GENESIS

Instructions For Use

α - Amylase (Kinetic Method)

Cat no.	size
1209 101	2*25
1209 102	4*25

INTENDED USE

Alpha Amylase reagent is intended for the in vitro quantitative, diagnostic determination of Amylase in human serum , heparinized plasma or urine .

DIAGNOSTIC CHARACTERISTICS

Alpha Amylase (AMS) is an enzyme that helps to digest the glycogen and the starch. It is produced mainly by exocrine pancreas and salivary glands. This determination is made mainly in diagnosis or to control diseases of the pancreas as acute or chronic pancreatitis. It can also reflect biliary or gastrointestinal disease and other upheavals .

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRINCIPLE OF THE METHOD

α-Amylase hydrolyzes the 2-chloro-4-nitrophenyl-α-D-maltotrioside (CNPG3) to release 2-chloro-4-nitrophenol (CNP) and form 2-chloro-4-nitrophenyl-α-D-maltoside (CNPG2), maltotriose (G3) y glucose (G) according to the following reaction:

10 CNPG3 $\xrightarrow{\text{Amylase}}$ 9 CNP + 1 CNPG2 + G3 + G

The rate of 2-chloro-4-nitrophenol formation, measured photometrically, is proportional to the catalytic concentration of α- amylase present in the sample1 .

COMPOSITION

Reagent (R)	MES pH 6.0	100 mmol/L
	CNPG3	2.25 mmol/L
	Sodium chloride	350 mmol/L
	Calcium acetate	6 mmol/L
	Potassium thiocyanate	900 mmol/L
	Sodium azide	0.95 gm/L

STORAGE AND STABILITY.

Store at 2-8ºC.

Reagent are stable until the expiry date shown on the Vial label when stored tightly closed and if contaminations are prevented during their use.

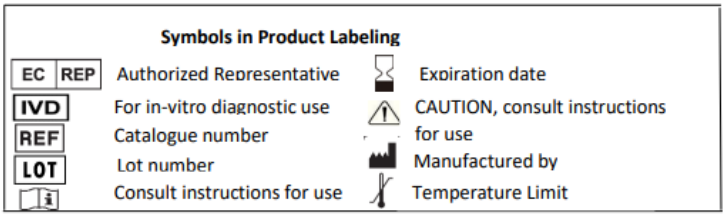
After opening, the reagent is stable for 60 days when properly capped immediately after each opening and stored at 2-8ºC.

REAGENT PREPARATION

Reagent and Standard are provided ready to use.

ADDITIONAL EQUIPMENT

− Analyzer, spectrophotometer able to read at 405 nm.



SPECIMEN

Serum, heparin or EDTA plasma.

Stability: at 20 – 25 °C 7 days
at 4 – 8 °C 7 days
at -20 °C 1 year

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.
- Avoid use of hemolysed samples.

PROCEDURE

- Bring reagents and samples to room temperature.

Pipette into test tubes	Blank	Sample
Reagent	1000 µl	1000 µl
dist. water or saline	25 µl	-----
Sample	-----	25 µl

Mix, incubate for 1 min. at 37°C and read absorbance.
Read absorbance again after exactly 1, 2 and 3 min.
Determine ΔA/min during the linear part of the assay.
Calculate: ΔA/min = [ΔA/min Sample] – [ΔA/min Blank]

CALCULATIONS (light path 1 cm)

α-Amylase (U/L) = ΔA/min x Factor

- Factor (37 °C) at 405 nm: 3178
- U/L x 0.01667 = µkatal/L

REFERENCE VALUES

Serum or Plasma	Up to 90 U/L of α-amylase
Urine	Up to 450 U/L of α-amylase

QUALITY CONTROL

It is recommended to use the Control Serum level I And II to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control.

METROLOGICAL CHARACTERISTICS

Measuring range: From detection limit of 2.0 U/L to linearity limit of 1500 U/L.

If the results obtained were greater than linearity limit, dilute the sample 1/2 with NaCl 9 g**/L** and multiply the result by 2. **Precision:**

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (U/L)	94.56	290.18	94.43	290
SD	1.34	3.42	1.61	3.08
CV (%)	1.42	1.18	1.7	1.06

Sensitivity: 1 U/L = 0.00025 ΔA/min

Accuracy: Results obtained using Genesis reagents (y) did not show systematic differences when compared with other commercial reagents (x).

The results obtained were the following:

Correlation coefficient (r)2: 0.98628.

Regression equation: y=0.746x – 1.2697.

The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

- Lipemia (intralipid 20 g/L) does not interfere.
- Bilirubin (40 mg/dL) does not interfere.
- Hemoglobin (16 g/L) does not interfere.
- Other drugs and substances may interfere.

BIBLIOGRAPHY

1. Winn-Deen, E.S., David, H., Sigler, G, and Chavez, R. Clin. Chem. 34 : 2005.
2. International Federation of Clinical Chemistry (IFCC). Clin. Chem. Lab. Med. 36 : 185.
3. Young DS. Effects of drugs on clinical laboratory tests, 4th ed. AACC Press, 1995.
4. Tietz. Textbook of Clinical Chemistr, 2 Edition. Burtis CA, Ashwood ER. WB Saunders Co., 1994.
5. Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press 2001.

GENESIS LAB FOR DIAGNOSTIC REAGENTS
1st industrial area, Obour City, Cairo, Egypt
☏ (+202) 44891632 Fax : (+202) 44891632
www.genesis-egy.com
info@genesis-egy.com

IFU-AMS-11
Rev. (2) 17/09/2023

ISO 13485:2016 Medical Devices

CE

EC REP CMC Medical device, C/ Horacio Lengo n18 C.P 29006, Málaga-Spain