Gcell

Lactate Dehydrogenase –L Assay Kit （LDH）

Method: DGKC

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.

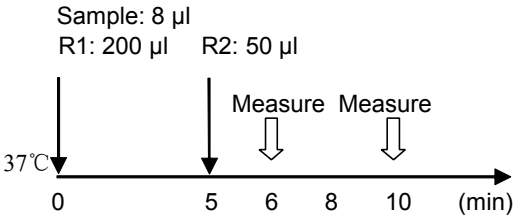
Stable up to the expiry date when stored at 2-8℃.The LDH assay kit reagents are stable for 1 month on-board the analyzer after opening and kept at 2-8℃.

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.

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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.

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.

SPECIFIC PERFORMANCE CHARACTERISTICS 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

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.

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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INSTRUMENT SETTINGS FOR HITACHI 917

Hitachi 7170 Parameter Application Gcell

LDH
Cat. No: GS231X-GB230X

Analysis

Test / Type	LDH			Ser/Pl					
Assay/Time/Point	Rate A	A	10	A	20	29	0	0	
Wave (Sub/Main)	405	A	340	A					
S.Vol (Normal)	8	0.0	0						
S.Vol (Decrease)	2	0.0	0						
S.Vol (Increase)	8	0.0	0						
Diluent	Water	0							
Reagent (R1) T1	200	0	*	0					
Reagent (R2) T2	0	0	00000	0					
Reagent (R3) T3	50	0	*	0					
Reagent (R4) T4	0	0	00000	0					
Abs. Limit	32000	Increase	A						
Prozone Limit	0	34	Lower	A					
Cell Detergent	Detergent 1	A							

Range

Application Code	*	Unit	U/L	A		
Report Name	LDH					
Data Mode	On Board	A				
Control Interval	0					
Instrument Factor (Y=aX+b)	a=	1.0	b=	0		
Technical Limit	0	1500				
Expected Value						

						Qualitative	
(Male)	0	Y	A				Cancel A
	100	Y	A			(1)	0
				135	225	(2)	0
(Female)	0	Y	A			(3)	0
	100	Y	A			(4)	0
				135	215	(5)	0

Calibration

Calibration type	Linear	A		A	
Point	1	Span Point	0		
Weight	0				
Auto calibration					
Time Out		Change Over			
Blank	0	Blank	A		
Span	0	Blank	A		
2Point	0				
Full	0				
SD Limit	0.1				
Duplicate limit	1000				
Sensitivity limit	0				
S1 Abs limit	-32000	32000			

STD Conc

<Standard>	(1)	(2)	(3)	(4)	(5)	(6)
Concentration	0	0	0	0	0	0
Position	Water	0	0	0	0	0
Volume	8	0	0	0	0	0
<Pre-Diluent>						
Volume	0	0	0	0	0	0
Diluent	0	0	0	0	0	0
Cal. Code	0	0	0	0	0	0

Attention: * entered by operator
K-factor= 5185

INSTRUMENT SETTINGS FOR Olympus400/640/2700

Olympus AU640/400/2700 Instrument Settings Gcell

LDH
Cat. No: GS231X-GB230X

Specific Test Parameters

Test Name:	LDH			Type:	Serum	Operation:	Yes
Sample: Volume	4	Dilution	0	Pre-Dilution Rate:			
Reagents: R1 Volume	200	Dilution	0	Min OD		Max OD	
R2 Volume	50	Dilution	0	L	-2.0000	H	2.5000
				Reagent OD Limit:			
Wavelength: Pri.	340	Sec.	410	First L	-2.0000	First H	2.5000
Method:	RATE			Last L	-2.0000	Last H	2.5000
Reaction Slope:	+			Dynamic Range:			
Measuring Point 1: First	14	Last	19	L	0	H	1512
Measuring Point 2: First		Last		Correlation Factor:			
Linearity:	30%			A	1.0	B	0.0
No-Lag-Time:	YES			Onboard Stability Period:			

Calibration Specific

Test No.:		Name:	LDH	Type:	SER
Cal. Type:	MB			Counts:	2
Formula:		Y = AX + B		Process:	CONC
Calibration Selection:					

	Cal. No.	OD	Conc.	Factor/OD-L	Factor/OD-H
Point 1					
Point 2					
Point 3					
Point 4					
Point 5					
Point 6					
Point 7					
1-Point Cal..Point:					
MB Type Factor:		10080			
Cali. Stability Period:					

Attention: * Entered By Operator

INSTRUMENT SETTINGS FOR HITACHI 902

Hitachi 7020 Instrument Settings Gcell

LDH

Cat. No: GB 230X/GS 231X/GH 231X

No.	<Chemistry>	
1	Test Name	LDH
2	Assay Code (Mthd)	Rate A
3	Assay Code (2. Test)	0
4	Reaction Time	10
5	Assay Point 1	20
6	Assay Point 2	30
7	Assay Point 3	0
8	Assay Point 4	0
9	Wave Leng. (SUB)	405
10	Wave Leng. (MAIN)	340
11	Sample Volume	4
12	**R1** VOLUME	200
13	R1 Pos.	*
14	R1 Bottle Size	Large
15	**R2** VOLUME	0
16	R2 Pos.	0
17	R2 Bottle Size	Small
18	**R3** VOLUME	50
19	R3 Pos.	*
20	R3 Bottle Size	Small
21	Calib. Type (Type)	K Factor
22	Calib. Type (Wght)	0
23	Calib. Conc. 1	0
24	Calib. Pos. 1	99
25	Calib. Conc. 2	0
26	Calib. Pos. 2	0
27	Calib. Conc. 3	0
28	Calib. Pos. 3	0
29	Calib. Conc. 4	0
30	Calib. Pos. 4	0
31	Calib. Conc. 5	0
32	Calib. Pos. 5	0
33	Calib. Conc. 6	0
34	Calib. Pos. 6	0
35	S 1 ABS.	0
36	K Factor	10080
37	K 2 Factor	10000
38	K 3 Factor	10000
39	K 4 Factor	10000
40	K 5 Factor	10000
41	A Factor	0
42	B Factor	0
43	C Factor	0
44	SD Limit	999
45	Duplicate Limit	1000
46	Sens. Limit	0
47	S 1 ABS Limit (L)	-32000
48	S 1 ABS Limit (H)	32000
49	ABS Limit	32000
50	ABS Limit (D/I)	Increase
51	Prz. Limit	0
52	Prz. Limit (U/D)	Lower
53	Prz. (End Point)	35
54	Expect. Value (L)	135
55	Expect. Value (H)	225
56	Instr. Fact. (a)	1
57	Instr. Fact. (b)	0
58	Key Setting	*

* Data entry by the user

INSTRUMENT SETTINGS FOR CX4/5/7/9

Synchron CX-4/5/7/9 User-defined Chemistries Gcell

LDH
Cat. No: GB230X/GS231X/GX231X

USER ID:
Chemistry Name: LDH
Test Name: LDH — Calculate Factor: 20160

Reaction Type: Rate 1 — Math Model: Linear
Reaction Direction: Positive — Cal Time Limit: 336 Hrs
Units: U/L — No. Of Calibrators: 0

Decimal Precision: X

Primary Wavelength: 340 nm — Secondary Wavelength: 410 nm

Sample Volume: 4 µl
Primary Inject Rgt:
A: 200 µl
None: µl
Secondary Inject Rgt:
B: 50 µl
Add Time: 512 sec

CALIBRATORS
#1:
#2:
#3:
#4:
#5:

MULTIPOINT SPAN
1 - 2 0.000
2 - 3 0.000
3 - 4 0.000
4 - 5 0.000
5 - 1 0.000

RAGENT BLANK
Start Read: 464 sec
End Read: 480 sec
Low ABS Limit: -1.500
High ABS Limit: 1.500

REACTION
Start Read: 256 sec
End Read: 346 sec
Low ABS Limit: -1.500
High ABS Limit: 1.500

USABLE RANGE
Lower Limit: 0
Upper Limit: 1500

SUBSTRATE DEPLETION
Initial Rate: 99. 999
Delta ABS: 1. 5

RECOVERY/SENSITIVITY
Std Dev (conc): *
CV (%): *
Std Dev (mA): *
Threshold: *

Attention: * Entered By Operator

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