LIPASE
(DGMRE method)

DIATEK

CLINICAL SIGNIFICANCE :

The measurement of serum lipase activity is widely used for the diagnosis of acute pancreatitis. A 10-fold increase of lipase activity above the upper reference limit is suggestive of pancreatitis, pancreatic injury, or inflammation of organs contiguous to the pancreas. It is recommended that other tests, such as trypsinogen and amylase isoenzymes be performed to supplement the diagnosis.

TEST PRINCIPLE :

Lipase catalyzes the following reaction :

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

Lipase /Colipase ↓

1,2-o-Dilauryl-rac-glycerol + Glutaric acid-(6-methylresorufin)-ester

Glutaric acid -(6-methylresorufin)-ester

Cleavage ↓

Glutaric acid + Methylresorufin

A synthetic substrate (DGMRE) is split by Lipase to yield the colored final product Methylresorufin. The increasing absorbance of the red Methylresorufin is measured photometrically. The reaction is highly specific on the human enzyme.

REAGENTS COMPOSITION :

R1: Buffer (pH 8.0) 50 mmol/l	R2 : Tartrate Buffer pH 4.0
Desoxycholate 1.6 mmol/l	(10 mmol/l)
Calcium Chloride 10 mmol/l	Taurodesoxycholate > 8 mmol/l
Colipase 1mg/l	DGMRE > 0.20 mmol/L

KIT CONTENTS :

	CODE No. LP02
Pack size :	(24 ml)
Reagent 1	2x7.5 ml
Reagent 2	1 x 9 ml

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2 - 8 ºC, and contaminations prevented during their use. Do not use reagents over the expiration date.

SAMPLES :

Serum or Heparinised plasma

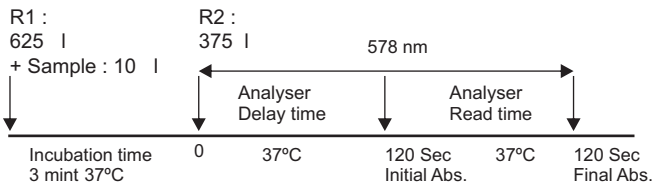
ASSAY CONDITIONS:

Wavelength :	578 nm (570 - 580 nm)
Cuvette:	1 cm light path
Constant temperature	37ºC
Reaction (Mode)	Fixed Time
Kinetic Factor	3846
Delay	120 sec
Read time	120 sec
Linearity	250 U/L
Unit	U/L
Blanking	D. Water
Slope of reaction	Increasing

PROCEDURE :

1. Pipette 625 l of R1 in a clean test tube.
2. Add 10 l of sample, mix carefully (do not shake) and incubate for 3 mints at 37ºC.
4. Add 375 l of R2 and read the change of absorbance (A) with delay time 120 sec and Read time 120 sec at 37ºC

Assay Procedure summary (Serum/Plasma):



CALCULATIONS :

Lipase Activity in U/L = Abs/mint of Test x 3846

REFERENCE RANGE :

Serum/plasma : < 60 U/l

The above reference range is guideline and all the laboratories must establish their own Age specific normal reference range. Final diagnosis should be made with correlation of clinical factors.

PRECAUTIONS :

1. Do not pipette by mouth therefore avoid contact of the reagent with skin.
2. Use fresh microtips while pipetting sample and R2
3. Avoid contamination of the reagent during the assay process.
4. **Before the assay begins, bring all the reagents to room temperature.**
5. Do not freeze or expose the reagents to high temperature and protect from direct sunlight as it will affect the performance of the kit.
6. Programmes for specific analysers are available on request.
8. For accuracy of results, the assay procedure, reagent preparation and storage has to be meticulously followed.
9. As with all the diagnostic procedures, the physician should evaluate data obtained by the use of this kit in light of other clinical information.

INTERFERENCES

The following analytes were tested up to the levels indicated and found not to interfere with Ascorbic Acid up to 30 mg/dL Bilirubin up to 60 mg/dL, Hemoglobin up to 500 mg/dL and Triglycerides up to 1000 mg/dL

LINEARITY AND DETECTION LIMIT :

The linearity limit of the standard serum procedure is up to the Lipase activity of 250 U/l. At higher activities the sample has to be diluted 1:2 with Normal saline and the final result to be multiplied by 2. The low detection limit for serum samples is equal to 3 U/L.

BIBLIOGRAPHY

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3. Tietz N, Shuey DF. Lipase in serum – the elusive enzyme:an overview. Clin Chem 1993;39:746-56.

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