

Lipase Colorimetric (DGMRE)

IVD

REF.	Pack size
188 01 020	(1 x 20 ml) 40 tests
188 02 020	(2 x 20 ml) 80 tests

Intended use

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

Background

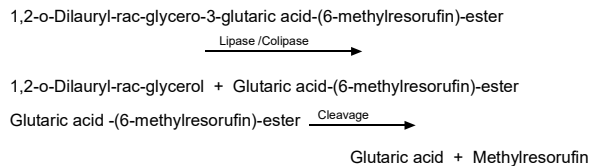
Pancreatic lipase in serum is closely associated with pancreatic diseases. The activity of this enzyme has been measured as an important marker for diagnosing pancreatic diseases and the associated monitoring of therapeutic effects. Pancreatic lipase test kits currently available include a turbidimetric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

Method

Kinetic method

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

Reagent 1 (R1)

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 (R2)

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

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

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 vial is stable for 3 months at 2-8°C, if contamination is avoid.

Calibrator : Reconstitute Carefully with distilled water as stated on the vial label ,close the vial carefully and allow the calibrator to stand for 30 minutes swirling occasionally. Avoid foaming .Do not shake. Divide Reconstituted calibrator into aliquots and store at -20°C. The reconstituted calibrator is stable up to 30 days.

Once opened, the reagent and the calibrator vials are stable for 3 month at the specified temperature.

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

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

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 (do not shake). After 2 minutes , read absorbance A1 of sample and calibrator. Then 2 minutes later, read A2 of sample and calibrator.

Calculations

$$\Delta A_{\text{Sample / Calibrator}} = A2 - A1$$

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

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 any indication.

Calibrators and controls

For the calibration of automated analyzers ,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 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

Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.

S56: dispose of this material and its container at hazardous or special waste collection point.









S57: use appropriate container to avoid environmental contamination.


S61: avoid release in environment. refer to special instructions/safety data sheets.

References

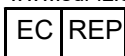
- 1.Moss DW, Henderson AR. Digestive enzymes of pancreatic origin. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 689-708.
- 2.Tietz N, Shuey DF. Lipase in serum – the elusive enzyme: an overview. Clin Chem 1993;39:746-56.
- 3.Lott J, Patel ST, Sawhney AK, Kazmierczak SC, Love JE. Assays of serum lipase: analytical and clinical considerations. Clin Chem 1986;32:1290-1302.
- 4.Leybold A, Junge W. Importance of colipase for the measurement of serum lipase activity. Adv Clin Enzymol 1986;4:60-7.
- 5.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.

SYMBOLS IN PRODUCT LABELLING

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

 Spectrum For Diagnostics Industries - Free Zone
Ismailia Free Zone , Block 5 .
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