Spectrum For Diagnostic Industries

α—Amylase (4+1)

IVD

Cat. No.	Pack size
161 02 020 161 10 010	2 x 20 ml (40 tests) 10 x 10 ml (100 tests)

Intended Use

α Amylase reagent is intended for the in-vitro quantitative and diagnostic determination of amylase in human serum, Heparinized plasma and Urine on both automated and manual systems.

Introduction

Amylase is found primarily in the pancreas and salivary glands. When released in the digestive tract, the enzyme hydrolyzes starch. Amylase determinations are useful in the diagnosis and treatment of diseases of the pancreas and parotids. Elevated serum levels are associated with acute pancreatitis and other pancreatic disorders as well as mumps and bacterial parotitis.

Method

Kinetic or Fixed Rate method - GALG2-CNP

Principle

Alpha amylase catalyzes the hydrolysis of 2-chloro-4-nitrophenyl-1-galactopyranosyl-maltoside (GALG2-CNP) to glucose polymers and p-nitrophenyl oligosaccaride at short chain producing 2-chloro-4-nitrophenol (CNP).

The increased extinction can be measured by spectrophotometry at 405nm and results proportional at the activity of alpha amylase present in the sample.

Reagents

Reagent 1(Buffer)

Goods Buffer pH 6.0	50 mmol/L
Sodium chloride	300 mmol/L
Calcium chloride	5 mmol/L
EDTA	0.2 mmol/L

Reagent 2 (Substrate)

Goods Buffer pH 6.0	50 mmol/L
Potassium thiocyanate	140 mmol/L
GALG2-CNP	10.6 mmol/L

Reagent contains potassium thiocyanate
R22: harmful if swallowed
S 36:Wear suitable protective clothing

Reagents preparation, storage and stability

Amylase reagents are supplied ready-to-use and stable till the expiration date labeled on the bottles when properly stored refrigerated at 2 – 8 °C. Once opened, the opened vial is stable for 2 month at the specified temperature.

Deterioration

Do not use Alpha Amylase reagent in case of presence of particulate material or if the absorbance is > 0.600 at 405 nm.Failure to recover control values within assigned range may indicate reagent deterioration.

Precautions and Warnings

-Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Saliva and skin contain alpha amylase: never pipette by mouth and avoid skin contact with the reagents (use gloves).Avoid use of hemolysed samples.The present method describes the manual use of this kit . For use with automatic analyzer see the specific applications.

Specimen Collection and Preservation

Serum, Heparinized plasma and Urine.

Note: -The activity of alpha amylase in serum or plasma is stable for 7 days at 2 - 8°C, one month at –20°C.

Procedure 1 (Kinetic method)

Wavelength	405 nm
Optical path	1 cm
Reaction	Kinetic (increase)
Temperature	37 °C
Measurement	Against Air
Reagent Blank Limits	Low 0.00 AU High 1.0 AU

Allow reagents to reach working temperature before use.

Reagent (R1) 800 µl

Reagent (R2) 200 µl

Mix well and incubate for 1 minute at 37 °C.

Specimen 25 µl

Read initial absorbance after 60 seconds and start timer simultaneously. Read again after 1, 2 and 3 minutes. Determine the mean absorbance change per minute (ΔA/min).

Calculation

Alpha amylase (U/L) = ΔA/min x 3060

Procedure 2 (Fixed rate method)

Wavelength	405 nm
Optical path	1 cm
Reaction	Fixed rate (increase)
Temperature	37 °C
Measurement	Against Air

Allow reagents to reach working temperature before use.

Reagent (R1) 800 µl

Reagent (R2) 200 µl

Mix well and incubate for 1 minute at 37 °C.

Specimen 25 µl

Read the absorbance A1 after 1 minute then after 4 minutes read the absorbance A2.

Calculation

ΔA= A2-A1

Alpha amylase (U/L) = ΔA x 765

Quality control

Normal and abnormal control serum of known concentration should be analyzed with each run.

Sensitivity

When run as recommended, the minimum detection limit of this assay is 2.0 U/L.

Linearity

The reaction is linear up to Alpha Amylase concentration of 1500 U/L.

Interference

The following substances don't interfere up to the concentration of:

Bilirubin conjugated	20 mg/dL
Bilirubin free	20 mg/dL
Hemoglobin	500 mg/dL
NaF	500 mg/dL
Ascorbic acid	500 mg/dL
Glucose	5.0 g/dL
Maltose	5.0 g/dL

Expected Values

	37 °C
Serum/ Plasma	Up to 100 U/L
Random Urine	Up to 450 U/L
24hrs Urine	Up to 410 U/24h

Performance Characteristics

A study using 20 human specimens between this Amylase reagent and reference method yielded a correlation coefficient of 0.998 and a linear regression equation of y= 1.012x + 0.0425

Precision

Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (U/L)	70.4	183
SD	0.186	0.219
CV%	0.021	0.011

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (U/L)	70.4	183
SD	0.181	0.234
CV%	0.022	0.012

Waste Disposal

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.

S56: dispose of this material and its container at hazardous or special waste collection point.

S57: use appropriate container to avoid environmental contamination.

S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1- Winn-Deen et Al., Clin. Chem. 24-10 (1989)

2- Henry, R.J., Chiamori, N., Clin. Chem., 6;434, (1961)

SYMBOLS IN PRODUCT LABELLING

IVD For in-vitro diagnostic use

LOT Batch Code/Lot number

REF Catalogue Number

Consult instructions for use

Temperature Limitation

Use by/Expiration Date

CAUTION. Consult instructions for use

Manufactured by

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