ l (0.050 ml)
- Reagent Volume : 1.0 ml.
- Factor : 1628
- Light Path : 1.0 cm.
- Zero setting with : Distilled Water

TEST PROCEDURE

Pipette into Test Tubes	Test
Reagent (ml)	1.0
Sample (ml)	0.05

Mix immediately and read first absorbance of test exactly at 60 seconds and then, second, third and fourth at an interval of 30 seconds at 405 nm. Determine the mean change in absorbance per minute. ($\Delta A/\text{min}$) and calculate the test results.

TEST RESULTS

Serum Amylase Activity (IU/L) = $\Delta A/\text{min} \times F$

$$F = \frac{1}{12.9} \times \frac{\text{T.V.}}{\text{S.V.}} \times 1000 = 1628$$

Where

T.V. = Total Volume = 1.05

S.V. = Sample Volume = 0.05

12.9 = Milimolar absorbance of 2 - Chloro - 4 Nitrophenol.

1000 = to convert activity per ml. to per liter

LIMITATIONS FOR INTERFERENCE

Avoid contaminants like Saliva, Cough, since these contain many units of Amylase which might effect the reagent for colour development.

NORMAL VALUES

35 - 140 IU / L at 37°C.

LINEARITY

This method is linear upto 1500 IU/L. For values above 1500 IU/L, dilute the sample suitably with 0.9 % saline and repeat the assay. Apply correction due to dilution to arrive at a final results.

NOTE

For laboratories using instruments with cuvette capacity more / less than 1.0 ml, sample volume and reagent volume may be increased / decreased proportionately.

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REFERENCES

1. I.D.P. Wootton and H. Freeman, Microanalysis Medical Biochemistry (1982).
2. JF Zliva and PR, Pannall, "Plasma Enzymes in Diagnosis" in Clinical Chemistry in Diagnosis and Treatment, Lloyd-Luke London 1979 : Chapter XV :
3. Young DS, Effects of Drugs on Clinical Laboratory Tests, Third Edition: 1990: 3: 34 - 6.
4. In house data and communications with substrate manufacturer (1995).



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