

LIPASE DGMRE LIP-CAL-040 (40T)

INTENDED USE

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

Background

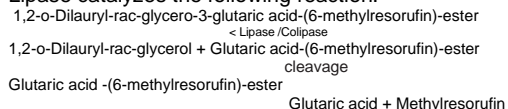
Pancreatic lipase in serum is closely associated with Pancreatic diseases. The activity of this enzyme has been Measured as an important marker for diagnosing pancreatic Diseases and the associated monitoring of therapeutic effects. Pancreatic lipase test kits currently available include a turbidimetric 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 .

The reaction is highly specific on the human enzyme.

REAGENT COMPOSITION

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		

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.

24 hr at 15 -25 °C

5 days 2- 8 °C

1 year -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

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

	calibrator	Sample /
Sample / Calibrator dist. water	10 µl	10 µl
Reagent 1	500 µl	500 µ
Reagent 2	125 µl	125 µl

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

CALCULATION

With Calibrator:

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

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 Q-SLAP Multicalibrator is recommended, for quality control use NS BIO-TEC 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.

- Precision

Within run	Mean [U/l]	SD [U/l]	CV [%]
n = 40	13,4	0,24	1,81
Sample 1	58,9	0,60	1,01
Sample 2	103	1,50	1,45
Sample 3			
Between run		0,24	1,81
Mean [U/l]		0,49	0,82
n = 40		0,65	0,63
Sample 113,4			
Sample 258,9			
Sample 3103			

Correlation

A comparative study has been performed between the NS BIO-TEC 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

1. Lorentz K. Lipase. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 95-7.
2. Moss DW, Henderson AR. Digestive enzymes of pancreatic origin. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 689-708.
3. Tietz N, Shuey DF. Lipase in serum – the elusive enzyme: an overview. Clin Chem 1993;39:746-56.
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.
5. Leybold A, Junge W. Importance of colipase for the measurement of serum lipase activity. Adv Clin Enzymol 1986;4:60-7.
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.
7. Gargouri Y, Julien R, Bois A, Verger R, Sarda L. Studies on the detergent inhibition of pancreatic lipase activity. J of Lipid Research 1983;24:1336-42.



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