INTENDED USE

The TRUEchemie Lipase Test Kit (Colourimetry) 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.

PRINCIPLE

The colorimetric substrate 1,2-o-dilauryl-rac-glycero-3-glutaric acid-(6-methylresoru-fin)-ester is cleaved by pancreatic lipase and the resulting dicarboxilic acid ester is hydrolysed under the alkaline test condition to yield the chromophore methylresorufi. The kinetic of color formation at 580 nm is monitored and it is prooprtional to lipase activity in sample.

PACK SIZE

Kit Size	2 x 15 ml
Cat No.	ADX386
Kit contents	
1) Lipase Reagent (R1)	2 x 12 ml
2) Lipase Reagent (R2)	2 x 3 ml
3) Lipase Calibrator	1 x 3 ml

REAGENT COMPOSITION

1) Lipase Reagent (R1)

Bicine Buffer	:	>40 mmol/L
Colipase	:	>0.98 mg/L
Na-Deoxycholate	:	>1 mmol/L
Calcium Chloride	:	>8 mmol/L

2) Lipase Reagent (R2)

Buffer	:	>8 mmol/L
Taurodeoxyl-Cholate	:	>8 mmol/L

3) Lipase Calibrator : Lipase concentration is as stated in vial

REAGENT PREPARATION

Ready to use reagents.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Handle in accordance with good laboratory procedures. Avoid ingestion and eye or skin contact.
3. Specimens should be considered infectious and handled appropriately.
4. The disposal of the residues has to be done as per local legal regulations

CALIBRATOR PREPARATION

Reconstitute with 3 ml of distilled water. Let it stand for 30 minutes at room temperature. Dissolve the content of the vial swirling gently to avoid the formation of foam.

REAGENT / CALIBRATOR STORAGE & STABILITY

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2-8°C. Do not use reagents over the expiration date.
Lipase Calibrator : Reconstituted calibrator is stable only for 7 days at 2-8°C and 3 months at -20°C

SPECIMEN COLLECTION AND STORAGE

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

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 (µl)	Calibrator/Standard (µl)	Sample (µl)
Lipase Reagent (R1)	-	800	800
Calibrator	-	16	-
Sample	-	-	16
DI water	1000	-	-
Mix well and incubate for 3 mins at 37ºC.			
Lipase Reagent (R2)	-	200	200

Reading & Calculations

Blank the photometer with Distilled water.
Mix well and read absorbance of sample and test against distilled water at 580 nm as follows
Initial absorbance A_0 - Extactly after 120 sec
Final absorbance A_1 - Extactly after 120 sec. after A_0.
Determine $\triangle A$ for standard (S) and Test (T)

$\triangle AS = AS_1 - AS_0$
$\triangle AT = AT_1 - AT_0$

Calculations

$$\text{Serum / Plasma Lipase (IU /L)} = \frac{\triangle AT}{\triangle AS} \times \text{Conc. of calibrator}$$

QUALITY CONTROL

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

EXPECTED VALUE

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

PERFORMANCE CHARACTERISTICS

Sensitivity: 3.0 IU/L
Linearity: Up to 300 IU/L under the described assay conditions. If the concentration is greater than linearity (300 IU/L), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor. The linearity limit depends on the sample / reagent ratio, as well as the analyzers used.

PRECISION:

Intra-assay precision within run (n=20)	Mean (IU/L)	SD (IU/L)	CV (%)
Sample - 1	44	1.34	3.07
Sample - 2	73	1.50	2.04

Inter-assay precision run to run (n=20)	Mean (IU/L)	SD (IU/L)	CV (%)
Sample - 1	38.7	1.11	2.87

The reagent was tested for 20 days, using two different Lipase concentrations. The coefficient of variation was <5%.

AUTOMATED PROCEDURE

Appropriate program sheet is available for different analyzers upon request.

METHOD COMPARISON

Results obtained using TRUEchemie Lipase reagent (y) did not show systematic differences when compared with another commercial reagent (x) with similar characteristics. The results obtained is below: The correlation coefficient (r^2) was 0.995 and the regression equation is y=1.044x-0.604. The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

Following substances do not interfere: Haemoglobin upto 4.5 g/L, bilirubin upto 40 mg/dL, triglycerides up to 1000 mg/dL.

WASTE MANAGEMENT

Please refer to local regulation requirements.

SYSTEM PARAMETERS

Mode	:	Fixed Time
Calibrator conc	:	As stated on vial
Wave length	:	580 nm
Units	:	IU/L
Flow cell Temp	:	37°C
Blank	:	Distilled Water
Lipease Reagent (R1)	:	800 µl
Lipease Reagent (R2)	:	200 µl
Sample volume	:	16 µl
Lag time	:	120 sec. (2 mins)
Read time	:	120 sec. (2 mins)
Low Normal	:	0
High Normal	:	60
Sensitivity	:	3.0
Linearity	:	300
Reaction Slope	:	Increasing

REFERENCES

1. Lorentz K Lipase. In: Thomas L, editor, Clinical laboratory diagnostics. 1st ed. Frankfurt; TH-Books Verlagsgesell schaft; 1998.p.95-7.
2. Moss DW, Henderson AR. Digestive enzymes of pancreatic orgin. In: Burtis CA, Ashwood ER, editors, Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B.Saunders Company; 1999.p.689-708.
3. Tietz N, Shuey DF. Lipase in serum - the elusive enzyme; an overvies. Clin Chem 1993;39:746-56.
4. ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

Index of Symbols

Consult instructions for use	REF Catalogue number	Caution
IVD *In vitro* diagnostic medical device	LOT Batch code	Non-sterile
2°C–8°C Temperature limit 2-8°C	Do not re-use	Use-by date
Manufacturer	Date of manufacture	Keep dry
Do not use if package is damaged	Keep away from sunlight	