

## 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-(6-methylresorufin) 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 specimen is proportional to the production of methylresorufin in the reaction and can be determined photometrically.

1,2-O-dilauryl-rac-glycero-3-glutaric 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
<b>Reagent 1 (R1)</b>	
BICN buffer	50 mmol/L
Na-deoxycholate	1.6 mmol/L
calcium chloride	10 mmol/L
colipase	≥1mg/L
<b>Reagent 2 (R2)</b>	
Tartrate buffer	10 mmol/L
DGGM	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°C.

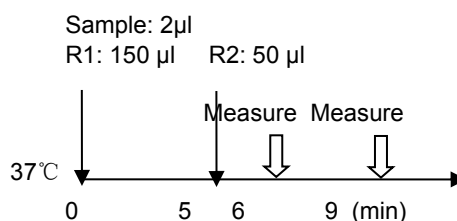
Once opened the reagent is stable for 1 month On-board the analyser at approximately 10°C.

### 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°C for 5 minutes.
2. Add 50µl R2 into cuvette, mix and incubate at 37°C 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 ( $\Delta A/\text{min}$ )

### CALIBRATION

Recommend that this assay should be calibrated using Gcell GC-LPS.

### 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(Gcell GQ-LPS) 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.

### NORMAL VALUE

Beijing Strong Biotechnologies, Inc.

Add: 5/F, KuangYi Building, No.15, Hua Yuan Dong Lu, Haidian District, Beijing 100191, P.R.China

Tel: +86 10 8201 2486 Fax: +86 10 8201 2812

Web: [www.bsbe.com.cn](http://www.bsbe.com.cn) Email: [jg.tech@bsbe.com.cn](mailto:jg.tech@bsbe.com.cn)

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

## MAIN PERFORMANCE CHARACTERISTICS

### LINEARITY

Linear range [5, 300] ng/ml, the linear correlation coefficient  $r$  should be  $\geq 0.990$ , in [5, 50] ng/ml range, the measured linear deviation should be no more than  $\pm 7.5\text{U/L}$ , in [50, 300] ng/ml range, the measured linear deviation should be no more than  $\pm 15\%$ .

### 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		
$(X_{\max} - X_{\min}) / \bar{x}$	$(53.7 - 52.2) / 52.7 * 100 = 2.91\%$		

### 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 to 1026mmol/l
Hemoglobin	up to 5g/l
Intralipid	up to 600mg/dl
Heparin	up to 100U/ml

### SAFETY PRECAUTIONS AND WARNINGS

- For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
- 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.
- 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.
- Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
- Reagents with different lot numbers should not be interchanged or mixed.

## REFERENCES

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

## INDEX OF SYMBOLS



Manufacture



Catalogue Number



Lot number



Date of manufacture



Use by (Expiration date)



For In-Vitro Diagnostic use only



Stored at 2-8°C



Attention: See instruction for use



Authorized Representative in the European Company

Manufacture: Beijing Strong Biotechnology, Inc.

Address: No. 15, Yanqi North Second Street, Yanqi Economic Development Area, Huairou District, Beijing 101400, P. R. China

Tel: +86 10 61667168

EC REP :Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

E-mail: peter@lotusnl.com

Tel: +31645171879(English), +31626669008 (Dutch)