LIPASE

Enzymatic Colorimetric Method

IVD CE

PRODUCT CODE

CZ011

INTENDED USE

Lipase kit is used for the determination of Lipase activity in serum/plasma.

CLINICAL SIGNIFICANCE

Lipase is a pancreatic enzyme necessary for the absorption and digestion of nutrients that catalyses the hydrolysis of glycerol esters of fatty acids. Determination of lipase is used for diagnosis of diseases such as acute and chronic pancreatitis and obstructionof the pancreatic duct. Clinical diagnosis should not be made on a single test result.

PRINCIPLE OF MEHOD

In the presence of colipase and bile acids Lipase splits the synthetic substrate (1, 2-O-Dilauryl-rac-glycero-3-glutaric acid (6-methyl-resorufin-ester) to glycerol and methylresorufin ester. The rate of methylresorufin formation, measured photometrically is proptional to the catalytic concentration of lipase present in the sample.

REAGENTS

R 1 Buffer	Goods buffer pH 8.0	40 mmol/L
	Colipase	> 1 mg/L
	Deoxycholate	1.8 mmol/L
	Taurodeoxycholate	7.2 mmol/L
	Calcium chloride	0.1 mmol/L
R 2 Substrate	Tartarate Buffer pH 4.0	15 mmol/L
	Color substrate	> 0.7 mmol/L
LIPASE CAL	Lipase calibrator concentration is stated on the vial label	

REAGENT PREPARATION

Lipase R1 and Lipase R2 are ready to use.

Calibrator: Reconstitute with 0.5 ml of distilled water. Dissolve the content of the vial by swirling gently to avoid the formation of foam.

Stability: Reconstituted calibrator is stable up to 7 days at 2 - 8º and for at least 4 weeks when stored at -20º C. don't repeatedly thaw and re-freeze.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC, protected from light and contaminations prevented during their use. Do not use reagents over the expiration date.

SAMPLE

Serum or Plasma with sodium citrate, EDTA or heparin

Lipase is reported to be stable in serum for 5 days at 2-8º C.

PRECAUTIONS

To avoid contamination use clean laboratory materials**,** use clean,dry disposable pipette tips for dispensing**.** Close reagent and calibrator bottles immediately after use. Avoid direct exposure of working reagent to light.

LIPASE CAL Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However, handle cautiously as potentially infectious.

GENERAL SYSTEM PARAMETERS

Reaction Type	Fixed Time
Reaction Slope	Increasing
Wave Length	580 nm
Temperature	37ºC
Delay Time	120 Sec
Read Time	120 Sec
Calibrator Concentration	As printed on label
Sample Volume	20 µL
Reagent Volume	1250 µL (1000 + 250)
Blank	Reagent blank
Cuvette	1 cm light path

ASSAY PROCEDURE

Pipette into a clean dry test tubes as Blank (B) Calibrator (C) and Test (T)

	(B)	(C)	(T)
Reagent 1 (µL)	1000	1000	1000
Calibrator (µL)	--	20	--
Sample (µL)	--	--	20
Distilled Water (µL)	20	--	--
Mix carefully (do not vortex), incubate for 1-5 min at 37ºC, then add			
Reagent 2 (µL)	250	250	250

Mix well immediately and incubate at 37º C for 2 minutes, and read first absorbance A1 for the Blank, Calibrator and Test. Read another absorbance A2 of the Blank, Calibrator and Test after exactly 2 minutes. Calculate the change in absorbance ΔA for Blank, Calibrator and Test.

CALCULATIONS

$$\text{Lipase in U/L} = \frac{\Delta A \text{ Test} - \Delta A \text{ Blank}}{\Delta A \text{ Calibrator} - \Delta A \text{ Blank}} \times \text{Calibrator Conc.}$$

NORMAL RANGE

Up to 60 U/L, It is recommended that each laboratory establish itsown normal range representing its patient population.

LINEARITY

The procedure is linear up to 300 U/L. If the activity is greater than 300 U/L, dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

QUALITY CONTROL

Control sera are recommended to monitor the performance of assay procedures.

If control values are found outside the defined range, check the instrument, reagents and technique for problems.

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

INTERFERENCES

Triglycerides at 300 mg/dL interfere on determination reducing the activity of enzyme of 6%. Hemoglobin concentration lower than 150 mg/dL and Bilirubin lower than 20 mg/dL do not interfere. A list of drugs and other interfering substances with lipase determination has been reported by Young et. al2,3.

NOTES

1. In some storage conditions (i.e. storage at a temperature lower that the one indicate) a precipitate may appear in the vial that will not influence that the reagent performance; however, it is recommended to resuspend the product with a slight rotation.
2. In order to avoid contamination it is recommended to use disposable material.

SYMBOL ON LABELS

Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

BIBILOGRAPHY

1. McNeely M. Lipase. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1130-1134, 892.
2. Neumann U et al. Comptes Rend. 4 colloque de Pont-a-Musson, Masson 627-634 (1979)
3. Junge W et al. J.Clin.Chem.Clin.Biochem., 21 445-451 (1983).
4. Neumann U et al. Methods of Enzymatics Analysis, 3rd ed. Vol.4, 26-34 (1984)
5. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
6. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.
7. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
8. Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

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