Lactate Assay Kit
（ LAC）

Method: Lactate Oxidase

Cat.No	Size	Instrument
GS8127T	R: 4×50 ml	Hitachi 717/917 and Olympus AU640/ 400/600
GB8126T	R: 4×50 ml	Hitachi 911 and Shimazu CL7200/8000
GX8127T	R:1×100 ml	Beckman CX,LX20,DXC600,800.
GT8127T	R: 4×50 ml	Toshiba 40
GD8127T	R:36×3.8ml	Dupont
GH8127T	R: 4×50 ml	Hitachi 902

INTENDED USE
For the quantitative *in vitro* determination of Lactate in serum or plasma.

CLINICAL SIGNIFICANCE
In muscle cells, lactate concentration showed metabolic acidosis, which may be lactic acidosis. Tissue hypoxia and strenuous activities will increase in serum lactate concentration. Tissue hypoxia caused by respiratory failure or hypoperfusion, which lactic acidosisi can threaten life. Dehydration can cause the reduction of muscle cells oxygen transfer. Lactic acidosis may often accompany with diabetes ketoacidosis. Tissue oxygen consumption increased, as seen in sepsis and malignant tumors can also cause lactic acidosis. The severity of lactic acidosis can help reveal the potential severity of the sexual disease.

Detection Principle
Lactate oxidase is oxidation with lactate, produce pyruvate and hydrogen peroxide, hydrogen peroxide reacts with a 4 - amino antipyrine, TOOS, produces purple reaction product, this product has a maximum absorption peak at 546nm, the absorption intensity is proportional to the lactic acid content in the samples.

$$\text{Lactate} + O_2 \xrightarrow{\text{LOX}} \text{pyruvate} + H_2O_2$$

$$H_2O_2 + \text{4 -ALDEHYDOANTIPYRINE} \xrightarrow{\text{POD}} \text{purple product} + H_2O + \text{TOOS}$$

REAGENT COMPOSITION

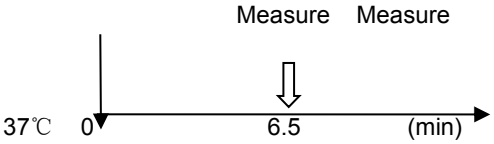
Contents	Concentration of Solutions
Reagent 1 (R1)	
Buffer	100 mmol/L
Aldehydiantipyrine-4	0.4 mmol/L
Ascorbic Acid Oxidase	≥1000U/L
Peroxidase	≥1000U/L
Lactate oxidase	≥600U/L
Toos	2.1 mmol/L

SAMPLE COLLECTION AND PREPARATION
Fresh serum or plasma.
Samples should be separated from the blood cells as soon as possible. Detected immediately after sampling.

STABILITY AND PREPARATION OF REAGENTS
All reagents are ready to use.
Reagents stabilize for one year under 2 - 8 ℃,and shelf life is 12 months.
The reagents are stable for 28 days on-board of the analyser after opening and kept at 2-8℃.

ASSAY PROCEDURE
Test Procedure for Analyzers (Hitachi 7180)
Assay Mode: 1 Point 15
Wave length (sub/main): 700/546nm

Sample 2 µl
R1: 200µl



1. Mix 2 µl sample with 200 µl R1 and incubate at 37℃ for 6.5 minutes.
2. At 1.5 minutes, read the absorbance A.By the absorbance of calibrator,calculated the concentration in the sample.

CALIBRATION
Recommend using Gcell calibrator (Cat .No. GC-LAC).

CALCULATIONS OF RESULTS
Plot calibrator concentrations against the corresponding A values using graph paper. The concentration of LAC in the sample is obtained by reading a value from the calibration curve. Do not attempt to extrapolate above or below the range of the calibrator.

QUALITY CONTROL
For quality control, use Gcell Assay LAC Control GQ-LAC as daily quality control and can be purchased separately. Values should fall within a specific range. If these values fall outside the range and repetitionexcludes 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
0.5-2.22mmol/L or 4.5-20mg/dl.
It is recommended that each laboratory should establish its own normal range to reflect the age, sex, diet and geographical location of the population.

MAIN PERFORMANCE CHARACTERISTICS

LINEARITY
The method is linear up to 150mg/dl,when the deviation of linearity is within ± 10%.

PRECISION
The CV of the test should be ≤ 10%.

Intar assay precision

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 Email: jq.tech@bsbe.com.cn

CE version 2014

N=20	level 1	level 2
Mean(mg/L)	27.43	187.01
SD	0.58	2.62
CV(%)	2.10	1.40

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(mgl/L)	25.37	25.17	25.77
$\bar{x}$	25.43		
(Xmax-Xmin)/$\bar{x}$	(25.77-25.17)/25.43*100=2.36%		

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

ascorbic acid: up to 10mg/dl
Bilirubin: up to 10 mg/dl
Hemoglobin: up to 400mg/dl
Intralipid: up to 500mg/dl

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. Henry RJ. Clinical Chemistry :Principles and Technics .Harper and Row New York 1974.
2. S.LACimura,S.Iyama, Y.Yamagychi S.hayashi，R.Fush-imimi and Amino .Ann.LACin.Biochem(1977),34:384-38 388.

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

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）