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A Division of Orchard Medical

Alpha Amylase

Order Information

Cat. No.	Kit Configuration
OMR1020	Reagent: 2 x 20 mL

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.

Method
Direct substrate method.

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.

$$\text{CNP - Gal - G2} + H_2O \xrightarrow{\alpha\text{-amylase}} \text{CNP} + \text{Gal-G2}$$

Reagents Storage Instructions and 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!

Reagent: Substrate
Solution Reagent ready to use.

Composition
Reagent: Triton X-100 2 mL/L, MES buffer 5.3 g/L, GAL-G2 CNP 1.8 g/L, stabilizer and preservative.

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!

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
Application sheets for automated systems are available on request.

Wavelength	405 nm (400-420 nm)
Optical path	1 cm
Temperature	37°C

	Serum/Plasma	Urine
Sample	20 µl	10µl
Reagent	1000 µl	1000µl
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 Alpha Amylase activity U/L (in Urine) = ΔA/min x factor

Factor

For Serum	3806
For Urine	7612

Conversion factor
Alpha amylase (U/L) x 16.67 = Alpha amylase (nkat/L)

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.

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.

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.

Sensitivity/Limit of Detection
The lower limit of detection is 3 U/L.

Linearity
Linearity of detection is 2000 U/L.

Precision

Intra-assay n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	209.72	6.51	0.03
Sample 2	58.27	1.94	0.03

Inter-assay n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	61.37	2.13	0.03
Sample 2	210.81	5.20	0.02

Method Comparison

A comparison of Nucleus Diagnosys Alpha Amylase (y) with a commercially available test (x) using 15 samples gave following results:
$y = 0.966x + 0.915$; $r^2 = 0.996$

Reference Range

Serum/Plasma	Upto 130 U/L
Urine	Up to 490 U/L

Each laboratory should check if the references range are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. 1st ed. Franklurt: 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 19978:38:185-203. 5. Clin Chem 2000:46:644-9.

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