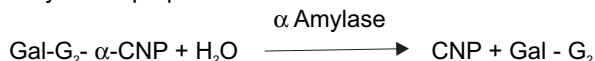


This reagent kit is for quantitative estimation of Amylase activity in serum or plasma.

PRINCIPLE:

The chromogenic substrate Gal-G2- α -CNP catalysed by α -Amylase releases 2-chloro-4-nitrophenol (CNP). Activity of Amylase is proportional to increase in absorbance at 405 nm.



CLINICAL SIGNIFICANCE:

Amylase assay performed in cases of detecting pseudocyst ascites and pleural effusion following acute pancreatitis. Increased level of amylase may also be related to disorders like biliary tract, diabetic ketoacidosis, severe glomerular dysfunction, salivary gland disorders and ruptured ectopic pregnancy. In case of acute pancreatitis, serum level of α -Amylase is elevated after 4 hours of onset of pain and reaches peak at 24 hours and remains elevated for 3-7 days.

SPECIMEN COLLECTION AND STORAGE:

- Fresh, clear, and fasting unhemolysed serum is preferred.
- Anticoagulants like oxalates, citrates, and EDTA should be avoided.

PRECAUTION:

Estrom Amylase reagent is for In Vitro diagnostic use only.

REAGENTS:

All the reagents are to be stored at 2-8°C.

	No. of bottles		
	12x1.1 ml	1x10 ml	5x10 ml
Reagent 1 (Substrate)	12	1	5
Reagent 2 (Buffer)	1	1	5

REAGENT RECONSTITUTION:

A) 12 x 1.1 ml: One vial/tablet of Reagent 1 (Substrate) is to be dissolved in 1.1 ml of Reagent 2 (Buffer). Mix gently. Keep for 5 minutes before use. Reconstituted reagent may be stored at 2-8°C, protected from light when not in use.

B) 1 x 10 ml: Transfer 1 vial/tablet of Reagent 1 (Substrate) using 10 ml of Reagent 2 (Buffer).

C) 5 x 10 ml: Transfer 1 vial/tablet of Reagent 1 (Substrate) to the bottle containing Reagent 2 (Buffer).

Mix gently. Keep for 5 minutes before use. Reconstituted reagent may be stored at 2-8°C, protected from light when not in use.

REAGENT STORAGE AND STABILITY:

All the reagents are stable up to expiry date stated on the label. Working reagent when stored at 2-8°C in a dark coloured bottle is stable for 12 months.

Note: Discard the working reagent if the blank value exceeds 1.00 at 405 nm.

GENERAL INSTRUMENT PARAMETERS:

Reaction Type	: Kinetic
Slope of Reaction	: Increasing
Wavelength	: 405 nm
Flowcell Temperature	: 37° C
Reagent Volume	: 1.0 ml
Sample Volume	: 50 μ l (0.05ml)
Delay Time	: 60 seconds
Interval	: 30 seconds
No. of readings	: 3
Factor	: 1628
Units	: IU/L
Zero Setting	: Distilled water
Path length	: 1.0 cm

PROCEDURE:

Allow the sample and reagent to attain room temperature prior to use

Dispense into Tubes	Volume
Working Reagent	1 ml
Sample	50 μ l

Mix and aspirate. Read absorbance after a delay of 60 seconds at an interval of 30 seconds i.e. at 60, 90, and 120 seconds at 405 nm. Obtain the mean change in absorbance per minute (Δ A/min.)

LINEARITY:

This method is linear for α -Amylase activity up to 1500 IU/L. For sample values exceeding the Linearity limit, dilute the sample suitably with normal saline and repeat the assay. Apply proper dilution factor while calculation.

CALCULATION:

Activity of α -Amylase in sample (IU/L):
 Δ A/min. X Factor

Factor = 1628

REFERENCE VALUES:

Normal Value : 35-140 IU/L at 37° C.

It is recommended that each laboratory establish its own reference values.

BIBLIOGRAPHY

- Harold Varley et. al Practical Clinical Biochemistry, 5th edition, Pg 1092 - 1093.
- Marshall, Analytical Biochemistry, 85 (1978), 541.

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	Attention, see instructions for use		Consult Instructions For Use
	For in vitro diagnostic use only		Catalog #
	Store between 2-8°C		Lot Number
	Do not use if package is damaged		Date of Manufacturing
	Manufacturer		Use by