

# Amylase Test Kit

REF	Pack Size	Reagent 1
AMYLMS01	25x1 ml	25x1 ml
AMYLMS02	1x25 ml	1x25 ml
AMYLMS03	2x25 ml	2x25 ml

## INTENDED USE

Amylase reagent used for the quantitative estimation of amylase in human serum or plasma.

## CLINICAL SIGNIFICANCE

$\alpha$  Amylase is secreted by the pancreas into the duodenum where it aids the catabolism of carbohydrates to simple sugar. Damage to the pancreas or obstruction to the pancreatic duct causes the enzyme to enter the blood stream. Elevated levels are found in acute pancreatitis, perforated / penetrating peptic ulcers, paraotitis (MUMPS). Patient with chronic pancreatic disorders having pancreatic cells destruction do not have high levels as less amylase is produced by the pancreas.

## METHOD

Enzymatic Kinetic, CNPG3

## TEST PRINCIPLE

Substrate CNP-G3 is hydrolyzed by catalytic action of alpha Amylase to produce CNP.

## KIT CONTENTS/COMPONENT

Reagent 1: Buffered Enzyme Reagent

## MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory instrumentation, spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi-automated, calibrated micropettes, glass or high-quality polystyrene cuvettes, test tubes/rack, heating bath, controls, saline.

## SAFETY PRECAUTIONS AND WARNINGS

1. For in-vitro diagnostics use only.
2. Do not pipette by mouth. Avoid contact with skin and eyes. If spilt thoroughly wash affected area with water.
3. Do not use the reagent after the expiration date printed on the kit.

## REAGENT PREPARATION, STORAGE AND STABILITY

Reagent is ready to use keep away from direct light source

Stability: up to expiration date on labels at 2-8 °C.

Stability since first opening of vials: 60 days at 2-8 °C.

## REAGENT DETORINATION

Discard the reagent if it turns turbid or its absorbance exceeds 1.0 against distilled water at 405 nm.

## SPECIMEN

Serum, plasma (heparinate only). Amylase in serum is stable for one month at -20 °C or 7 days at 2-8°C.

## PROGRAM

Reaction Mode	Kinetic
Wavelength	405 nm
Light Path	10 mm
Reagent Volume	1000 $\mu$ l
Sample Volume	20 $\mu$ l
Delay Time	60 sec.
Interval Time	60 sec.
Factor	3954
Linearity	2000 U/L

## PROCEDURE

Reagent	1000 $\mu$ l
Sample	20 $\mu$ l

Mix & incubate for 60 sec. at assay temperature, read the first reading at 60second and subsequently two more readings with 60 seconds interval at 405 nm.

## CALCULATION

Activity in Serum or Plasma (U/L) =  $\Delta$ Abs./ min x 3954

## NORMAL VALUE

0 - 90 U/L

## LIMITATIONS

If the value exceeds 2000U/L dilute the sample with 0.9% saline solution rerun and result multiplied by dilution factor.

## QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal and assayed abnormal, to confirm the validity of the test and assure the accuracy of patient result. Using the recommended calibrator or the Standard included, calibrate the assay.

1. When using a new reagent or lot
2. When QC values are out of range

## WASTE DISPOSAL

This Product is made to be used in professional laboratories.










## HIGHLIGHTS

1. The Reagents are sensitive to light & higher temperature. Reagents may develop a slight yellow coloration on ageing which does not interfere with the functionality of reagent.
2. If the volume of the reagent is not sufficient to fill the cuvette, double all the specified volumes.
3. Storage condition mentioned on the kit is to be maintained.
4. Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
5. Before testing bring the reagents to the specified temperature.
6. Avoid reagents contamination.
7. Every time use new pipette-tips for pipetting out the reagents.
8. These Reagent kits meant for laboratory / professional use only, not for Drug use.

## REFERENCES

Tietz NW, ed. Clinical Guide to Laboratory Tests, 3<sup>rd</sup> ed. Philadelphia Pa: WB Saunders, 1995:22-24

Lords Data File.

 REF	Catalog No.		Contain Sufficient for test
 LOT	Batch No.		Instruction for use
	Manufacturing Date		In-vitro Diagnostics
	Expiry Date		Storage temperature
	Manufacturer		

IFU/AMY/01 Rev.: 01; Rev Dated.: 22/07/2024

