Lactate Dehydrogenase –L Assay Kit （LDH）

Method: L

Cat .No.	Size	Instrument
GB230X	R1: 2×80 ml R2: 1×40 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS231X	R1: 2×70 ml R2: 1×35 ml	For Hitachi 917 & OlympusAU640/400/600
GH231X	R1: 2×50 ml R2: 1×25 ml	For Hitachi 902
GX231X	R1: 2×80 ml R2: 2×20 ml	For SYNCHRON CX4-5-7-9 /LX20/DXC600-800
GT231X	R1: 5×48 ml R2: 2×30 ml	For TOSHIBA

INTENDED USE

For the *in vitro* quantitative determination of lactate dehydrogenase activity in human serum.

CLINICAL SIGNIFICANCE[1,2]

The enzyme lactate dehydrogenase (LDH-L) is distributed in tissues particularly heart, liver, muscle, and kidney. The enzyme found in circulation is a mixture of five isoenzymes based on their mobility. Elevated serum levels of LDH-L are found in serum in myocardial infraction, liver disease, renal disease, certain forms of anemia, malignant diseases and progressive muscle dystrophy.

ASSAY PRINCIPLE[3]

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

LDH catalyzes the oxidation of lactate to pyruvate, and NAD is reduced to NADH, which can be measured at 340 nm.

SAMPLE COLLECTION AND PREPARATION

Serum samples.

REAGENT COMPOSITON

Contents	Concentration of Solutions
Reagent 1 (R1)	
N-methyl-D-glucamine	325 mmol/L
Lactate	50 mmol/L
Reagent 2 (R2)	
NAD^+	10 mmol/L

STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.

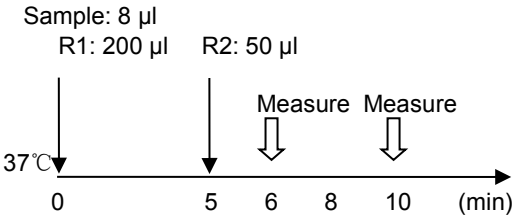
Stable up to the expiry date when stored at 2-8℃.The LDH assay kit reagents are stable for 1 month on-board the analyzer after opening and kept at 2-8℃.

ASSAY PROCEDURE

Test Procedure for Analyzers (HITACHI7170/917)

Assay Mode: 2 Point Rate 20-29

Wave Length (main/sub): 340 nm/405 nm



1. Mix 8 µl sample with 200 µl R1 and incubate at 37℃ for 5 minutes.
2. Add 50 µl R2 into cuvette, mix and incubate for 1 min at 37℃.
3. Read initial absorbance and start timer simultaneously, read again after 1 and 2 minutes.
4. Calculate absorbance change per minute (ΔA/min)

CALCULATION

$$\text{Concentration} = \frac{A_{sample}/\text{min}}{A_{calibrator}/\text{min}} \times \text{Calibrator value}$$

$$\text{LDH (U/L)} = \frac{\Delta A/\text{min} \times Tv}{\varepsilon \times Sv \times L} = \Delta A/\text{min} \times 10080$$

(ε=6.22)

CALIBRATION

Recommend that this assay should be calibrated using Randox Calibration Serum Level 3 or Level 2.

QUALITY CONTROL

Randox Assayed Multisera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls 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

	Female（U/L）	Male（U/L）
Adult	135 - 215	135 - 225
1 - 3 years old	165 - 395	155 - 345
4 - 6 years old	135 - 345	155 - 345
7 - 9 years old	140 - 280	145 - 300
10 -12 years old	120 - 260	120 - 325
13 -15 years old	100 - 275	120 - 290
16-18 years old	105 - 230	105 - 235

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The method is linear up to 1000 U/L. If the sample above this concentration should be diluted 1+1 with 0.9% NaCL and repeat assay. Multiply the result by 2.

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PRECISION

The CV of the test should be less than 5%

Inter assay precision		
N=5	Level1	Level 2
Mean (U/L)	210.4	337.3
SD	2.6	3.1
CV	1.3%	0.92%
Intra assay precision		
N=20	Level1	Level 2
Mean (U/L)	185.3	318.4
SD	1.1	2.3
CV	0.6%	0.7%

SENSITIVITY

The minimum detectable level that can be distinguished from zero has been determined as 5.02 U/L.

INTERFERENCE

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

Hemoglobin: 50 mg/dl
Intralipid: 1000 mg/dl
Bilirubin: 80 mg/dl
Ascorbic acid: 50 mg/dl

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:
Y=0.940X+3.993, R^2=0.997; 60 patient samples were analyzed .

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. The reagents 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 build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES

1. Amador E., Dorfman L.E., Wacker W.E., Clin. Chem.,1963; 9: 331.
2. Henry, R.J., Clinical Chemistry, Principles andTechniques, 2nd Edition, Harper and Row, p. 819, 1974.
3. Tietz, N., Fundamentals of Clinical Chemistry, W.B.Saunders Co., Philadelphia, PA, p. 652, 1976.

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℃


Attention:See instruction for use

Authorized Representative in the European Company

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