Lipase Assay Kit (LPS)

Method: Methoxyresorufin Substrate

Cat . No.	Size	Instrument
GSLPS	R1: 1×60 ml R2: 1×20 ml	For Hitachi917 &OlympusAU640/400/600
GBLPS	R1: 1×60 ml R2: 1×20 ml	For Hitachi 717 &ShimadzuCL7200/8000
GHLPS	R1: 1×45 ml R2: 1×15 ml	For Hitachi902
GTLPS	R1: 1×45 ml R2: 1×15 ml	For TOSHIBA
GXLPS	R1: 1×60 ml R2: 1×20 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-800
GDLPS	R1: 24×4.2 ml R2: 12×2.9 ml	For DATE DEMENSION

INTENDED USE

For the quantitative *in vitro* determination of Lipase in human serum and plasma.

CLINICAL SIGNIFICANCE

A lipase test system is a device intended to measure the activity of the enzyme lipase in serum and plasma. Lipase measurements are used in the diagnosis and treatment of diseases of the pancreas such as acute pancreatitis and
obstruction of the pancreatic duct.

ASSAY PRINCIPLES

The chromogenic Lipase substrate 1,2-o-dilauryl-racglycero-3-glutaric acid-(6ı-methylre-sorufin) ester is cleaved by the catalytic action of Lipase to form 1,2-o-dilauryl racglycerol and an unstable intermediate, glutaric acid-(6-methyl resorufin)ester.This decomposes spontaneously in alkaline solution to form glutaric acid and methylresorufin.The lipase activity in the speci-men is proportional to the production of methy-lresorufin in the reaction and can be determined photometrically.

1,2-O-dilauryl-rac-glycero-3-glutar acid-(6-methylresorufin) ester $\xrightarrow{\text{Lipase}}$ 1,2-O-dilauryl-rac-glycerol + glutaric acid-(6-methylresorufin) ester $\xrightarrow[\text{dicomposition}]{\text{Spontaneous}}$ glutaric acid+methylresorufin

The color intensity of the red dye formed is directly proportional to the lipase activity and can be determined photometrically.

SAMPLE COLLECTION AND PREPARATION

Serum or plasma samples.
Use fresh patient serum or Li-heparin plasma.
samples.

REAGENT COMPOSITION

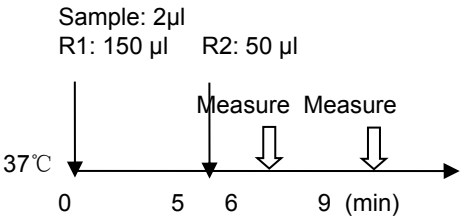
Contents	Concentration of Solutions
Reagent 1 (R1)	
BICN buffer	50 mmol/L
Na-deoxycholate	1.6 mmol/L
calcium chloride	10 mmol/L
colipase	≥1mg/L
Reagent 2 (R2)	
Tartrate buffer	10 mmol/L
DGGMR	0.27 mmol/L

STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.
Once opened the reagent is stable for 1 month On-board the analyser at approximately 10°C.

ASSAY PROCEDURE

Test Procedure for Analyzers
Assay Mode: Rate A
Wave Length (main/sub): 570nm/700nm



1. Mix 2µl sample with 150 µl R1 and incubate at 37℃ for 5 minutes.
2. Add 50µl R2 into cuvette, mix and incubate at 37℃ for 1 minute.
3. Read initial absorbance and start timer simultaneously, read again after 1, 2 and 3 minutes.
4. Calculate absorbance change per minute (ΔA/min)

CALIBRATION

Recommend that this assay should be calibrat-ed using Gcell Calibration Serum Level 3 or Level 2.

CALCULATION OF RESULTA

$$\text{Concentration} = \frac{\Delta A_{\text{sample}}/\text{min}}{\Delta A_{\text{calibrator}}/\text{min}} \times \text{calibrator value}$$

QUALITY CONTROL

Gcell quality control are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

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NORMAL VALUE

Normal range 13 – 60 U/L. It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geograph-ical location of the population.

MAIN PERFORMANCE CHARACTERISTICS

LINEARITY

Linear range [5, 300] ng/ml, the linear correlation coefficient r should be≥0.990, in [5, 50] ng/ml range, the mesured linear deviation should be no more than ±7.5U/L, in [50, 300] ng/ml range, the mesured linear deviation should be no more than ±15%.

PRECISION

Intra assay precision		
N=20	level 1	level 2
Mean(U/L)	38.6	53.6
SD	0.54	0.73
CV(%)	1.39	1.35

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(U/L)	52.2	52.3	53.7
$\bar{x}$	52.7		
(Xmax-Xmin)/$\bar{x}$	(53.7-52.2)/52.7*100=2.91%		

INTERFERENCE

Serum analytes other than Lipase were added to normal serum. The following analytes were tested up to the following levels and found not to interfere:

Bilirubin	up to1026mmol/l
Hemoglobin	up to 5g/l
Intralipid	up to 600mg/dl
Heparin	up to 100U/ml

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

1. Greiling H, Gressner AM, eds. Lehrbuch d-er Klinischen Chemie und Pathobiochemie, 3rd ed. Stuttgart/New York: Schattauer V-erlag, 1995.
2. Keller H, ed. Klinisch-chemische Labordia-gnostik für die Praxis, 2nd ed.Stuttgart/New York: Georg Thieme Verlag, 1991:354-361.
3. Kazmierczak S, Catrou P, Van Lente F. Diagnostic accuracy of pancreatic enzymes evaluated by use of multivariate data ana-lysis. Clin Chem 1993; 39: 1960-1965.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

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