Lipase Test Kit
Chromogenic Method

Quantitative determination of Lipase in human Serum / Plasma / other body fluids. Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Pack Size
LIP 25	1 X 25 ml
LIP 50	1 X 50 ml
LIP 100	2 X 50 ml
LIP 1000	1X1000 ml
LIP 5000	1X5000 ml
LIP 10000	1X10000 ml

CLINICAL SIGNIFICANCE
Lipase is a pancreatic enzyme necessary for the absorption and digestion of nutrients that catalyzes the hydrolysis of glycerol esters of fatty acids. Determination of Lipase is used for the diagnosis of diseases of pancreas such as acute and chronic pancreatitis and obstruction of pancreatic duct.

Method
Chromogenic Method.

PRINCIPLE
The pancreatic lipase in presence of colipase, desoxycholate and calcium ions hydrolyses the substrate 1-2-O-dilauryl-rac-glycero-3-glutaric acid (6'methylresourfin)- ester. to 1-2-O-dilauryl-rac-glycerol and Glutaric(6'methylresourfin)- ester which is monitored as increase in the absorbance. The rate of methylresorufin formation measured photometrically is proportional to the catalytic concentration of lipase present in the sample.

REAGENT
Reagent I : Buffer Reagent
Reagent 2 : Substrate Reagent
Lipase calibrator : (Lyophilized) Human Serum. (Concentration Stated on Vial Labels)

REAGENT PREPARATION
Reagent 1 & 2: Ready to use
Lipase calibrator: Reconstitute the calibrator with the exact volume of D/W as mentioned on the label , cap and mix gently to dissolve contents. stability ; 7 days at 2-8° or 3 months at -20°c aliquot into small volume and freeze.

REAGENT STORAGE AND STABILITY
When stored between 2-8°C the reagent is stable until the expiration date stated on the bottle and kit box label.
R1 - Ready to use stability after opening 90 days at 2-8°C.
R2 - Mix gentle before use.

WARNING AND PRECAUTIONS
- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

WASTE MANAGEMENT
Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED
- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION
Serum or heparin plasma or EDTA plasma
Stability: 7 days at 20 – 25°C
7 days at 4 – 8°C
1 year at –20°C
Only freeze once! Discard contaminated specimens!

ASSAY PROCEDURE
Operating Instructions
- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, Calibrator and samples to room temperature 18 - 28ºC, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	578 nm
Reaction Temperature	37°C
Measurement	Against D/W
Reaction	Fix time Kinetic
Reaction Direction	Increasing
Sample Volume	20 µl
Reagent Volume 1	800 µl
Reagent Volume 2	200 µl
Delay	5 Sec.
Measuring Time	300 Sec.
Low normal	5 U/L
High Normal	60 U/L
Linearity	250 U/L

MANUAL ASSAY PROCEDURE
Pipette into Test Tubes

	Calibrator	SAMPLE
Reagent 1	800 µl	800 µl
Sample	-	20 µl
Calibrator	20 µl	-
Mix Well and Incubate for 5 min.		
Reagent 2	200 µl	200 µl

Mix well and incubate at 37°C for 5 Sec. (Delay Time). Measure the absorbance increase for 300 Sec. (Interval Time) and determine the Δ Absorbance for sample (ΔA_{sample}) And Calibrator ($\Delta A_{calibrator}$).

SAMPLE DILUTIONS
- This method is linear upto a concentration of 250 U/L.
- Dilute samples above this concentration 1:1 with 0.9% saline
- Repeat assay. Multiply the result by 2.

CALCULATION
Results are calculated, usually automatically by the instrument, as follows:

$$\text{LIPASE (U/L)} = \frac{(\Delta A_{sample})}{(\Delta A_{calibrator})} \times \text{Calibrator Value}$$

CLIBRATORS AND CONTROLS
For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

The assigned values of the calibrator have been made traceable to the molar extinction coefficient of an available measuring method

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

Each laboratory should establish corrective action in case of deviations in control recovery.

PERFORMANCE CHARACTERISTICS
WITHIN RUN

Sample	Mean Concentration	SD	CV %
Randox 2	40.27	0.26	0.65%
Randox 3	68.19	0.14	0.20%

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Randox 2	40.02	0.27	0.67%
Randox 3	68.31	0.21	0.30%

LINEARITY
The method is linear upto a concentration of 250 U/L. Dilute samples above this concentration 1:1 with 0.9% saline solution and repeat assay. Multiply the result by 2.
Limit of detection: The limit of detection for Lipase is 5 U/L.

METHOD COMPARISON
A comparison of Lipase with a commercially available assay (x) using 20 samples gave following results: $R^2 = 0.9900$

REFERENCE VALUES

Serum/plasma	< 60 U/L

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE
- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

INTERFERENCE
- Hemoglobin: No interference found upto 400 mg/dL.
- Bilirubin: No interference found upto 50mg /dL.
- Ascorbic Acid: No interference found upto 50 mg/dL.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

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

GLOSSARY OF SYMBOL

	Consult Instruction for Use
	For *in vitro* Diagnostic use only
	Store between
	Manufacturer
	Keep away from sunlight



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