ALPHA AMYLASE SL

Kinetic Method (CNPG3)

Liquid Reagent ready to use

REF 12004120 R 6X20mL

IVD

PRODUCT CODE: AMY-6D20

Company with Quality System ISO 9001 – ISO 13485 Certified by LMS

INTENDED USE

Quantitative determination of α-Amylase in serum and plasma.

PRINCIPLE

The α-Amylase hydrolizes 2-chloro-4-nitrophenyl-α-D-maltotrioside (CNPG3) into 2-chloro-4-nitrophenyl-α-D-maltoside (CNPG2), maltotriose (G3), glucose and 2-chloronitrophenol. The absorbance change in unit time measured at 405 nm is proportional to the enzyme activity in the sample.

SAMPLE

Serum, heparinized plasma, urine.

Do not use other anticoagulants like EDTA, citrate and oxalate as they inhibit the enzyme. Avoid hemolyzed samples.

Dilute urine 1:3 with saline solution.

Amylase activity is stable one week at 15-25°C and some months at 2-8°C.

KIT COMPONENTS

Reagent (A) AMY Volume = 10/50 ml	Good buffer pH 6 CNPG3 Sodium chloride Calcium acetate Sodium azide	100 mmol/l 3.1 mmol/l 10 mmol/l 1 mmol/l 15 mmol/l

The reagent is stable until the expiration date indicated on the label if stored at 2-8°C and protected from light. Do not freeze. Once opened reagent is stable for 2 months at 2-8°C if contamination is avoided.

Keep bottles closed when not in use.

REAGENT PREPARATION

Liquid Reagent, bring to room temperature (15-25°C) before use.

PRECAUTIONS AND WARNINGS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow. Use the normal precautions required in the laboratory.

Dispose of waste according to local laws.

PROCEDURE

Wavelength:	405 nm
Lightpath :	1 cm
Temperature:	37°C
Reading:	against distilled water
Method:	Increasing Kinetic
Sample/Reagent:	1/50

pipette:

Reagent (A)	300 µl
sample	6 µl

Mix, incubate at 37°C for 1 minute, read the initial absorbance against water. Perform 3 readings at 60 seconds intervals. Calculate the average value of the absorbance variations per minute (ΔA/min).

RESULTS CALCULATION

Perform calculation in units per litre, multiplying the ΔA/min by the factor:

activity in U/L: ΔA/min x 3517

EXPECTED VALUES

Serum/plasma: 25 – 110 U/L

Urine: < 480 U/L

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL

You must perform the controls at each kit's use and verify that the values obtained are within the reference range reported in the operating instructions.

For this purpose we recommend the use of Sicurobio control sera: ACUTROL 1 (REF. SB-8334) and ACUTROL 2 (REF. SB-8335).

PERFORMANCE

Sensitivity: the sensitivity of the method is: 1 U/L

Linearity: the method is linear up to 2350 U/L. For higher values, dilute the sample 1:2 and multiply the result by 2.

Precision intra-assay:

	Level 1	Level 2	Level 3
Mean (U/l)	42.90	184.2	497.5
SD	0.64	2.25	5.64
CV %	1.49	1.22	1.13

Precision inter-assay:

	Level 1	Level 2	Level 3
Mean (U/l)	44.15	181.2	524.5
SD	0.48	2.82	2.22
CV %	1.09	1.56	0.42

Interferences: bilirubin does not interfere up to 30 mg/dl. Triglycerides up to 1500 mg/dl do not interfere. Hemoglobin up to 500 mg/dl does not interfere. Glucose up to 500 mg/dl does not interfere.

Correlation against a reference method:

Y = 0.4582x + 1.089 r = 0.999

REFERENCES

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2. Vassault, A. et al. Ann. Biol. Clin., 44,686 (1986).
3. Young, D.S., et al., Clin. Chem. 21:1D (1975).

Sicuro Bioengineering Ltd

19 East West Road, Portharcourt – Nigeria.

e-mail: info@sicurobio.com– web site: www.sicurobio.com

Ed. 2026/11 rev. 01