SPECTRUM

The Creative Approach to Bioscience

LIPASE-LS
COLORIMETRIC (DGMRE)

REF:281 001 40 test
R1 1 x 20 ml **R2** 1 x 5 ml **Calibrator** 1x3ml

Intended use
Spectrum diagnostics 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
Colorimetric Test, Kinetic

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
Reagents Composition (concentrations in the test):

Reagent 1:

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:

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

SYMBOLS IN PRODUCT LABELLING

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

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

Precautions
- For in vitro diagnostic use only.

Stability
When stored at 2-8° C and protected from light, the reagents are stable up to the expiry date printed on the labels.

Preparation and stability of Working reagents
The reagents are ready to use.

Stability : 3 months at 2-8°C, if contamination is avoided.

Calibrator : The calibrator is vacuum sealed; therefore the vial should be reconstituted carefully with exactly 3 ml of distilled water. Close the vial carefully and allow the calibrator to stand for 30 minutes swirling occasionally.
Avoid foaming! Do not shake!
After reconstitution the tightly closed calibrator can be used within 30 days at – 25°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
This reagent can be used manually (see method below) and on most analyzers. Applications are available on request.

Wavelength	580 nm, Hg 578 nm
Cuvette	1 cm
Temperature	37 °C
Measure	Against air

	Reagent Blank	Sample / Calibrator
Sample / Calibrator	-	10 µl
dist. water	10 µl	-
Reagent 1	500 µl	500 µl

Mix carefully (do not shake), incubate 1 to 5 min, then add R2 to start the reaction :

Reagent 2	125 µl	125 µl

Mix carefully (do not shake), incubate for 2 min at 37 °C, read absorbance and start stopwatch. After 1 min and after 2 min read absorbance again .

Calculations

$\Delta A/min = [A/min_{Sample / Calibrator}] - [A/min_{Reagent Blank}]$

$$\text{Lipase (U/l)} = \frac{\Delta A/min_{Sample}}{\Delta A/ min_{Calibrator}} \times \text{Conc.Calibrator}$$

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 an 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	1,81
Sample 2	58,9	0,60	1,01
Sample 3	103	1,50	1,45

Beween run n = 40	Mean [U/l]	SD [U/l]	CV [%]
Sample1	13,4	0,24	1,81
Sample 2	58,9	0,49	0,82
Sample 3	103	0,65	0,63

Correlation
A comparative study has been performed between the Spectrum method and another commercial reagent on 67 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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ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
281 001	40 test

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