CE IVD

LDH Reagent Kit (Lactate Substrate Method)

Instructions for Use

REF CC1054

PRODUCT NAME

LDH Reagent Kit (Lactate Substrate Method)

PACKAGE SPECIFICATION

R1: 1×20 mL	R2: 1×10 mL	R1: 1×40 mL	R2: 1×20 mL
R1: 1×60 mL	R2: 1×30 mL	R1: 2×60 mL	R2: 2×30 mL
R1: 2×30 mL	R2: 2×15 mL	R1: 2×40 mL	R2: 2×20 mL
R1: 2×50 mL	R2: 1×50 mL	R1: 2×60 mL	R2: 1×60 mL
R1: 2×60 mL	R2: 3×20 mL	R1: 2×65 mL	R2: 1×65 mL
R1: 2×65 mL	R2: 1×70 mL	R1: 2×80 mL	R2: 1×80 mL
R1: 2×120 mL	R2: 2×60 mL	R1: 3×20 mL	R2: 3×10 mL
R1: 3×40 mL	R2: 3×20 mL	R1: 4×40 mL	R2: 4×20 mL
R1: 4×50 mL	R2: 2×50 mL	R1: 4×55 mL	R2: 2×55 mL
R1: 4×60 mL	R2: 2×60 mL	R1: 4×60 mL	R2: 4×30 mL
R1: 4×60 mL	R2: 6×20 mL	R1: 4×65 mL	R2: 2×65 mL
R1: 4×65 mL	R2: 2×70 mL	R1: 4×100 mL	R2: 2×100 mL
750 T (R1: 1×80 mL R2: 1×18 mL)			
12×72 T (R1: 12×16.8 mL R2: 12×8.4 mL)			

INTENDED USE

This kit is intended for the *in vitro* quantitative determination the activity of lactate dehydrogenase (LDH) in human serum or plasma. Clinically, it is mainly used for the auxiliary diagnosis of myocardial infarction and liver diseases.
For professional and laboratory use only.

TEST PRINCIPLE

Lactate dehydrogenase can catalyze lactate into pyruvate (L→P indicates the direction of this reaction) and reduce NAD+ to NADH, resulting in an increase of absorbance at 340 nm. The increase rate is proportional to the LDH activity in the sample, and the reaction formula is as follows:

$$\text{L-lactate} + \text{NAD} \xrightarrow[\text{pH9.3}]{\text{LDH}} \text{Pyruvate} + \text{NADH}$$

MAIN COMPONENTS

Reagent	Main components	Content
Reagent 1	N-acetyl-d-meglumine buffer (pH9.3)	100 mmol/L
	Lithium L-lactate	11.13 g/L
Reagent 2	Oxidizing coenzyme I	2.3 g/L

The components in different batches of a multi-component kit should not be interchangeable.

STORAGE AND SHELF LIFE

The kit can be stored at 2-8°C in the dark and unopened state with the validity period of 18 months. Once opened, it can be stored at 2-8°C for 42 days.
See the production date or expiry date on the label.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

1. It is recommended to use fresh serum or heparin plasma for test;
2. Samples should be separated timely after collection;
3. Avoid hemolysis;
4. The serum and plasma samples can be stored for 7 days at 15-25°C, for 4 days at 2-8°C and for 6 weeks at -20°C.

TEST PROCEDURE

1. The reagent R1 and R2 can be used directly.
2. Test conditions:

Primary / Secondary Wavelength	340 nm/415 nm	**Calibration type**	Linearity
Sample/R1/R2	6/200/100	**Sample + R1 Time**	3-5 min
Method	Rate assay	**After +R2, reaction time**	3 min
Calibration method	Two-point method	**Direction of reaction**	Upward

3. Operating procedures:
   Operation using two reagents

Sample	6 μL
R1	200 μL
Mix well, incubate at 37°C for 3-5 min	
R2	100 μL
Mix thoroughly and incubate at 37°C for 90 seconds. Using distilled water as blank, zero the instrument at the test wavelength, then continuously monitor absorbance changes for 2 minutes. Calculate ΔA/min.	

4. Calibration procedure:
   A calibrator from Getein is recommended, and a calibration serum from Randox can also be used.
5. Quality control procedure:
   Use the quality control product of Randox, and its measured value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:
   5.1 Check whether the parameter settings and light source are correct.
   5.2 Check whether the cuvettes and sampling probes are clean.
   5.3 Check whether water is contaminated, and bacterial growth will cause incorrect results.
   5.4 Check reaction temperature.
   5.5 Check the expiration date of the kit.
6. Result calculation

$$\text{The activity of LDH (U/L)} = \triangle A/\text{min} \times K\ (8199)\ K = \frac{\text{Reaction volume(mL)}}{\text{Sample volume(mL)} \times 6.22 \times 10^{-3} \times 1.0}$$

Note: 6.22×10^{-3} is the micromolar absorbance at 340 nm; 1.0 is the light diameter of the cuvette.

REFERENCE RANGE

100-240 U/L(37°C)

The reference ranges quoted are for reference only.
It is recommended that each laboratory establish its own reference range based on the region and population.

RESULT INTERPRETATION

Hemolysis interferes with the determination, and hemolysis should be avoided during operation. Sample storage time also influences the test result.

LIMITATIONS

There is no interference with measurement when bilirubin ≤ 40 mg/dL, Ascorbic acid ≤ 30 mg/dL and triglycerides ≤ 2000 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Reagent 1 in the kit is a colorless clear liquid, which may contain a small number of insoluble particles that do not affect determination. Reagent 2 is a colorless clear liquid, which may contain a small number of insoluble particles that do not affect determination.
2. Reanget blank
   Reanget blank absorbance should not be greater than 0.500 at 37°C, 340 nm wavelength and 1cm optical diameter.
   Under the conditions of 37°C, 340 nm wavelength and 1cm light diameter, when normal saline is used as sample to add the reagent test, the reagent blank absorbance change rate (△A/min) should not be greater than 0.002.
3. Accuracy
   The relative deviation should be within ±10%.
4. Linear range
   Linear correlation coefficient (r) should be ≥ 0.990 in the range of [10, 1000] U/L;
   In the range of [10, 65] U/L, the linear absolute deviation should not exceed ±10 U/L; In the range of (65, 1000] U/L, the linear relative deviation should not exceed ±10%.
5. Analyze sensitivity
   When the sample concentration is 259 U/L, the absorbance difference should be no more than 0.060.
6. Precision
   Repeatability: CV should not be greater than 5.0%.
   Between-run precision: should not be greater than 10.0%.

PRECAUTIONS

1. General precautions
   1.1 This product is for *in vitro* diagnosis only.
   1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
   1.3 Please use this product according to the IFU.
2. Precautions for operation
   2.1 Please treat the specimens as dangerous substances that may be infected with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
   2.2 If the reagents get into the eyes or mouth, or contact with the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
   2.3 Avoid hemolysis as much as possible during operation.
3. Precautions for use
   3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
   3.2 Please do not use expired reagents whose test results may be inaccurate.
   3.3 Please avoid adding reagents halfway during a test.
   3.4 Please avoid direct sunlight during operation.
   3.5 The latex reagent should be well mixed before use.
4. Precautions for waste disposal
   Samples, waste liquids, etc. are potentially biologically contaminated. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
   5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
   5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
   5.3 Please do not use the reagent bottles for other purposes.
   5.4 Oxalate has an inhibitory effect on LDH, so it is not appropriate to use oxalate anticoagulant plasma as specimen.
   5.5 A result calculated with the k value is not as reliable as that obtained using calibrator.
   5.6 Please do not mix reagents in different batches.

REFERENCE

1. A. Di Cello et al. A more accurate method to interpret lactate dehydrogenase (LDH) isoenzymes' results in patients with uterine masses. European Journal of Obstetrics & Gynecology and Reproductive Biology 236 (2019) 143–147.
2. W. Wang et al. Determination of lactate dehydrogenase in human erythrocytes by capillary electrophoresis with electrochemical detection J. Chromatogr. B 798 (2003) 175–178.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on LDH Reagent Kit (Lactate Substrate Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

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CÔNG TY TNHH XUẤT NHẬP KHẨU VÀ THƯƠNG MẠI ROKO VIỆT NAM

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DN: C=VN, CN=CÔNG TY TNHH XUẤT NHẬP KHẨU VÀ THƯƠNG MẠI ROKO VIỆT NAM, L=Huyện Đông Anh, O=CÔNG TY TNHH XUẤT NHẬP KHẨU VÀ THƯƠNG MẠI ROKO VIỆT NAM, ST=Hà Nội, UID=MST:0106416199