Lipase (BR-160/ BR-120) IVD

Enzymatic Colorimetric Method

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
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 methyl resorufin formation, measured photometrically is proptional to the catalytic concentration of lipase present in the sample

REAGENT COMPOSITION

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

REAGENT PREPARATION
Lipase R1 and Lipase R2 are ready to use.
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.

REAGENT 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.

SPECIMEN
Serum or Plasma with sodium citrate, EDTA or heparin
Lipase is reported to be stable in serum for 5 days at 2-8º C.

PRECAUTION
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.

PROCEDURE
APPLICATION ON AUTO BIOCHEMISTRY ANALYZERS

BR-160 AUTO BIOCHEMISTRY ANALYZER

TEST NAME	lipase			SAMPLE VOLUME	4	
FULL NAME	lipase					
					R1	R2
	PRI.	SEC.		REAGENT VOLUME	200	50
WAVE LENGTH	578	700				
		START	END			
ASSAY /POINT	FIXED - TIME	17	22			
DECIMAL PLACE	2					
UNIT	u/L					
	LOW	HIGH				
LINEARITY RANGE	0	300				

Bio Research For Medical Diagnostics
Muslim Al Attar Street,P.O.Box:1235,
Amman-11953,Jordan
Tel:+962 64892525, Fax: +962
64892526, www.bioresearch.com.jo

Lipase (BR-160/ BR-120) IVD

Enzymatic Colorimetric Method

BR-120 AUTO BIOCHEMISTRY ANALYZER						
TEST NAME	lipase			SAMPLE VOLUME	4	
FULL NAME	lipase					
	PRI.	SEC.			R1	R2
WAVE LENGTH	578	700		REAGENT VOLUME	200	50
		START	END			
ASSAY /POINT	FIXED - TIME	26	34			
DECIMAL PLACE	2					
UNIT	u/L					
	LOW	HIGH				
LINEARITY RANGE	0	300				

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.

NORMAL RANGE

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

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.

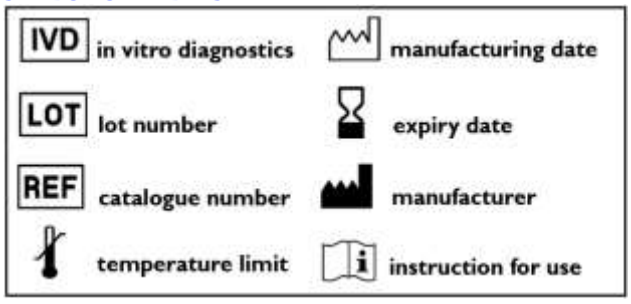
INTERFERENCES

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.

NOTE

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



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