LIPASE – L (Single Liquid)

(TURBIDIMETRIC)

ENZOPAK

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Ref. CC3-LPS.15M, 4x5 ml

INTENDED USE

This reagent is intended for the *in-vitro* quantitative determination of Lipase (Triacylglycerolase) in human serum. Determination can be done by Fixed Time method.

DIAGNOSTIC SIGNIFICANCE

Lipase is most frequently measured to assist with the investigation of pancreatitis. In acute pancreatitis, Lipase increases within 4-8 hours, peaks at approximately 24 hours and decreases within 4-18 days. Lipase may also be elevated in chronic pancreatitis but, if severe destruction of the acinar tissue has occurred, serum levels may be below those normally detected.

Obstruction of the pancreatic duct, caused by a calculus or carcinoma, may also result in increased serum lipase levels. Increased serum lipase may also be observed in chronic or acute renal disease, after endoscopic retrograde pancreatography or treatment with opiates.

PRINCIPLE

The Lipase reagent utilises the method of Ziegenhom et al.

$$\text{Triolein} + 3H_2O \xrightarrow{\text{Lipase}} \text{Glycerol} + 3\ \text{Fatty Acids}$$

Lipase catalyses the hydrolysis of Triolein in the presence of Colipase to form glycerides and fatty acids. The rate of decrease in turbidity, measured at 340 nm, is proportional to the lipase activity.

WARNING: Avoid ingestion and contact with skin, mouth and eyes. The toxicity of this reagent has not been determined. Flush with plenty of water when disposing.

PRESENTATION

All reagents to be stored at 2-8^{0}C.	No. of Bottles/Pouch 4 x 5ml
• Lipase Liquid	4
• Lipase Calibrator (value stated on vial)	2
• Lipase Diluent	1

REAGENT STORAGE AND STABILITY

When stored refrigerated at 2-8^0 C, the reagent is stable until the expiry date stated on the bottle and kit box label.

PREPARATION OF LIPASE CALIBRATOR & STABILITY

Add 1 ml of Diluent to the vial of Lipase Calibrator. Mix well to dissolve the contents. The reconstituted calibrator is stable for atleast 7 days when stored at 2-8ºC and for 4 weeks when stored at -20ºC

SPECIMEN COLLECTION

Collection : No special preparation of the patient serum is required.

Serum : Use non-hemolyzed serum.

Storage : In serum, lipase is stable for 1 week at room temperature (18-25^{0}C) or for 3 weeks at 2-8^{0}C. If frozen, lipase is stable for several months.

REACTION PARAMETERS

- Type of Reaction : Fix Time (Decreasing O.D)
- Wavelength : 340 nm
- Flowcell Temperature : 37^{0}C
- Delay time : 240 Secs. (4 mins)
- Interval Time : 300 Secs. (5 mins)
- No. of Readings : 2
- Sample Volume : 0.04 ml / 0.02 ml
- Working Reagent Volume : 1.0 ml / 0.5 ml

TEST PROCEDURE

Pipette Into Test Tubes	Calibrator	TEST
Reagent	1.0 ml	1.0 ml
Sample	-	0.04 ml
Calibrator	0.04 ml	-

Mix and read 1st absorbance of test exactly at 240 seconds (4 min) and 2nd absorbance at 540 seconds (9 min) at 340 nm. Determine the mean change in absorbance as per Δ A = (A1-A2) Value.

TEST RESULTS

For Fixed Time:

$$\text{Lipase activity (U/L)} = \frac{\Delta\ A/\text{min of Sample}}{\Delta\ A/\text{min of Calibrator}} \times \text{Calibrator Value}$$

Calibrator value obtained as per U/L mentioned on calibrator.

LIMITATIONS FOR INTERFERENCE

1. Cholesterol and Triglycerides reagents typically contain high levels of activity of lipase and esterase. Care should be taken to avoid contamination with these reagents.
2. Studies to determine the level of interference from haemoglobin and bilirubin were carried out.
3. The following results were obtained :-

Haemoglobin : No interference from hemoglobin upto 124 µmol/L.

Bilirubin : No interference from bilirubin upto 342 µmol/L.

NORMAL VALUES

Using the method described, the expected values were determined to be upto 200 U/L.

The quoted values are representative of the expected range for this method and should serve as a guide only. It is recommended that each laboratory should verify this range or derive a reference interval for the population that it serves.

LINEARITY

When run as recommended, the assay is linear up to 700 U/L.

NOTES

Reagents such as cholesterol/Triglycerides/HDL/LDL contains high concentrations of detergents and hydrolyzing enzymes; cross contamination from such reagents should be avoided.

All glassware / tips and cuvette being used for the test should be thoroughly cleaned.

REFERENCES

1. Tietz N.W., and Shuey D.F., Lipase in serum-the Elusive Enzyme: An Overview. Clin Chem 1993: 39:746-56
2. Ziegenhorm j. et al, Clin. Chem. 1979:25:1067.
3. Moss D.W. and Henderson M.B., "Enzymes" in Tietz Textbook of Clinical Chemistry, Burtis, C.A. and Ahwood, E.R. (Eds). WB Saunder Company 1994.

Regd. Office.3/7, B.I.D.C., Gorwa, Vadodara 390 016 (INDIA)
Web: www.reckondiagnostics.com Ph: +91·265·2281631
Email: mail@reckondiagnostics.com
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