Lactate Assay Kit
（LAC）

Method:Lactate Oxidase Method

Cat.No	Size	Analyzer
EGS8127T	4×50 ml	For Hitachi917& OlympusAU640/400/600
EGB8126T	4×50 ml	For Hitachi 717 &ShimadzuCL7200/8000
EGH8127T	4×50 ml	For Hitachi902
EGD8127T	36×3.8ml	For Siemens Dupont/Siemens Behring Series
EGLAC460 BS	1x20ml	For Mindray BS120/180/190/200/220/230 /240/430/460/830
EGGLAC	1x20ml	For Semi Auto Analyser

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

CLINICAL SIGNIFICANCE
Lactic acid is an intermediate product of glucose metabolism, and the level of lactic acid concentration is an indirect indicator reflecting glucose metabolism, peripheral circulation, and tissue blood and oxygen supply. The increase of lactic acid in the body can cause lactic acidosis, and blood lactic acid level can be examined, which is mainly used to judge the severity and prognosis of the disease.It can also be used for differential diagnosis of metabolic acidosis.

ASSAY PRINCIPLE
Lactic acid oxidase oxidizes lactic acid to produce pyruvate and hydrogen peroxide, and hydrogen peroxide reacts with 4-aminoantipyrine and TOOS to produce purple product, which has the maximum absorption peak at 546nm, and the absorption intensity is proportional to the content of lactic acid in the specimen.

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

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

REAGENT COMPOSITION

Contents	Concentration
Reagent 1 (R1)	
Buffer	100 mmol/L
Aldehydiantipyrine-4	0.4 mmol/L
Ascorbic Acid Oxidase	≥10000U/L
Peroxidase	≥1000U/L
Lactate oxidase	≥600U/L
Toos Preservative	2.1 mmol/L

STABILITY AND PREPARATION OF REAGENTS
1. Stable up to the expiry date when the reagent is sealed and stored in dark at 2-8 ℃.
2. Reagents should not be frozen.
3.The production date and expiry date are shown on the label.
4.Once opened, the reagents are stable for 28 days when refrigerated on the analyzer or refrigerator.

APPLICABLE INSTRUMENT
This kit is theoretically suitable for all biochemistry analyzers and spectrophotometers covering the wavelength range of 540nm.
It is recommended to use this kit on a biochemistry analyzer for testing according to laboratory conditions.

SAMPLE COLLECTION AND PREPARATION
Fresh serum or plasma (EDTA or heparin anticoagulant). Stability of serum samples: Stored at 4 ℃ for 7 days;The measured values of plasma samples increased with the extension of time.It can be stabilized at -20℃ for 4 weeks.

ASSAY PROCEDURE
Test condition(Hitachi 917)：

Main wavelength	546nm	Sample（S）	2μL
Secondary wavelength	700nm	Reagent 1（R1）	200μL
Reaction temperature	37℃	Reaction type	End point
Cuvette diameter	1cm		

Operate Procedure:

Add to cuvette：	
Sample（S）	2μL
Reagent 1（R1）	200μL
Mix well and incubate at 37 ℃ for 10 minutes, and measure the absorbance A1.	

Note: Parameters above are only introduced with Hitachi 917 as an example. The parameters of different biochemistry analyzers are slightly different. Please read the manual carefully before setting parameters.

CALIBRATION
Recommend using Gcell LAC calibrator,trace to internal calibration product. The value of the calibrated product is assigned by weighing the pure product.
1. According to the requirements of the calibration procedure in the operation manual of biochemistry analyzer, each laboratory establishes its own calibration procedure according to the specific conditions.
2. Requirements for calibration and frequency: It is recommended to calibrate at least once every two weeks. When the following situations occur, it is recommended to re-calibrate: change the reagent batch number, the indoor quality control runs out of control, the biochemistry analyzer carries out major maintenance or replaces the main parts such as light source or cuvette.

QUALITY CONTROL
It is recommended to use Gcell LAC control**.** The absorbance of quality control should be within the

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labeled value range. If the results deviate from the scope, please find out the reason by following steps:
1. Check the parameter setting and light source.
2.Check the cleanliness of the cuvette and sampling needle.
3.Check whether water is contaminated or not. Bacterial growth can lead to incorrect results.
4. Check the reaction temperature.
5. Check the validity of the kit.

CALCULATIONS OF RESULTS

According to the specific calibration mode of the project, the calibration curve is automatically generated by the instrument, and the content of the measured object is calculated from the absorbance change value of the measured object in the sample.
Unit conversion: mmol/L×9 = mg/dl

REFERENCE RANGE

0.5-2.22mmol/L or 4.5-20mg/dl.
Laboratories are suggested to establish its own reference interval according to age, sex, diet and region.

INTERFERENCE

The effect of ascorbic acid ≤ 10mg/dL, hemoglobin ≤ 400mg/dl, Bilirubin ≤ 10 mg/dl, heparin sodium ≤ 500u/ml is less than 10%.

ACCURACY

Compared with competitors, in the range of [0.5, 15] mmol/L, the correlation coefficient r≥0.975; in the range of [0.5, 2] mmol/L, the absolute deviation should ≤±0.2 mmol/L; in the range of (2, 15] mmol/L, the relative deviation should ≤ ±10%.

SENSITIVITY

When the sample concentration is 4.5mmol/L, the absorbance change should between 0.4000～0.8000.

LINEARITY

In the range of [0.5, 15] mmol/L, the linear correlation coefficient r≥0.99; in the range of [0.5, 2] mmol/L, the absolute deviation should ≤±0.2 mmol/L; in the range of (2, 15] mmol/L, the relative deviation should ≤ ±10%.

PRECISION

Repeatability precision was obtained by testing control or sample for 20 times of repeated measurement. Intermediate precision was obtained by testing human samples or control for 2 batches per day, and each batch was measured for 2 times separately in morning and afternoon, for total 20 days. The results are as follows:
a)Repeatability(N=20)

	Mean(mg/dl)	CV（%）
Level1	13.56	0.71
Level 2	51.93	0.63

b)Intermediate precision(N=80)

	Mean(mg/dl)	CV（%）
Level1	13.47	1.07
Level 2	50.94	1.01

SAFETY PRECAUTIONS AND WARNINGS

1. The reagent contains preservatives. If it enters the eyes, mouth or contact on the skin, please rinse it thoroughly with clean water immediately and go to the hospital if necessary.
2. The reagent contains preservatives, which can react strongly with copper, lead and other metals to form azide metal. Therefore, please dilute the waste liquid and flush the drain pipe to avoid residual when disposal.
3. Do not mix or exchange reagents with different batches in the process of detection.
4. Opened reagents should be sealed and stored according to the specified method. Expired product should not be used.
5. Please dispose test tubes and other instruments that have touched the test sample according to the relevant medical waste disposal regulations.
6. Calibrator and control use human matrix serum, passed the detection of HIV (HIV 1, HIV 2) antibodies, hepatitis B surface antigen (HbsAg) and hepatitis C virus (HCV). All of them are negative. Although the detection method is highly accurate, it can not be guaranteed that all infected donors are found, so the control should also be treated as infectious specimens.

References

Liu Junjie, Zhao Junjie. Modern anesthesiology [M]. 3 edition. Beijing: people's Health Publishing House, 2004 / 55.

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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