TRUEchemie LIPASE Test Kit

(ENZYMATIC COLORIMETRIC METHOD)

for the direct quantitative determination of Serum Lipase in human serum or plasma

INTENDED USE

The TRUEchemie LIPASE liquid reagent test kit is used for the direct quantitative determination of LIPASE in human serum or plasma.

INTRODUCTION

Lipase is defined as group of enzymes, which hydrolyze the glycerol esters of long-chain fatty acids. The measurement of lipase activity in serum and other fluid is to evaluate condi tions associated with pancreas. Voget et al. proposed an olive oil emulsion in measuring the rate of change in turbidity over a specific unit of time. Later, Shihabi et al. modified the pre vious method and eliminated some of interference. Our method is based on the above modifications.

PRINCIPLE

The pancreatic lipase in presence of colipase, desoxycholate and calcium ions, hydrolyses the substrate 1-2-O-dilauryl-rac-glycero-3- glutaric acid-(6' -methylresorufin)-ester. The sequence of reactions involved in the enzymatic direct lipase determination is the following:

1-2-O-dilauryl-rac-glycero-3-glutaric-(6' -methylresorufin)-ester
Lipase
−−−−−−→1-2-O-dilauryl-rac-glycerol + Glutaric-6'-methylresorufin-ester
(unstable) −−−−−−−→Glutaric acid + Methylresorufin OH

The rate of methylresorufin formation, measured photometrically, is proportional to the catalytic concentration of lipase present in the sample.

PACK SIZE

Kit Size	2 x 15 ml	2 x 30 ml
Cat No.	ADX381	ADX382
Kit contents		
1) Lipase Reagent – 1 (R1)	2 x 12 ml	2 x 24 ml
2) Lipase Reagent – 2 (R2)	2 x 3 ml	2 x 6 ml

REAGENTS COMPOSITION

Lipase Reagent-1 and 2 come in separate containers, and both reagents are clear, colorless liquid in ready to use format. After combining Lipase Reagent – 1 (R1) and Lipase Reagent – 2 (R2) the working reagent composition is

Working Reagent composition

TRIS pH 8.3	:	35 mmol/L
Colipase	:	1.20 mg/L
Desoxycholate	:	1.60 mmol/L
Taurodesoxycholate	:	7.8 mmol/L
Lipase	:	1.0 mmol/L
Calcium Chloride (CaCl2)	:	0.2 mmol/L
Stabilizers and Preservatives		

STORAGE AND STABILITY

The components of the kit, stored at 2 - 8 °C, will remain stable until the expiry date stated on the label.

REAGENT PREPARATION

The working reagent is prepared by mixing 4 volumes of R1 with 1 volume of R2 in a disposable container.

SAMPLE / SPECIMEN AND STORAGE

Serum and Heparinred plasma with no hemolysis is essential.EDTA, Oxalate, Fluoride or citrate plasma lead to decreased results.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Specimens should be considered infectious and handled appropriately.
3. Avoid ingestion. DO NOT PIPETTE BY MOUTH.
4. The disposal of the residues has to be done as per local legal regulations.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipettes to accurately measure required volumes.
2. Test tubes/rack
3. Timer
4. 37 °C heating block or water bath
5. Photometer capable of accurately measuring absorbance at 580 nm

TEST PROCEDURE

Wavelength	:	580 nm
Temperature	:	37 °C

Prewarm the Reagent to reaction temperature.

	Blank (ml)	Sample (ml)
Distilled Water	1.000	--
Lipase Reagent -1 (R1)	--	0.800
Lipase Reagent -1 (R2)	--	0.200
Sample	--	0.010

Reading & Calculations

Mix immediately and read **Ist** absorbance of test exactly at 60 seconds and then, **IInd,** at an interval of 60 seconds at 580nm. Determine the change in absorbance (Abs) and calculate the test results.

$$\text{Lipase Activity (IU/L)} = \frac{\Delta\text{Abs of Sample}}{\Delta\text{Abs of Calibrator}} \times \text{Cone. of calibrator}$$

(or)

$$\Delta A = (\text{Avg } \Delta E/\text{min.}) \times 3846 = \text{U/L of Lipase}$$

QUALITY CONTROLS

Control Sera are recommended to monitor the performance of manual and automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

NORMAL VALUES

Normal Range: Up to 60 IU/L (37 °C)
It is strongly recommended that each laboratory establish its own normal range

AUTOMATED PROCEDURE

Appropriate Program sheet is available for different analyzers upon request.

LIMITATIONS

Linearity: Up to 250 IU/L.

For values above 250 IU/L, dilute the sample suitably with 0.9 % saline, and repeat the assay. Apply correction due to dilution to arrive at a final result.

INTERFERENCES

The following analytes were tested up to the levels indicated and found not to interfere with Ascorbic acid up to 30 mg/dL Bilirubin up to 60 mg/dL, Hemoglobin 1000 mg/dl.

SYSTEMS PARAMETERS

Mode	:	Fixed Time
Factor	:	3846
Wave length	:	580 nm
Units	:	IU/L
Flow cell Temp	:	37 °C
Blank	:	Distilled Water
Enzyme Reagent (R1)	:	0.800 ml
Substrate Reagent (R2)	:	0.200 ml
Sample volume	:	0.010 ml
Lag time	:	60 sec. (1 min.)
Read time	:	60 sec. (1 min.)
Low Normal	:	0
High Normal	:	60

REFERENCES

1. Lorentz K. Lipase In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 95-7.

2. Tietz N, Shuey DF. Lipase in serum – the elusive enzyme: an overview. Clin Chem 1993;39:746-56.

Index of symbols

Consult instructions for use	Catalogue number	Use-by date
For *in vitro* diagnostic use only	Batch code	Do not use if package is damaged
Temperature limit 2-8 °C	Date of manufacture	Keep dry
Keep away from sunlight	Manufacturer	European Conformity
If device is non-sterile	Warnings / Precautions	Authorized Representative