

N BIO - ALPHA AMYLASE

(Direct substrate method)

N BIO - Alpha Amylase	4 x 5 ml	MAMY04005M
Alpha amylase monovalials	10 x 1 ml	VAMY01001M



INTRODUCTION

α -Amylase is a digestive enzyme secreted by salivary glands and pancreas. Low level of amylase is also found in skeletal muscle, adipose tissue and fallopian tubes. α -Amylase is measured generally in pancreas diseases. Elevation of amylase activity is observed also due to inflammation of abdominal cavity or salivary glands.

METHOD PRINCIPLE

2-chloro-4-nitrophenyl- α -maltotrioidase (CNP-G3) is a direct substrate for determination of α -amylase activity, which does not require the presence of ancillary enzymes.

10 CNP-G3 α -amylase > 9 CNP + CNP-G2 + 9 maltotriose + glucose
The rate of 2-chloro-4-nitrophenol formation can be monitored at 405 nm and is proportional to the α -amylase activity.

KIT CONTENTS

Reagent Name	MAMY0405M	VAMY01001M
R1 - Amylase Reagent	5 X 5 ml	10 X 1 ml

WORKING REAGENT PREPARATION AND STABILITY

Reagent is ready to use.

The reagents when stored at 2-8°C are stable up to expiry date printed on the package.

The reagents are stable for 8 weeks on board the analyser at 2 10°C.

Prevent the reagent from microbiological contamination and from saliva and sweat α -amylase.

CONCENTRATIONS IN THE TEST

MES	100 mmol/l
Potassium hydroxide	30 mmol/l
Calcium acetate	6 mmol/l
Potassium thiocyanate	900 mmol/l
2-chloro-4-nitrophenyl- α -maltotrioidase	2.27 mmol/l

WARNINGS AND NOTES

- Product for in vitro diagnostic use only.
- Saliva and sweat contain α -amylase. Do not pipette by the mouth, avoid skin contact with reagent, specimens, tips, cuvettes. Ensure to use automatic pipettes and laboratory gloves.
- The reagents are usable when the absorbance of the working reagent is less than 0.140 (read against distilled water, wavelength $\lambda=405$ nm, cuvette l=1 cm, at temp. 25
- Reagent 1-AMYLASE is classified as a harmful



Ingredients: potassium thiocyanate, sodium azide; Xn - Harmful

R 20/21/22-32: Harmful by inhalation, in contact with skin and if swallowed. Contact with acids liberates very toxic gas.

S 24-36-46: Avoid contact with skin. Wear suitable protective clothing. If swallowed, seek medical advice immediately and show this container or label.

ADDITIONAL EQUIPMENT

- Automatic analyzer or photometer able to read at 405 nm
- Thermostat at 37°C
- General laboratory equipment

SPECIMEN

Serum, heparinized plasma free from hemolysis, urine.

Do not use EDTA, citrate and oxalate as anticoagulants because of amylase activity inhibition.

Urine - before storage pH should be adjusted to about 7.0.

Amylase activity remains stable in specimen up to 7 days at 15-25°C or up to 2 months at 2-8°C but it is recommended to perform the assay with freshly collected samples.

PROCEDURE

These reagents may be used both for manual assay and in several automatic analysers. Applications for them are available on request.

Wavelength	405 nm
Temperature	37°C
Cuvette	1 cm

Pipette into the cuvette :

Reagent	Test (T)
R1 Amylase Reagent	1000 μ l
Bring up the temperature of determination. Then add,	
Sample	20 μ l

Mix and incubate at adequate temperature. After about 1 min. read the absorbance against air or water. Repeat the reading after exactly 1, 2 and 3 minutes. Calculate the mean absorbance change per minute ($\Delta A/\text{min}$).

If $\Delta A/\text{min}$ exceeds 0.400, dilute the sample with 0.9% NaCl in the ratio of 1 to 4 and repeat the assay. Multiply the result by 5.

CALCULATION

α -amylase activity [U/l] = $\Delta A/\text{min} \times 3498$

REFERENCE VALUES

Serum / Plasma	upto 80 U/L
Urine	upto 380 U/L

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

To Ensure adequate quality control, each run should include assayed normal and abnormal controls. If commercial controls are not available it is recommended that known value samples be aliquoted, frozen and used as controls.

For Fully Automated analyzers by using multi calibrator, the calibration curve can plot and the same should be prepared every 8 weeks or with change of reagent lot number.

PERFORMANCE CHARACTERISTICS

- Sensitivity / Limit of Quantitation:** 2 U/L
- Linearity:** up to 1500 U/L
- Specificity / Interferences**
Haemaglobin up to 3.75 g/dl, ascorbate up to 62 mg/l, bilirubin up to 20 mg/dl and triglycerides up to 500 mg/dl do not interfere with the test.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Winn-Deen E.S., David M., Sigler G., Chavez R.: Clin. Chem., 34/10, 2005-2008(1988).
2. Bertholf R.L., Winn-Deen E.S., Bruns D.E.: Clin. Chem., 34/4, 754-757(1988).
3. Genzyme's New Direct Amylase Technology. Update data. Genzyme Diagnostic(1992-1993).
4. Direct Amylase Technology CNPG3. Summary Document July 1997. Genzyme Diagnostic.
5. Burtis C.A., Ashwood E.R.: Tietz Textbook of Clinical Chemistry, 3rd Ed., W.B. Saunders Company, Philadelphia, 1999, p. 696.
6. Kaplan L.A., Pesce A.J.: Clinical Chemistry. Theory, analysis and correlation 3rd Ed., The C. V. Mosby Company, St. Louis 1996, p.568.
7. Tietz N.W., ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia, PA: WB Saunders, 46-8(1995).

SYSTEM PARAMETERS

Method	Kinetic
Wavelength	405 nm
Zero Setting	Distilled Water
Temperature Setting	37° C
Incubation Temperature	37° C
Incubation Time	----
Delay Time	60 secs
Read Time	180 secs
No. of Reading	3
Interval Time	60 secs
Sample Volume	0.02 ml (20 ul)
Reagent Volume	1.0 ml (1000 ul)
Standard Concentration	----
Units	U/L
Factor	3498
Reaction Slope	Increasing
Linearity	1500 U/L



Genuine Biosystem Private Limited

Plot No.97 & 98, kattabomman street,
Parvathy Nagar Extension,
Old Perungalathur, Chennai - 600063, India.
Ph: +91-44-48681845
Email: genuinebiosystem@gmail.com
website: www.genuinebiosystem.com