Pariksha Biotech
A game changer in IVD

Lipase Estimation Kit

High-Q Lipase

(Enzymatic/Colorimetric Method)

HIGH Q
Command on Quality

Intended Use:

Kit for the quantitative determination of Lipase in human Serum and Plasma.

Summary:

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.

Method:

A synthetically produced lipase substrate (1,2-o-dilaurylrac-glycero-3-glutaric acid-(6-methylresorufin) ester) is added to a micro-emulsion which is specifically split by lipase in the presence of colipase and bile acids. The combination of lipase and bile acids make this specific and reliable for pancreatic lipase without any reaction due to lipolytic enzymes or esterases. The reagent composition has been thoroughly optimized so there are no serum matrix effects.The generated methylresorufin-ester is spontaneously degraded to methylresorufin. The absorbance by this red dye is directly proportional to the lipase activity in the sample.

Principle:

Lipase catalyses the reaction

1,2-o-Dilauryl-rac-glycero-3-glutaric acid(6-methylresorufin) ester

Lipase / Colipase

<----------> 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.

Reagents:

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		

Calibrator: Calibrator is available as Lyophilized vial. Carefully open the vial without losing the materials.

Add 1.0 ml distilled water and keep at 30 Minutes at room temperature. Reconstituted Calibrator is stable for 15 Days at 2-8°C and 30 days when frozen as aliquots at -20 °C. Look for the Calibrator Concentration on the vial for the calibration.

Storage Instructions and Reagent 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!

Reagent Preparation:

The reagents are ready to use. Do not shake.

Specimen:

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.

Assay Procedure

System Parameters:

Reaction Type (Mode)	:	**Fixed Time**
Reaction Direction	:	**Increasing**
Wave Length	:	**578 nm**
Flow Cell Temp.	:	**37°C**
Zero Setting with	:	**Distilled Water**
Delay Time	:	**5 Seconds**
Measuring Time	:	**120 Seconds**
Reagent Volume	:	**500 µL (R1) + 100 µl (R2)**
Calibrator / Sample Volume	:	**10 µl**
Calibrator Concentration	:	**34 U/L**
Linearity	:	**300**
Units	:	**U/L**
High Normal	:	**64 U/L**

Reagent	Calibrator	Sample
Reagent 1	500 µL	500 µL
Calibrator (Conc: 34 U/L)	10 µL	---
Serum/ Plasma	----	10 µL
	Mix and incubate for 5 min at 37 °C	
Reagent 2	100 µL (Calibrate and Derive the factor)	----
Reagent 2	----	100 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 for Calibrator and Serum/Plasma Samples seconds.

Aº	-	Exactly after 5 Seconds.
A1, A2	-	Exactly after every 60 seconds for 120 seconds.

Calculations with calibrator:

$$\text{Lipase [U/L]} \xrightarrow{\frac{A2-A1\ \text{Sample}}{A2-A1\ \text{Calibrator}}} \times 34\ \text{(Conc.Calibrator [U/L])}$$

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Performance Characteristics:

Measuring range

The test has been developed to determine lipase concentrations up to 300 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.

Specificity/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.

Sensitivity / Limit of Detection:

The lower limit of detection is 3 U/L.

Precision:

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

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

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

Method Comparison:

A comparison between High-Q 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.

Interference:

The following concentrations were not found to affect the assay:
Conjugated Bilirubin 40 mg/dl, Free Bilirubin 70 mg/dl, Haemoglobin 1000mg/dl , Intralipid 800 mg/dl, Triglycerides 1000 mg/dl

Reference Range: 0 - 64 U/L

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

Literature

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.

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Ordering information:

Ref./Cat. No.	Pack Size	Presentation
P-LIP - 12	12 ml	(10 ml R1 + 2 ml R2
P-LIP - 50	50 ml	(4 x 10.5 ml R1 + 4 x 2 ml R2)
P-LIP© - 50	50 ml	(4 x 10.5 ml R1 + 4 x 2 ml R2) Calibrator-1 ml

Product Features

- Two Liquid Reagents (5 Parts R1+ 1 Part R2) with Calibrator
- • Uses 1,2-O-dilauryl-rac-glycero-3-glutaric acid (6'-methylresorufin)-ester as Lipase Specfic Substrate.
- Linearity : 300 U/L.
- Measuring wavelength 578 nm.
- Two Step Fixed Time Assay : 5 Sec Delay+ 120 Sec Measuring.
- No interference from Conjugated Bilirubin 40 mg/dl, Free Bilirubin 70 mg/dl, Haemoglobin 1000 mg/dl, Intralipid 800mg/dl, Triglycerides 1000 mg/dl, Ascorbic Acid 40 mg/dl

Symbols used with IVD devices

- Date of manufacture
- In vitro diagnostic medical device
- Do not freeze
- Use-by date
- Keep dry
- Consult instructions for use
- Consult electronic instructions for use
- Catalogue number
- Caution
- Manufactured by
- Keep away from sunlight
- This way up
- Do not use if package is damaged
- Batch Code
- Reagent
- Calibrator Material

eIFU Indicator

Pariksha's world inside
SCAN TO EXPLORE MORE

Manufactured in India by :
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