SPECTRUM

The Creative Approach to Bioscience

Amylase (4+1)

REF: ZL-219 001 (2 x 25 ml) 50 test
R1 2 X 20 ml
R2 2 X 5 ml

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(Xi) - Irritant
	Temperature Limitation		

Intended Use

Spectrum Alpha Amylase reagent is intended for the in-vitro quantitative, diagnostic determination of Alpha Amylase in human serum , heparinized plasma or urine on both automated and manual systems.

Background

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

Assay 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 405 nm and results are proportional to 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

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.

Reagent 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 ^{O}C.
Once opened, the reagent is stable for 2 months at the specified temperature.

Deterioration

Do not use Alpha Amylase reagent in case of presence of particulate material or if the absorbance is > 1.0 at 405 nm.Failure to recover control values within assigned range may indicate reagent deterioration.

Specimen Collection and Preservation

Use serum or Heparinized plasma or urine.
The activity of alpha amylase in serum or plasma is stable for 7 days at 2-8 ^{O}C, one month at –20^{O}C.

System Parameters

Wavelength	405 nm
Optical path	1 cm
Assay type	Kinetic
Direction	Increase
Temperature	37 ^{O}C
Zero adjustment	Against Air
Sensitivity	2 U/L
Linearity	1500 U/L
Reagent Blank Limits	Low 0.0 AU High 1.0 AU

Procedure 1 (Kinetic Method)

Reagent (R1)	800 µl
Reagent (R2)	200 µl

Mix well and incubate for 1 minute at 37 ^{O}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
Assay type	Fixed Rate
Direction	Increase
Temperature	37 ^{O}C
Zero adjustment	Against Air
Sensitivity	2 U/L
Linearity	1500 U/L
Reagent (R1)	800 µl
Reagent (R2)	200 µl

Mix well and incubate for 1 minute at 37 ^{O}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

Performance Characteristics

Precision

Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (U/L)	70.4	183
SD	0.186	0.219
CV%	0.26	0.12

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (U/L)	70.4	183
SD	0.181	0.234
CV%	0.26	0.13

Methods Comparison

A comparison between Spectrum amylase reagent and a commercial reagent of the same methodology was performed on 200 human sera. A correlation of 0.988 was obtained.

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.

Interfering Substances

The following substances do not interfere up to the concentrations of:

Bilirubin	10 mg/dL
Hemoglobin	400 mg/dL
Triglycerides	600 mg/dL

Expected values

Serum/plasma up to 100 U/l

Random Urine up to 450 U/l

24 hrs Urine up to 410 U/24h

Analytical Range

2 – 1500 U/L.

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.Henry, R.J., Chiamori, N., Clin. Chem., 6;434, (1961).
2.Winn-Deen et Al., Clin. Chem. 24-10 (1989).
3.Lorentz, K., Clin. Chem. Clin. Biochem. 17,499 (1979).

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
ZL-219 001	50 test

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