LiquiMAX Lipase

(Enzymatic/Colorimetric Method)

ORDERING INFORMATION

Ref. No.	Pack Size	Presentation
AVLIP - 12	12 ml	(10 ml R1 + 2.0 ml R2
AVLIP - 24	24 ml	(R1:2 x 10 ml, R2:2 x 2ml)
AVLIP - 48	48 ml	(R1:4 x 10 ml, R2:4 x 2ml)

INTENDED USE:

LiquiMAX Lipase is an in-vitro diagnostic kit is use for the quantitative determination of Lipase in human Serum and Plasma.

PRODUCT FEATURES

1. Two Liquid Reagents (5 parts R1+ 1 part R2).
2. Uses 1,2-O-dilauryl-rac-glycero-3-glutaric acid (6'-methylresorufin) ester as Lipase Specfic Substrate.
3. Linearity : 220 U/L.
4. Measuring wave length 578 nm.
5. Two Step Kinetic Assay : 5 Sec Delay+ 120 Sec Measuring.

CLINICAL SIGNIFICANCE :

Lipases are enzymes which hydrolyze glycerol esters of long fatty acids. The enzyme and its cofactor colipase are produced in the pancreas, lipase being also secreted in small amounts by the salivary glands as well as by gastric, pulmonary and intestinal mucosa. Bile acids and colipase form micellar complexes with the lipids and bind lipase on the substrate / water interface. Determination of lipase is used for investigation of pancreatic disorders. In acute pancreatitis the lipase concentrations rise to 2-50 fold the upper reference limit within 4-8 hours after the beginning of abdominal pain peaking at 24 hours and decrease within 8 to 14 days. Elevated lipase values can also be observed in chronic pancreatitis and obstruction of the pancreatic duct.

PRINCIPLE:

Lipase / Colipase

1,2-o-Dilauryl-rac-glycero-3-glutaric acid(6-methylresorufin) ester <----------> 1,2-o-Dilauryl-rac-glycerin + Glutaric acid-(6-methylresorufin)-ester

Spontaneous degradation

Glutaric acid-(6-methylresorufin)-ester <----------> Glutaric acid + Methylresorufin

The increase in absorbance is determined photometrically.

STORAGE AND STABILITY

The reagents are stable up to the end of the indicated expiry date if stored at 2 – 8 °C and when the contamination is avoided. Do not freeze the reagents!

KIT COMPONENTS

1. Buffer Reagent R1
2. Substrate Reagent R2

COMPOSITION:

Components and Concentrations

Reagent 1:

Goods Buffer	(pH 8.0)	50 mmol/L
Taurodesoxycholate		4.3 mmol/L
Desoxycholate		8.0 mmol/L
Calcium chloride		15 mmol/L
Colipase		2.2 mg/L
Detergent		
Preservative		

Reagent 2:

Tartrate Buffer	(pH 4.0)	7.5 mmol/L
Taurodesoxycholate		17.2 mmol/L
Lipase Substrate		0.65 mmol/L
Coemulgator		
Stabilizer		
Preservative		

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at 2 - 8 °C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard any turbid reagent if blank reagent absorbance exceeds 0.5 at 578 nm against distilled water or R2 reagent precipitate.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN COLLECTION & STORAGE

Serum or Heparin Plasma

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

Discard contaminated specimens.

SYSTEM PARAMETERS

Reaction Type (Mode)	:	Kinetic
Reaction Direction	:	Increasing
Wave Length	:	578 nm
Flow Cell Temp.	:	37°C
Zero Setting with	:	Distilled Water
Delay Time	:	5 Sec.
Kinetic Interval	:	120 Seconds
Reagent Volume	:	1000 µl (R1) + 200 µl (R2)
Sample Volume	:	20 µl
Kinetic Factor	:	**Printed on & inside the vial**
Linearity	:	220
Units	:	U/L
High Normal	:	64 U/L

TEST PROCEDURE :

Lipase Buffer (R1)	**1000 µL**
Serum/ Plasma	**20 µL**
Lipase Substrate(R2)	**200 µL**

Mix well and after 5 Sec incubation, measure the change of optical density per 60 seconds during 120 seconds against distilled water at 578 nms as follows:

A0 - Exactily after 5 Seconds.

A1, A2 - Exactily after every 60 seconds for 120 seconds.

CALCULATION:

From absorbance readings calculate Δ A/min and multiply by the corresponding factor at 578 nm

Lipase Activity (IU/L) = Δ Abs / Min X (Kinetic Factor) Printed on & inside the kit

EXPECTED VALUES :

0-64 U/L

It is strongly recommended that each laboratory establish its own normal range.

QUALITY CONTROL & CALIBRATION

It is recommend to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.
Using the recommended calibrator (Avecon) or the standard included, calibrate the assay:
a) When using a new reagent or lot.
b) When QC values are out of range.

PERFORMANCE CHARACTERISTICS

1. Linearity

Linearity : 220 U/L

2. Sensitivity/ Limit of Detection (LOD)

The lower limit of detection is 3 U/L.

3. Interferences

No interference was observed by ascorbic acid up to 30 mg/dL, free and conjugated bilirubin up to 60 mg/dL, hemoglobin up to 500 mg/dL and lipemia up to 1000 mg/dL triglycerides.

4. Precision:

According to protocol EP-5 of the NCCLS (National Committee of Clinical Laboratory Standards)

Intra -Assay	Mean	SD	CV
n = 40	[U/L]	[U/L]	[%]
Sample 1	13.4	0.24	1.81
Sample 2	58.9	0.60	1.01
Sample 3	103	1.50	1.45

Inter -Assay	Mean	SD	CV
n = 40	[U/L]	[U/L]	[%]
Sample 1	13.4	0.24	1.81
Sample 2	58.9	0.49	0.80
Sample 3	103	0.65	0.63

5. Method Comparison:

A comparison between Avecon LiquiMAX Lipase (y) and a commercially available colorimetric test (x) using 67 samples gave following results:

y = 0.96 x – 1.15 U/L; r= 0.999.

LIMITATIONS

The test has been developed to determine lipase concentrations 3-220 U/L. When values exceed this range samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result should be multiplied by 2.

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

REFERENCES:

1. Lorentz K. Lipase. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books
   Verlagsgesellschaft; 1998. p. 95-7.
2. Moss DW, Henderson AR. Digestive enzymes of pancreatic origin. In: Burtis CA, Ashwood ER, editors.Tietz
   Textbook of Clinical Chemistry. 3rd ed.Philadelphia: W.B Saunders Company; 1999.p. 689-708.
3. Tietz N, Shuey DF. Lipase in serum – the elusive enzyme: an overview. Clin Chem 1993; 39: 746-56.
4. Lott J, Patel ST, Sawhney AK, Kazmierczak SC, Love JE. Assays of serum lipase: analytical and clinical considerations. Clin Chem 1986; 32: 1290-1302.

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		

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