LIPASE

1 x 25 mL
51417001

INTENDED USE

This reagent is intended for *in vitro* quantitative determination of lipase in human serum or plasma.

- Methyl resorufin method
- Linear up to 300 U/L
- Reagent is ready for use

CLINICAL SIGNIFICANCE

Lipase is a pancreatic enzyme necessary for the absorption and digestion of nutrients that catalyses the hydrolysis of glycerol esters of fatty acids. Determination of lipase is used for diagnosis of diseases such as acute and chronic pancreatitis and obstruction of the pancreatic duct. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRINCIPLE

In the presence of colipase and bile acids lipase splits the synthetic substrate (1,2-O-Dilauryl-rac-glycero-3-glutaricacid (6-methyl-resorufin-ester) to glycerol and methylresorufin-ester, which is spontaneously degraded to glutaric acid and methylresorufin. The rate of methylresorufin formation, measured photometrically is proportional to the catalytic concentration of lipase present in the sample.

REAGENT COMPOSITION

LIPASE (S.L) R1	**2 x 10 mL**
Goods Buffer (pH 8.0)	40 mmol/L
Taurodeoxycholate	3.4 mmol/L
Deoxycholate	6.4 mmol/L
Calcium chloride	12 mmol/L
Colipase	1.7 mg/dL
LIPASE(S.L) R2	**1 x 5 mL**
Tartrate Buffer (pH 4.0)	1.5 mmol/L
Taurodeoxycholate	3.4 mmol/L
Color substrate	0.13 mmol/L
LIPASE CALIBRATOR	1 x 3 mL

Lipase calibrator concentration is stated on the vial label.

STORAGE & STABILITY

The sealed reagents are stable up to the expiry date stated on the label, when stored at 2 - 8°C, protected from light.

LINEARITY

This reagent is linear up to 300 U/L.

If the concentration is greater than linearity (300 U/L), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

NORMAL RANGE

It is recommended that each laboratory establish its own reference values.

The following value may be used as guide line.

Serum / Plasma : Up to 60 U/L

PREPARATION AND STABILITY OF REAGENT

Lipase R1 and Lipase R2 are ready to use.

Calibrator : Reconstitute with 3 mL of distilled water. Dissolve the content of the vial by swirling gently to avoid the formation of foam.

Stability : Reconstituted calibrator is stable only for 7 days at 2-8°C and 3 months at -20°C.

PRECAUTION

To avoid contamination, use clean laboratory wares. Use clean dry disposable pipette tips for dispensing. Close reagent and calibrator bottles immediately after Use. Avoid direct exposure of reagent to light.

SAMPLE

Serum or plasma with sodium citrate, EDTA or heparin.

GENERAL SYSTEM PARAMETER

Mode of Reaction	Kinetic	Fixed Time
Slope of reaction	Increasing	Increasing
Wavelength	580 nm	580 nm
Temperature	37°C	37°C
Calibrator concentration	As on the vial	As on the vial
Linearity	300 U/L	300 U/L
Blank	Reagent	Reagent
Delay time	120 sec.	120 sec
No of reading	2	-
Interval	60 sec	120 sec
Sample volume	20 µL	20 µL
Reagent volume	300 µL(250+50)	300 µL(250+50)
Cuvette	1cm light path	1 cm light path

LABORATORY PROCEDURE

	Blank	Calibrator	Sample
Reagent 1	250 µL	250 µL	250 µL
Calibrator	-	5 µL	-
Sample	-	-	5 µL
Dist. water	5 µL	-	-
Mix carefully (do not vortex); incubate for 1-5 minutes at 37°C. Then add			
Reagent 2	50 µL	50 µL	50 µL

Mix and incubate for 2 min at 37°C, read absorbance against reagent blank. Measure the change in absorbance per minute (ΔOD/min) during 2 min.

or

Mix and read the optical density (T_1) 120 seconds after the Reagent 2 addition. Take second reading (T_2) exactly after 120 seconds.

CALCULATION

Lipase U/L =

$$\frac{(\Delta OD/min)\ \text{Sample} - (\Delta OD/min)\ \text{Blank}}{(\Delta OD/min)\ \text{calibrator} - (\Delta OD/min)\ \text{Blank}} \times \text{Calibrator concentration}$$

or

$$\frac{(T_2-T_1)\ \text{of sample}}{(T_2-T_1)\ \text{of standard}} \times \text{Calibrator concentration}$$

BIBLIOGRAPHY

1. Mc Neely , M. ; Lipase. Kaplan, A. *et al.*; Clin. Chem. The C.V.Mosby Co. St Louis, Toronto. Princeton 1984, 1130-1135
2. Burtis, A., *et al.* ; Tietz Textbook of Clinical chemistry, 3rd ed AACC
3. Neumann, U., *et al.*; Methods of Enzymatic Analysis, Vol 4, 3rd Ed.

SYMBOLS USED ON THE LABELS : IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

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