

LIPASE-LS COLORIMETRIC (DGMRE)

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

Intended use

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

Background

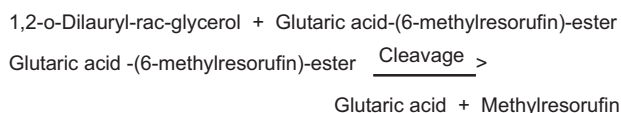
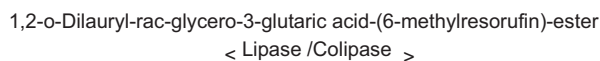
Pancreatic lipase in serum is closely associated with pancreatic diseases. The activity of this enzyme has been measured as an important marker for diagnosing pancreatic diseases and the associated monitoring of therapeutic effects. Pancreatic lipase test kits currently available include a turbidimetric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

METHOD

Colorimetric Test, Kinetic

PRINCIPLE

Lipase catalyzes the following reaction :



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
Calciumchloride		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
Coemulgator		

SYMBOLS IN PRODUCT LABELLING

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

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

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 dist. water	- 10 µl	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
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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 .

CALCULATION

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

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

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 an indication.

CALIBRATOR & 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

Between run n = 40	Mean [U/l]	SD [U/l]	CV [%]
Sample 1	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:

$$y = 0,96 x - 1,15 \text{ U/l} \quad r = 0,999$$

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

References

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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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6. Borgström B. The action of bile salts and other detergents on pancreatic lipase and the interaction with colipase. Biochimica et Biophysica Acta 1977;488:381-91.
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ORDERING INFORMATION

CATALOG NO.	QUANTITY
281 001	40 test

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IFUFCC50

Rev.(4), 10/5/2014