

Alpha Amylase (Direct substrate and CNPG₃ method)

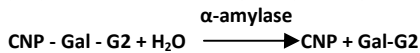
In vitro Diagnostic reagent/kit for quantitative determination of Alpha Amylase in human serum/plasma and urine samples on Photometric System.

Reagent

Reagent: Substrate Solution

Principle

Alpha Amylase is responsible for the hydrolysis of a 2 - chloro - 4 nitrophenol salt to chloro nitrophenol (CNP). The rate of hydrolysis is estimated as an increase in absorbance due to the formation of Chloro Nitrophenol. The concentration of chloro Nitrophenol is directly proportional to the activity of alpha amylase in the sample.



Summary

Alpha Amylase is secreted by the pancreas into the duodenum where it aids the catabolism of carbohydrates to simple sugars. Damage to the pancreas or obstruction to the pancreatic duct causes the enzyme to enter the blood stream. Elevated levels are found in acute pancreatitis, perforated or penetrating peptic ulcers, parotitis (mumps). Patients with chronic pancreatic disorders having pancreatic cell destruction do not have high levels as less amylase is produced by the pancreas.

Storage Instructions and Reagent Stability

Reagent are stable up to the end of the indicated month of expiry, if stored at 2° – 8°C, protected from light and contamination is avoided. Do not freeze the reagent!

Components and concentrations

Reagent: Potassium thiocyanate-6.0 g/l, MES buffer - 5.3 g/L, GAL-G2 CNP - 1.8 g/L, stabilizer and preservative.

Waste Management

Please refer to local legal requirements.

Reagent Preparation

Reagent is ready to use.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum, heparin plasma or EDTA plasma Stability:
1 month at 2° – 8 °C, 3 months at -20 °C
Only freeze once!
Discard contaminated specimens.

Assay Procedure

Wavelength 405 nm
Optical path 1 cm
Temperature 37°C

	Serum/Plasma
Sample	20 µl
Reagent	1000 µl
Mix, incubate for 1 min. and read absorbance after every 1 min. for 3 min.	

Calculation

For activity, take ΔA/min and multiply by the corresponding factor from table below:

Alpha Amylase activity U/L (in serum) = ΔA/min x factor

Quality Control

For internal quality control any normal and abnormal controls should be assayed with each batch of samples.
Each laboratory should establish corrective action in case of deviations in control recovery.

Warnings and Precautions

1. The reagent contains microbiologically preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. In very rare cases, samples of patients with gammopathy might give falsified results.
3. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
4. For professional use only!

Performance Characteristics

Measuring range

The test has been developed to determine alpha amylase activities within a measuring range from 3-2000 U/L. When values exceed this range samples should be diluted 1 + 4 with NaCl solution (9 g/L) and the result multiplied by 5.

Linearity/Limit of Maximum Detection

Linearity of detection is 2000 U/L.

Sensitivity/Limit of Detection

The lower limit of detection is 3 U/L.

Specificity/Interferences

No interference was observed by, Ascorbic Acid up to 30 mg/dL, Bilirubin up to 40 mg/dL and Triglycerides up to 1000 mg/dL.

Precision

Intra-assay n = 20	Sample 1	Sample 2	Sample 3
Mean[U/L]	36.44	75.52	235.00
SD[U/L]	0.37	0.40	1.50
CV [%]	1.01	0.53	0.64

Inter-assay n = 20	Sample 1	Sample 2	Sample 3
Mean[U/L]	37.31	112.16	225.46
SD[U/L]	0.69	1.84	1.07
CV [%]	1.84	1.64	0.47

Method Comparison

A comparison of Precision Biomed Alpha Amylase (y) with a commercially available test (x) using 15 samples gave following results:
 $y = 1.006x - 0.742$; $r^2 = 0.997$

Reference Range

Serum/Plasma	Up to 80 U/L
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Each laboratory should check if the references range are transferable to its own patient population and determine own reference ranges if necessary.

Quick Reference

Parameter	Alpha Amylase
Mode	Kinetic
Reaction slope	Increasing
Wavelength	405 nm
Path length	10 mm
Temperature	37° C
Reagent volume	1000 µL
Sample volume	20 µL
Delay	60 Sec.
Read	180 Sec.
Interval	30 Sec.
Factor	3498
Linearity	2000 U/L
Sensitivity	3 U/L
Reference range serum	up to 80 U/L

Pack Size





Cat No.	Configuration	Pack
AMY00020	Reagent - 2 x 10mL	20mL
AMY00050	Reagent - 2 x 25mL	50mL






Literature

1. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998.p.192-202.
2. Tietz Textbook of clinical chemistry. 3rd ed. Philadelphia: W.B saunders company; 1999.p.689-98.
3. J Clin Chem Biochem 1989;27:103-13.
4. Clin Chem Lab Med 1997;35:185-203.
5. Clin Chem 2000;46:644-9.

Version : AMY/00



 In Vitro Diagnostic Use
  See Pack Insert For Procedure
  Single Use only
  CE

 Temperature Limit
  Manufacturer's Address
  Manufacturing Date
  Expiry Date
  LOT Lot Number



Manufactured in India by:

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