Amylase Test Kit

REF	Pack Size	Reagent
AMYLMB01	2 x 70	2 x 70ml

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

CLINICAL SIGNIFICANCE
α 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
CNPG3 Enzymatic Kinetic

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

KIT CONTENTS/COMPONENT
Reagent : Buffered Enzyme Reagent

MATERIAL REQUIRED BUT NOT PROVIDED
Fully Auto Biochemistry Analyzer: LM1016-400TPH.
Calibrator
Controls.

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.

ON - BOARD REAGENT STABILITY-
On board reagent stability is 15 days.

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

APPLICATION For LM1016-400 TPH

Method	Kinetic
Reaction	Increasing
Primary filter	405
Secondary filter	No
R1 Volume	300
R1 Position	*
Incubation time (Sec)	60
R2 Volume	-
R2 Position	-
Incubation time (Sec)	-
Sample Volume	6
Read Time	180
Calibrator Concentration	As on the vial label
Mix speed set	Middle
Unit	U/L
Decimal	2

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CALIBRATION
For calibration, it is recommended to use any multi calibrator.

CALCULATION
Calculations Fully automated systems automatically calculate the Amylase concentration of each sample.

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.

SAFETY PRECAUTIONS AND WARNINGS
1.For in-vitro diagnostics use only.
2.Do not use the reagent after the expiration date printed on the kit.
3.Avoid reagents contamination.
4.These Reagent kits meant for laboratory/professional use only, not for Drug use.

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 multi calibrator, calibrate the assay.
1.When using a new reagent or lot
2.When QC values are out of range

PRECISION
Reproducibility was determined using quality control sera as shown below

	Intra run		Inter run	
Control	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (gm/dl)	72.1	477.4	73.2	477.0
SD	1.68	1.8	0.83	1.60
CV (%)	0.02	0.01	0.01	0.00

WASTE DISPOSAL
This Product is made to be used in professional laboratories.

REFERENCES
Tietz NW, ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia Pa: WB Saunders, 1995:22-24.
Lords Data File.

REF	Catalog No.		Instruction for use
LOT	Batch No.	IVD	*In-vitro* Diagnostics
	Manufacturer		Storage temperature
	Expiry Date		Manufacturing Date

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