LIPASE
(Colorimetric Method)

Intended Use
Lipase is a reagent set for determination of Lipase activity in serum and plasma based on colorimetric method.

Principle
The chromogenic lipase substrate 1,2-0-dilauryl-rac-glycero-3-glutaric acid-(6-methylresorufin) ester is cleaved by the catalytic action of alkaline lipase solution to form 1,2-O-dilauryl-rac-glycerol and an unstable intermediate glutaric acid-(6-methylresorufin)ester. This decomposes spontaneously in alkaline medium to form glutaric acid and methylresorufin.
The lipase activity in the specimen is proportional to the formation of methylresorufin in the reaction and can be determined photometrically at 578 nm.

1,2-O-dilauryl-rac-glycero-3-glutaric acid-(6-methylresorufin)ester —(Lipase / Co-lipase)→ 1,2-O-dilauryl-rac-glycerol + glutaric acid-(6methylresorufin)ester

glutaric acid + methylresorufin ←(Alkaline medium)— 1,2-O-dilauryl-rac-glycerol + glutaric acid-(6methylresorufin)ester

Reagents provided
1. Reagent R_1
2. Reagent R_2

Reagent storage and stability
The reagent kit should be stored at 2 - 8°C and is stable till the expiry date indicated on the label.
R_1 and R_2 reagents are stable till expiry at 2 - 8°C.Do not freeze the reagent.

Specimen collection and preservation
Blood should be collected in a clean dry container. Do not use calcium complexing anticoagulants such as EDTA, citrate and fluoride.Lipase in serum/plasma is stable for 1 week at 15 - 25°C/1 week at 2 - 8°C/1 year at- 20°C.. Centrifuge samples containing precipitate before performing the assay. The samples should be brought to room temperature prior to use.

Assay guidelines for Analyzer

Reaction type	Fixed Time
Reaction slope	Increasing
Wavelength	578 nm
Flow cell temperature	37°C
Zero setting	Distilled Water
Delay Time	60 seconds
Read Time	60 seconds
Reagent Volume	1000µl (800µl + 200 µl)
Sample volume	10 µl (0.010 ml)
Linearity	250 U/L

Perform the assay as given below:

	Calibrator	**Sample**
Reagent 1	800 µl	800 µl
Reagent 2	200µl (0.200 ml)	200 µl (0.200 ml)
Sample	10 µl (0.010 ml)	10 µl (0.010 ml)

1. Mix thoroughly and transfer the assay mixture immediately to the thermo stated cuvette and start the stop watch simultaneously.
2. Record the first reading at 60th second and subsequently 1 more readings with 60 seconds interval at 578 nm.

Calculation

$$\text{Activity of Lipase in U/L} = \frac{\Delta\text{Abs. /min of Sample}}{\Delta\text{Abs. /minof Calibrator}} \times \text{Conc. of Calibrator}$$

Normal Range

Adults: upto 60 U/L (0.22-1.00 µkat/L)

Note: Expected range varies from population to population. It is therefore recommended that each laboratory should establish its own normal range.

Limitations

- If the Lipase activity exceeds 250 U/L, dilute the specimen with normal saline and repeat the assay. In such cases the results obtained should be multiplied with the dilution factor to obtain correct Lipase activity.

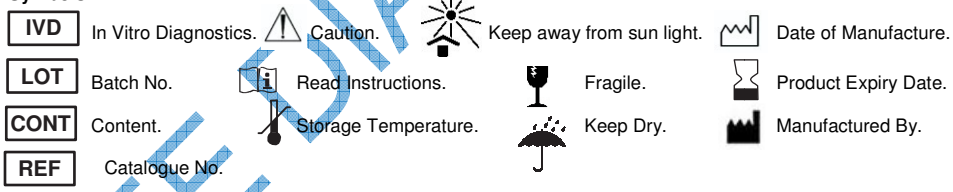
Quality Control

To ensure adequate quality control, it is recommended that each batch should include normal and abnormal commercial reference control serum. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glassware, and accuracy of pipetting.

References

1. Greiling H, GressnerAM, eds, Lehrbuch der Kinischen **Chemie und Pathobiochemie,** 3rd ed. Stuttgart / New York: Schattauer Veriag 1995.
2. Keller H, ed. **Klinisch-chemische Labordiagnostikfur** die Praxis, 2nd ed. Stuttgart/ New York: Georg Thieme Veriag 1991:354-361.
3. Tietz NW, Shuey DF. Lipase in serum - the elusive enzyme: An overview. **Clin Chem** 1993;39 (5): 746-756.
4. **Tietz NW, ed. Clinical Guide to Laboratory Tests,** 3rd ed. Philadelphia PA: WB Saunders Company 1995;865.
5. **Neumann U, Junius M, Batz HG, et al.** New substrates for the optical determination of lipase; EP 2072521987.

Symbols



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