LIPASE

Colorimetric Method

Liquid Reagent ready to use

REF 17200160 R1 8X20mL
REF 12005040 R2 8X5mL

IVD

PRODUCT CODE: LIP-2D14

Company with Quality System ISO 9001 – ISO 13485 Certified by LMS

INTENDED USE

Quantitative determination of Lipase in serum and plasma.

PRINCIPLE

The colorimetric substrate, 1,2-O-Dilauryl-rac-glycero-3-glutaric acid-(6'methyl-resorufin)-ester, is cleaved by pancreatic lipase and the resulting dicarboxilic acid ester is hydrolysed under the alkaline test conditions to yield the chromophore methylresorufin.

The formed methylresorufin , photometrically measured, is proportional to the amount of lipase in the sample.

SAMPLE

Serum, plasma with heparin.

Lipase activity is stable 7 days in samples stored at 2-8 °C.

KIT COMPONENTS

Reagent (A) Volume = 10 ml	Good's Buffer pH 8.0, colipase ≥ 2 mg/l, desoxycolate ≥ 1.0 mM, taurodesoxycolate ≥ 1.0 mM, calcium ions ≥ 1 mM, detergent and preservative.
Reagent (B) Volume = 10 ml	Tartrate buffer pH 4.0, lipase substrate ≥ 0.1 mM, stabilizerc and preservative.

The reagents are stable until the expiration date indicated on the label if stored at 2-8°C. Do not use over expiry date.

Once opened reagents are stable for 2 months at 2-8°C if contamination is avoided. Keep bottles closed when not in use.

The Reagent (B) is a orange-colored micro-emulsion. A slight apparent precipitation could occur, showing a light red deposit on the bottom of vial. It is a normal behaviour and it is recommended to resuspend solution before analysis, with a mild shaking.

REAGENT PREPARATION

Liquid Reagents, ready to use.

Reagent (B): Mix gently before use.

PRECAUTIONS AND WARNINGS

Reagent (A): Not classified as hazardous

Reagent (B): Danger. Causes serious eye damage (H318).

Wear protective gloves. Protect eyes (P280). IN CASE OF CONTACT WITH EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305+P351+P338). Immediately call a doctor (P310).

P501: Dispose of waste according to local laws.

PROCEDURE

Wavelength:	580 nm (570-590 nm)
Lightpath :	1 cm
Temperature:	37°C
Reading:	against distilled water

pipette:	blank	sample	calibrator
Reagent (A)	300 µl	300 µl	300 µl
water	6 µl		
sample		6 µl	
calibrator			6 µl
Mix carefully, incubate at 37°C for 5 minutes.			
Reagente (B)	75 µl	75 µl	75 µl

Mix, execute a first reading of absorbance after 2 minutes , incubating at 37°C. Perform other 2 reading at 60 seconds intervals. Calculate il ΔA/min.

RESULTS CALCULATION

$\Delta A/min = \Delta A/min_{(sample\ or\ calibrator)} - \Delta A/min_{(blank)}$

Lipase (U/L) = $[\Delta A/min_{(sample)} / \Delta A/min_{(calibrator)}]$ x Calibrator Value

EXPECTED VALUES

≤ 60.0 U/L

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL

You must perform the controls at each kit's use and verify that the values obtained are within the reference range reported in the operating instructions.

PERFORMANCE

Sensitivity: the sensitivity of the method is 1 U/l.

Linearity: the method is linear up to 300 U/l. For higher values, dilute the sample 1:2 and multiply the result by 2.

Precision intra-assay (n=10):

	Level 1	Level 2
Mean (U/l)	60.6	90.4
SD	0.54	0.70
CV %	0.89	0.77

Precision inter-assay (n=20):

	Level 1	Level 2
Mean(U/l)	59.9	90.3
SD	1.76	1.80
CV %	2.94	1.99

Interferences: bilirubin does not interfere up to 50 mg/dl. Hemoglobin does not interfere up to 400 mg/dl. Ascorbic acid does not interfere up to 50 mg/dl. Lipids do not interfere up to 1000 mg/dl.

Correlation against a reference method: Y = 0.93x + 0.50 r = 0.99.

REFERENCES

1. Tietz N. and Shuey DF., Clin. Chem. 1993, 39, 746-756.
2. Tietz Textbook of Clinical Chemistry, Fourth Edition, Burtis-Ashwood-Bruns (2006) 619-621.

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