NS Bio-Tec

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:

1,2-o-Dilauryl-rac-glycero-3-glutaric acid-(6-methylresorufin)-ester
< Lipase /Colipase
1,2-o-Dilauryl-rac-glycerol + Glutaric acid-(6-methylresorufin)-ester
cleavage
Glutaric acid -(6-methylresorufin)-ester
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 .
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/min = [A/min Sample / Calibrator] – [A/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-TECnormal 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 n = 40 Sample 1 Sample 2 Sample 3	Mean [U/l] 13,4 58,9 103	SD [U/l] 0,24 0,60 1,50	CV [%] 1,81 1,01 1,45
Beween run Mean [U/l] n = 40 Sample113,4 Sample 258,9 Sample 3103		0.24 0.49 0.65	1,81 0,82 0,63

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 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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MEDICAL EQUIPMENT

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CE

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