LIPASE

METHOD – UV-TURBIDIMETRIC
PRODUCT CODE – LL03

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of Lipase activity in serum/plasma using UV-Turbidimetric method.

SUMMARY AND PRINCIPLE

High levels of serum Lipase are associated with Cholecystatis, Hemodialysis, chronic renal failure, Peritonitis and primary biliary cirrhosis. Lipase is a single reagent kit for quantitative determination of Lipase in human serum based on turbidimetric principle. Lipase catalyses the breakdown of Triolein in the presence of Colipase to form glycerol and fatty acids which is measured as rate of decrease in turbidity at 340 nm.

$$\text{Triolein} + 3\,H_2O \xrightarrow{\text{Lipase}} \text{Glycerol} + 3\,\text{Fatty Acid}$$

KIT COMPONENTS

Reagent 1: Substrate Reagent

REAGENT PREPARATION, STORAGE & STABILITY

The reagent is ready to use. The reagent kit should be stored at 2-8 ^{0}C and is stable till the expiry date indicated on the label.

PRECAUTIONS & HANDELING

The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent. Do not shake the reagent vigorously. Discard the reagent if the absorbance of the reagent goes below 1.000 O.D. against D/W at 340 nm. Contamination of the reagent should be avoided.

TEST PARAMETERS

Name	Lipase
Reaction Type	UV-Kinetic (↓)
Wavelength Primary	340 nm
Flow Cell Temp.	37 °C
Blank setting	D.W.
Blank Abs Limit	> 1.000
Linearity	1275 IU/L

Reagent Volume	1000 µl
Sample Volume	50 µl
Incubation Temp.	37 °C
Delay Time	60 sec.
Read Time	120 sec.
Factor	5810
Standard Conc.	-

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls, Incubation chamber.

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Serum is can be used. Avoid venous stasis. Lipase in serum or plasma is stable for 3 weeks days at 2-8 ^{0}C and several months at -20 ^{0}C.

COMPONENTS OF REAGENT

Component	Concentration
Tris Buffer, pH 9.2	26 mMol/L
Triolein	0.30 mMol/L
Sodium deoxycholate	19 mMol/L
Calcium Chloride	0.01 mMol/L
Colipase	3 mMol/L

ASSAY PROCEDURE

	Test
Reagent	1000 µl
Serum / Plasma	50 µl
Mix the reagent and sample in the above-mentioned ratio and start the stop watch.	
Record the absorbance at 60th, 90th 120th and 150th sec. (30 sec interval).	

CALCULATION

Calculate average Δ Abs/min.	= Δ Abs/30 sec. x 2
Lipase (IU/L)	= Δ Abs per min x 5810.

REFERENCE VALUES FOR NORMAL PEOPLE

Less than : 200 IU/L at 37 ^{0}C
Panic levels : 600 IU/L at 37 ^{0}C

Note: Children below 2 years have virtually no levels of Lipase.

PERFORMANCE CHARACTERISTICS

Measuring Range: The assay is linear between 29 - 1275 IU/L. If the Lipase value exceeds linearity limit (above 1275 IU/L), dilute the specimen suitably with normal saline and repeat the assay. In that case, assay value should be multiplied with the dilution factor to obtain correct Lipase value of the specimen.

Interference: There is no significant interference in samples containing Bilirubin upto 20 mg/dL. Gross haemolysis should be avoided. Care should be taken to avoid contamination of Lipase reagent with Cholesterol and Triglycerides reagent since they contain high levels of Lipase and Esterase.

Precision: Precision studies has been carried out using quality control sera as shown below:

(n=10)	Within Run			Between Run		
Specimen Material	Mean (IU/L)	SD (IU/L)	CV %	Mean (IU/L)	SD (IU/L)	CV %
Low Value Serum	196.2	1.40	0.7	211.8	1.75	0.8
High Value Serum	322.8	2.15	0.7	336.3	2.11	0.6

Note: We recommend all the laboratories to establish its own accuracy and precision data.

QUALITY CONTROL

Inclusion of a normal value and abnormal value chemistry control serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides between run precision and accuracy data for Lipase. We recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

PRECAUTIONS

1. Discard the working reagent if its absorbance is less than 1.000 at 340 nm against distilled water.

2. Do not use strongly haemolysed serum.

BIBLIOGRAPHY

1. Tietz NW, and shuey D.F. Lipase in serum- the Elusive Enzyme. An Overview Clin Chem 1993 : 39 : 746-56.

2. Ziegenhorm j. et al, Clin Chem 1979:25:1067.

3. A.R. Henderson & D.W. Moss in "Enzymes" (Tietz Textbook) Fundamentals of Clinical Chemistry 5th edition page 375-378.

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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ISO 9001: 2015
ISO 13485 : 2016
GMP
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