

LIPASE-LS (DGMRE)

REF:281 001 40 test

R1 1 x 20 ml R2 1 x 5 ml Calibrator 1 vial

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 < Lipase /Colipase >

1,2-o-Dilauryl-rac-glycerol + 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 .

Reagents

Reagent 1 (R1) Goods Buffer (pH 8,0) Taurodesoxycholate 40 mmol/l 3.4 mmol/l Desoxycholate 2.6 mmol/l Calcium chloride 12 mmol/l Colipase 1 ma/l

Reagent 2 (R2) Tartrate Buffer (pH 4,0) 1.5 mmol/l Taurodesoxycholate 3.4 mmol/l 0.13 mmol/l **DGMRE**

Calibrator (C): Serum based calibrator with assigned value printed

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.

SYMBOLS IN PRODUCT LABELLING

ECREP Authorised Representative

Use by/Expiration Date IVD LOT Batch Code/Lot number Catalogue Number Consult instructions for use (Xi) - Irritant Temperature Limitation

For in-vitro diagnostic use A CAUTION. Consult instructions for use

Manufactured by

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 1 year at 2 - 8 °C -20 °C

Procedure

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

Sample / Calibrator				
Sample / Calibrator	10 μΙ			
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

Activity of Lipase (U/I) $= \frac{\Delta A_{Sample}}{\Delta A_{Calibrator}}$ x Conc.Calibrator

Expected Values

< 60 U/I

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/I.

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/I - 300 U/I

Precision

Within run n = 40	Mean [U/I]	SD [U/I]	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/I]	SD [U/I]	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:

$$y = 0.96 x - 1.15 U/I$$
 $r = 0.999$

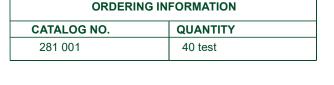
Interfering Substances

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

Refrences

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