

Alpha Amylase - GALG2-CNP 2 Reagents (4+1)

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

REF: 219 002-D (5 x 20 ml) 100 test
R1 5 X 16 ml
R2 1 X 21 ml

Intended Use

Spectrum Diagnostics Alpha Amylase reagent is intended for the in-vitro quantitative, diagnostic determination of Alpha Amylase in human serum and heparinized plasma 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 oligosaccharide 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

The present method describes the manual use of this kit. For use with automatic analyzer see the specific applications. Presence of particulate material indicates deterioration of the reagent.

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

Quality control data sheet of the reagent is available upon request. Refer to the batch number on the label

Reagent Storage and Stability

All reagents are stable until expiration date stated on label when stored refrigerated at 2 - 8 °C.

SYMBOLS IN PRODUCT LABELLING

	Authorised Representative		Temperature Limitation
	For in-vitro diagnostic use		Use by/Expiration Date
	Batch Code/Lot number		CAUTION. Consult instructions
	Catalogue Number		for use
	Consult instructions for use		Manufactured by

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 °C, one month at -20°C.

Procedure1 (Kinetic Method)

Wavelength	405 nm
Optical path	1 cm
Assay type	Kinetic
Direction	Increase
Temperature	37 °C
Zero adjustment	Against Air
Sensitivity	2 U/L
Linearity	1500 U/L

Procedure

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 ($\Delta A/\text{min}$).

Calculation

Alpha amylase (U/L) = $\Delta A/\text{min} \times 3060$

Procedure 2 (Fixed Rate Method)

Wavelength	405 nm
Optical path	1 cm
Assay type	Fixed Rate
Direction	Increase
Temperature	37 °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 °C.

Specimen 25 µl

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

Calculation

$\Delta A = A2 - A1$

Alpha amylase (U/L) = $\Delta A \times 765$

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%	0.021	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

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

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 g/dL
Maltose	5 g/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.

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
219 001-D	50 test
219 002-D	100 test



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