Lactate Dehydrogenase Assay Kit

（LDH）

Method: Lactic Acid Substrates Method

Cat.NO.	Package Size	Analyzer
EGS231X	R1:2×70ml R2:1×35 ml	For Hitachi917& OlympusAU640/400/600
EGB230X	R1:2×80ml R2:1×40 ml	For Hitachi 717 &ShimadzuCL7200/8000
EGH231X	R1:2×50ml R2:1×25 ml	For Hitachi 902
EGD231X	R1:24×4.3 ml R2: 6×4.3 ml	For Siemens Dupont/Siemens Behring Series
EGLDH460 BS	R1: 2×20 ml R2: 1×10 ml	For Mindray BS120/180/190/200/220/2 30/240/430/460/830
EGGLDH	R1: 2×20 ml R2: 1×10 ml	For Semi Auto Analyzer

INTENDED USE

For in vitro quantitative determination of lactate dehydrogenase activity in serum,plasma ,pleuroperitoneal fluids, cerebrospinal fluid (CSF).

CLINICAL SIGNIFICANCE[1,2]

LDH exists in various tissues, with the most in liver, kidney, myocardium, skeletal muscle, pancreas and lung. Acute myocardial infarction begins to increase at 6-12h, peaks at 24-60h, and returns to normal within 7-5 days. LDH is used for the auxiliary diagnosis of acute, especially subacute myocardial infarction [1-3]. Due to its wide distribution, in various acute phase reactions, such as hepatitis, pulmonary infarction, pernicious anemia, and LDH increase, it is often used to observe whether this enzyme is normal to remove tissue and organ damage or to observe the efficacy of cancer chemotherapy. The determination of pleural effusion, serum LDH and their ratio is helpful for the identification of benign and malignant diseases and infectious diseases. In general, patients with malignant pleural fluid LDH>serum LDH value, patients with tuberculous pleural fluid serum LDH>pleural fluid LDH, pleural fluid LDH/serum LDH>2, the possibility of malignancy should be considered [4].

ASSAY PRINCIPLE

$$\text{L—lactate} + NAD^+ \xrightarrow{LDH} \text{pyruvate} + NADH + H^+$$

LDH catalyzes the oxidation of lactate to pyruvate, and NAD is reduced to NADH, which can be measured at 340 nm. The test should be performed under physiological pH conditions, which is conducive to the balance of lactic acid.

REAGENT COMPOSITION

Contents	Concentration
Reagent 1 (R1)	
N-methyl-D-glucamine Lactate	325 mmol/L 50 mmol/L
Reagent 2 (R2)	
NAD^+	10 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.
5.Reagents should not be contaminated.

APPLICABLE INSTRUMENT

This kit is theoretically suitable for all biochemistry analyzers and spectrophotometers covering the wavelength range of 340/405nm.

It is recommended to use this kit on biochemistry analyzer for testing according to laboratory conditions.

SAMPLE COLLECTION AND PREPARATION

Serum, plasma, pleuroperitoneal fluids and cerebrospinal fluid.

Samples stability: Stable at room temperature (20℃~25℃) for 2~3 days.

Avoid refrigeration or freezing.

Hemolysis easily leads to high activity of LDH.

ASSAY PROCEDURE

Test Condition(Hitachi 917)

Main wavelength	340 nm	Sample (S)	4 μl
Secondary wavelength	405 nm	Reagent 1(R1)	200 μl
Reaction temperature	37℃	Reagent 2(R2)	50 μl
Cuvette diameter	1cm	Reaction type	Rate method

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:http://en.bsbe.com.cn/ Email:overseas@bsbe.com.cn

Operate procedure

Add into cuvette;	
Sample(S)	4 μl
Reagent 1(R1)	200 μl
Mix well and incubate for 5 minutes at 37℃	
Reagent 2(R2)	50μl
Mix well and incubate for 60s. Continuously measure the absorbance within 160 seconds, calculate the rate of absorbance change (△A/min)n	

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

It is recommended to use Gcell calibrator.

Calibrator traces to LDH reference method which is suggested by IFCC.

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 its 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 control. The absorbance of quality control should be within the 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.

CALCULATION RESULT

According to the specific calibration mode of the project, the instrument will automatically generate calibration curve and calculate the content of the measured object from the change value of absorbance in the sample.

REFERENCE RANGE

Human serum or plasma: 120-250U/L

Laboratories are suggested to establish its own reference interval according to age, sex, diet and region.

INTERFERENCES

The effect of Intralipid ≤600mg/dL, TBil ≤ 40 mg/dL, VitC≤30mg/dL, HGB≤50mg/dL, is less than 10%.

ACCURACY

The kit is tested with JCCLS CRM001 international reference material. The deviation of the results should ≤ ±10%.

SENSITIVITY

When the sample concentration is 300U/L, the change of absorbance should ≥ 0.0100.

LINEARITY

In the range of [25,750]U/L ,the linearity correlation coefficient r ≥ 0.990,In the range of [25,100]U/L, the absolute deviation should ≤±10U/L; In the range of (100,750]U/L, the relative deviation ≤ ±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(U/L)	CV（%）
Level1	190.2	0.76
Level 2	348.8	0.54

B)Intermediate precision(N=80)

	Mean(U/L)	CV（%）
Level1	199.8	0.5
Level 2	346.4	1.8

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.

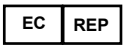
5. Please dispose of test tubes and other instruments that have been in contact with test specimens in accordance with relevant medical waste disposal regulations. The following treatment methods can be selected:

Autoclave at 121℃ for 15 minutes (but do not use autoclave to treat waste containing hypochlorous acid solution), or soak in hypochlorous acid solution (effective concentration greater than 1000ppm) for one hour the above.

REFERENCES

1.Amador E., Dorfman L.E., Wacker W.E., Clin. Chem., 1963; 9: 331
2.Henry, R.J., Clinical Chemistry, Principles and Techniques, 2nd Edition, Harper and Row, p. 819, 1974
3.Tietz, N., Fundamentals of Clinical Chemistry, W.B.Saunders Co., Philadelphia, PA, p. 652, 1976
4. Zhang Xiuming, Li Jianzhai Modern clinical biochemical laboratory science, people's military medical publishing house

INDEX OF SYMBOLS

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

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:http://en.bsbe.com.cn/ Email:overseas@bsbe.com.cn