

α-AMYLASE

METHOD – Gal G2 – α-CNP
PRODUCT CODE – LA04

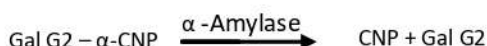


INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of Amylase activity in serum / plasma using Gal G2 – α-CNP method.

SUMMARY AND PRINCIPLE

Amylase determination is useful in diagnosis of diseases of Pancreas and Parotid gland. Elevated serum levels are associated with acute pancreatitis, acute abdominal disorders, biliary tract disease, diabetic ketoacidosis, severe glomerular dysfunction, ruptured ectopic pregnancy and macroamylasaemia. Amylase is a reagent kit for quantitative determination of amylase in human serum and plasma based on kinetic method using GalG2 – α-CNP. Amylase is a single ready to use reagent.



KIT COMPONENTS

Reagent 1: Substrate Reagent

REAGENT PREPARATION, STORAGE & STABILITY

Amylase is ready to use reagent and stable till the expiry date indicated on the label when stored at 2- 8 °C.

PRECAUTIONS & HANDLING

The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent. Do not shake the reagent vigorously. Discard the reagent if the absorbance of the reagent exceeds 0.500 O.D. against D/W at 405 nm. Contamination of the reagent should be avoided.

TEST PARAMETERS

Name	Amylase	Reagent Volume	1000 µl
Reaction Type	Kinetic (↑)	Sample Volume	20 µl
Wavelength	405 nm	Temperature	37 °C
Flow Cell Temp.	37 °C	Delay Time	30 sec.
Blank setting	DW	Read Time	120 sec
Blank abs. limit	<0.500	Factor	3806
Linearity	2000 IU/L	Standard Conc	-

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls, Incubation chamber.

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Serum, heparinized or EDTA plasma can be used. Oxalate & citrate inhibit amylase activity hence cannot be used as anticoagulant. -Amylase activity in serum is stable for 30 days at 2 – 8 °C.

COMPONENTS OF REAGENT

Component	Concentration
Buffer pH 6.0	50 mmol/l
Gal G2 – α-CNP	2.6 mmol/L
KSCN	140 mmol/L
Stabilizers and inactive ingredients.	-

ASSAY PROCEDURE

	Test
Reagent	1000 µl
Serum / Plasma	20 µl
Mix the reagent and sample in the above-mentioned ratio and start the stop watch.	
Aspirate reaction mixture into flow cell.	
Record absorbance at 30 th , 60 th , 90 th , 120 th & 150 th sec. (30 sec. interval).	

CALCULATION

$$\text{Amylase Activity (IU/L)} = \Delta \text{ Absorbance of sample/min} \times 3806$$

REFERENCE VALUES FOR NORMAL PEOPLE

Upto 96 IU/L at 37 °C.

PERFORMANCE CHARACTERISTICS

Measuring Range: The assay is linear between 20 - 2000 IU/L. If the Amylase value exceeds linearity limit (above 2000 IU/L), dilute the specimen suitably with normal saline and repeat the assay. In that case, assay value should be multiplied with the dilution factor to obtain correct Amylase value of the specimen.

Interference: There is no significant interference in samples containing Bilirubin upto 10 mg/dL, Ascorbic Acid upto 8 mg/dL and Haemoglobin upto 500 mg/dL.

Precision: Precision studies has been carried out using quality control sera as shown below:

(n=10)	Within Run			Between Run		
	Mean (IU/L)	SD (IU/L)	CV %	Mean (IU/L)	SD (IU/L)	CV %
Specimen Material						
Low Value Serum	72.3	0.53	0.7	81.5	0.88	1.1
High Value Serum	502.9	0.99	0.2	451.7	1.16	0.3

Note: We recommend all the laboratories to establish its own accuracy and precision data.

QUALITY CONTROL













Inclusion of a normal value and abnormal value chemistry control serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides between run precision and accuracy data for Amylase. We recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

PRECAUTIONS

1. Discard the reagent if its absorbance exceeds 0.500 at 405 nm against distilled water.
2. If Amylase activity exceeds 2000 IU/L then dilute the specimen suitably with normal saline & repeat the assay. In such case the results obtained should be multiplied by dilution factor to obtain the correct Amylase activity.

BIBLIOGRAPHY

1. Tietz NW, ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia Pa : W.B. Saunders, 1995 : 46 -51.
2. Winn -deen,E.S.David,H.siglet E.and Chavzer r.Clin chem. 34/10, 2005-2008(1988).
3. Junge W. et al., Clin. Biochem. 22, 109 (1989).

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry