SPECTRUM

The Creative Approach to Bioscience

LIPASE-LS (DGMRE)

REF:281 001 **40 test**
R1 1 x 20 ml **R2** 1 x 5 ml **Calibrator** 1 vial

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(Xi) - Irritant
	Temperature Limitation		

Intended use

Spectrum Lipase-LS reagent is intended for in-vitro quantitative determination of Lipase in human serum, heparinized or EDTA plasma.

Background

Pancreatic lipase in serum is closely associated with pancreatic diseases. The activity of this enzyme has been measured as an important marker for diagnosing pancreatic diseases and the associated monitoring of therapeutic effects.Pancreatic lipase test kits currently available include a turbidimetric method using triglyceride as substrate and a colorimetric method using synthetic substrates.

Method

Fixed Rate method

Principle

Lipase catalyzes the following reaction :

1,2-o-Dilauryl-rac-glycero-3-glutaric acid-(6-methylresorufin)-ester

$$\xrightarrow{\text{Lipase /Colipase}}$$

1,2-o-Dilauryl-rac-glycerol + Glutaric acid-(6-methylresorufin)-ester

Glutaric acid -(6-methylresorufin)-ester $\xrightarrow{\text{Cleavage}}$

Glutaric acid + Methylresorufin

A synthetic substrate (DGMRE) is split by Lipase to yield the colored final product Methylresorufin. The increasing absorbance of the red Methylresorufin is measured photometrically .

Reagents

Reagent 1 (R1)

Goods Buffer (pH 8,0)	40 mmol/l
Taurodesoxycholate	3.4 mmol/l
Desoxycholate	2.6 mmol/l
Calcium chloride	12 mmol/l
Colipase	1 mg/l

Reagent 2 (R2)

Tartrate Buffer (pH 4,0)	1.5 mmol/l
Taurodesoxycholate	3.4 mmol/l
DGMRE	0.13 mmol/l

Calibrator (C): Serum based calibrator with assigned value printed on the label.

Precautions

For *in vitro* diagnostic use only.

Reagents Preparation , Storage and Stability

Reagent : The reagents are ready to use.When stored tightly capped at 2-8°C and protected from light,the reagents are stable up to the expiry date printed on the labels.
Once opened, the reagent is stable for 2 months at the specified temperature if contamination is avoided.

Calibrator : The calibrator is vacuum sealed; therefore it should be reconstituted carefully with distilled water as stated on the vial label. Close the vial carefully and allow the calibrator to stand for 30 minutes with occasional swirling.
Avoid foaming! Do not shake!
After reconstitution the tightly closed calibrator can be used within 30 days at -20°C.

Samples

Serum free of hemolysis, Heparin plasma.

Stability : 24 hrs at 15 - 25 °C
5 days at 2 - 8 °C
1 year at -20 °C

Procedure

Wavelength	580 nm, Hg 578 nm
Optical Path	1 cm
Assay type	Fixed rate
Direction	Increase
Temperature	37 °C
Zero adjustment	Against air
Sensitivity	3 U/L
Linearity	300 U/L

	Sample / Calibrator
Sample / Calibrator	10 µl
Reagent 1	500 µl

Mix carefully (do not shake), incubate for 5 min at 37°C, then add R2 to start the reaction :

Reagent 2	125 µl

Mix carefully , **read absorbance A1 after 5 seconds** for both sample and calibrator.
Read A2 of sample and calibrator 2 minutes later.

Calculations

$$\text{Activity of Lipase (U/l)} = \frac{\Delta A_{\text{Sample}}}{\Delta A_{\text{Calibrator}}} \times \text{Conc.Calibrator}$$

Expected Values

< 60 U/l

***Note**: It is recommended for each laboratory to establish and maintain its own reference values. The given data are only any indication.*

Calibrators and controls

For the calibration of automated analyzers ,Spectrum Multicalibrator is recommended.
For quality control , use Spectrum normal and abnormal controls.

Sensitivity

The detection limit is equal to 3 U/l.

Linearity

The reagent is linear up to 300 U/l.
If this level is passed, repeat the test using serum diluted 1 +1 with sodium chloride solution(9 g/L). Multiply result by 2.

Analytical range

3 U/l - 300 U/l

Precision

Within run n = 40	Mean [U/l]	SD [U/l]	CV [%]
Sample 1	13,4	0,24	1.79
Sample 2	58,9	0,60	1.02
Sample 3	103	1,50	1.46

Beween run n = 40	Mean [U/l]	SD [U/l]	CV [%]
Sample1	13,4	0,24	1.79
Sample 2	58,9	0,49	0.83
Sample 3	103	0,65	0.63

Correlation

A comparative study has been performed between the Spectrum method and another commercial reagent on 200 human serum samples. The parameters of linear regression are as follows:

y = 0,96 x – 1,15 U/l r = 0,999

Interfering Substances

- Ascorbic Acid: no interference up to 30 mg/dL
- Bilirubin: no interference up to 60 mg/dL
- Hemoglobin: no interference up to 500 mg/dL
- Triglycerides: no interference up to 1000 mg/dL

Refrences

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4. Lott J, Patel ST, Sawhney AK, Kazmierczak SC, Love JE. Assays of serum lipase: analytical and clinical considerations. Clin Chem 1986;32:1290-1302.
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ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
281 001	40 test

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