LDH FS* IFCC

Diagnostic reagent for quantitative in vitro determination of lactate dehydrogenase (LDH) in serum or plasma on Sysmex BX-Series

Order information

Cat. No.	Kit size		Number of tests
1 4211 99 10 972	R1 3 x 11.8 mL	BX-3010	3 x 90 tests
		BX-4000	3 x 62 tests
	R2 3 x 5.1 mL	BX-3010	3 x 90 tests
		BX-4000	3 x 62 tests

Method

Optimized UV-test according to IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) and DGKC (German Society of Clinical Chemistry)

Principle

L-Lactate + NAD^+ $\xleftrightarrow{LDH}$ Pyruvate + NADH + H^+

Reagents

Components and Concentrations

R1:	N-Methyl-D-Glucamine	pH 9.40	420 mmol/L
	L-Lactate		65 mmol/L
R2:	NAD^+		50 mmol/L

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions

1. In very rare cases, samples of patients with gammopathy might give falsified results [8].
2. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
3. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent trays.

Specimen

Serum, heparin plasma or EDTA plasma

Stability [1]:

4 days	at	20 – 25°C
6 weeks	at	4 – 8°C

Discard contaminated specimens.

Calibrators and Controls

For calibration DiaSys TruCal U calibrator is recommended. This method has been standardized against the original IFCC formulation. For internal quality control DiaSys TruLab N and P controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL

Performance Characteristics

Measuring range up to 1200 U/L (20 µkat/L) LDH (in case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	6 U/L (0.1 µkat/L) LDH
On-board stability	6 weeks
Calibration stability	1 week

** lowest measurable activity which can be distinguished from zero mean + 3 SD (n=20) of an analyte free specimen

Interfering substance	Interferences < 10%	Analyte concentration
Ascorbate	up to 30 mg/dL	183 U/L (3.06 µkat/L)
Hemoglobin	up to 11 mg/dL	286 U/L (4.77 µkat/L)
Bilirubin, conjugated	up to 55 mg/dL	185 U/L (3.08 µkat/L)
Bilirubin, unconjugated	up to 40 mg/dL	182 U/L (3.03 µkat/L)
Lipemia (triglycerides)	up to 2000 mg/dL	256 U/L(4.26 µkat/L)
	up to 2000 mg/dL	184 U/L(3.06 µkat/L)
For further information on interfering substances refer to Young DS [7].		

Precision (BX-3010)			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	123	199	346
Mean [µkat/L]	2.06	3.31	5.76
Coefficient of variation [%]	2.84	2.27	1.47
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	130	197	343
Mean [µkat/L]	2.17	3.28	5.71
Coefficient of variation [%]	3.48	2.69	2.06

Method comparison (n=100)	
Test x	LDH FS IFCC (Biomajesty 6010C)
Test y	LDH FS IFCC (BX-4000)
Slope	1.03
Intercept	–6.30 U/L (–0.105 µkat/L)
Coefficient of correlation	0.983

Conversion factor

LDH [U/L] x 0.0167= LDH [µkat/L]

Reference Range

	Female	**Male**
Adults [2]	< 247 U/L	< 248 U/L
Children [3]		
1 – 30 day(s)	145 – 765 U/L	125 – 735 U/L
31 days – 1 year	190 – 420 U/L	170 – 450 U/L
1 – 3 year(s)	165 – 395 U/L	155 – 345 U/L
4 – 6 years	135 – 345 U/L	155 – 345 U/L
7 – 9 years	140 – 280 U/L	145 – 300 U/L
10 – 12 years	120 – 260 U/L	120 – 325 U/L
13 – 15 years	100 – 275 U/L	120 – 290 U/L
16 – 18 years	105 – 230 U/L	105 – 235 U/L

	Female	**Male**
Adults [2]	< 4.12 µkat/L	< 4.14 µkat/L
Children [3]		
1 – 30 day(s)	2.42 – 12.8 µkat/L	2.09 – 12.3 µkat/L
31 days – 1 year	3.17 – 7.01 µkat/L	2.84 – 7.52 µkat/L
1 – 3 year(s)	2.76 – 6.60 µkat/L	2.59 – 5.76 µkat/L
4 – 6 years	2.25 – 5.76 µkat/L	2.59 – 5.76 µkat/L
7 – 9 years	2.34 – 4.68 µkat/L	2.42 – 5.01 µkat/L
10 – 12 years	2.00 – 4.34 µkat/L	2.00 – 5.43 µkat/L
13 – 15 years	1.67 – 4.59 µkat/L	2.00 – 4.84 µkat/L
16 – 18 years	1.75 – 3.84 µkat/L	1.75 – 3.92 µkat/L

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 36-7.
2. Schumann G, Bonora R, Ceriotti F, Férard G et al. IFCC primary reference procedure for the measurement of catalytic activity concentrations of enzymes at 37 °C. Part 3: Reference procedure for the measurement of catalytic concentration of lactate dehydrogenase. Clin Chem Lab Med 2002; 40: 643-48.
3. Soldin JS, Hicks JM. Pediatric reference ranges. Washington: AACC Press. 1995: p. 95.
4. Deutsche Gesellschaft für Klinische Chemie. (German Society for Clinical Chemistry). Recommendation for the determinaion of the catalytic concentration of lactate dehydrogenase at 37 °C. Eur J Clin Chem Clin Biochem 1993; 31: 897-9.
5. Thomas L. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 89-94.
6. Moss DW, Henderson AR. Clinical enzymology In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. 617-721.
7. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanisms, detection and prevention. Clin Chem Lab med 2007; 45(9): 1240–1243.

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

LDH FS IFCC

Chemistry Code 100 56

Chemistry Parameters 1

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No.	*	Method Name	LDH	Reagent Name	Reagent (µL)	Water (µL)
Print Name	LDH	MethodColor		R1 LDH	100	
Sample Type	Serum			R2 LDH	25	
Unit	U/L			Diluent Disable		
Assay Type	Rate			Sample Ppt. Wash Disable		

Measuring points

	Start		End
1	30	–	45
2	Disable	–	

Stirring Speed R1 Middle R2 Middle

Wave Length: Prim. 340 Sec. 415

Normal Range

No.	Normal Range Name	Min	Max
1	Male-G1	*	*
2	Male-G2	*	*
3	Male-G3	*	*
4	Female-G1	*	*

Normal	Sample Volume (µL) Low	Normal	High	Diluted Sample (µL)	Diluent (µL)	Technical Range		
						(Conc)	6 –	1200
☐ Diluent	0.0 <	1.9 <	0.0			(mAbs/10)	* –	*
Rerun (High/Prozone)								
☐ Diluent	0.0 <	1.9 <	0.0			Previous Result Comparison (%)	*	* %
Rerun (Low)								
☐ Diluent	0.0 <	1.9 <	0.0			Abnormal Range (Conc)	* –	*
						Panic Range (Conc)	* –	*

Decimal Point 0 Profile SI Disable

***Entered by user**

Chemistry Parameters 2

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. * Method Name LDH Sample Serum

Limit Checks

- ✓ Duplicate Limit 20 mAbs/10
- ✓ Sensitivity Limit 250 mAbs/10
- ✓ Linearity Limit 10 %
- 140 (mAbs/10)/min
- ☐ Prozone Limit Higher %
- SL1-S – SL1-F
- SL2-S – SL2-F
- Sensitivity mAbs/10
- ✓ Absorbance Limit
  - Abs. in reaction Increase
  - Limit 14000 mAbs/10

Blank measurement

- Blank measurement: Disable reagent blank and C1 blank
- Measurement of Reagent Blank during Run: None
- Reagent blank measurement at calibration: Reagent blank (No sample)
- The number of measurement: Duplicate
- Reagent blank limit checks:
  - ✓ Duplicate Limit 20 mAbs/10

Instrument Factor

a 1.00 b 0.00

LDH FS IFCC

Chemistry Code 100 56

Calibration Registration

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. *

Method Name LDH

Sample Type Serum

Replication Duplicate

Check Interval 7

Test without calibration

Disable

Calibration Type Linear

Reagent Lot New Add

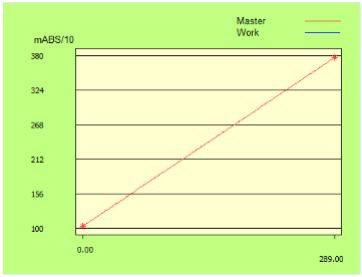
Calibrator Name TruCal U

	Conc.	WORK	MASTER	Calibr. Lot No.	☐ All
C1	0	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

K Automatic entry ☐ C1 Blank
☐ Reagent Blank for C1

***Entered by user**

Reagent Lot No.
(R1) *
(R2) *
Last



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank Automatic entry mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10 Recalculation

LDH FS IFCC

Chemistry Code 100 56

Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method	*	Name	LDH		Reagent Name	Reagent (µL)	Water (µL)
Print Name	LDH			R1	LDH	150	
Sample	Serum			R2 ✓ Enable	LDH	38	
Unit	U/L						
Assay Type	Rate			Diluent ☐ Enable			

Measuring points

	Start		End
1	44	–	68
☐ Enable 2		–	

Decimal Points: 0

Wave Length: Prim. 340 Sec ☐ Disable 415

Normal Range

No.	Normal Range Name	Min	Max
1	Male-G1	*	*
2	Male-G2	*	*
3	Male-G3	*	*
4	Female-G1	*	*

	Sampling	Sample (µL)	Diluent (µL)
Normal ☐ Dilution	2.8		
Rerun (High/Prozone) ☐ Dilution	2.8		
Rerun (Low) ☐ Dilution	2.8		

Technical Range

(Conc) 6 – 1200

(mAbs/10) –

SPT Wash ☐ Enable — Reagent Name

Stirring Speed R1 Middle R2 Middle

***Entered by user**

Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method No. * Name LDH Sample Serum

Limit Checks

✓ Duplicate Limit 20 mAbs/10

✓ Sensitivity Limit 250 mAbs/10

✓ Linearity Limit 10 % 140 (mAbs/10)/min

☐ Prozone Limit % Upper

SL1-S – SL1-F

SL2-S – SL2-F

Sensitivity mAbs/10

✓ Absorbance Limit

Reaction Increase

Limit 14000 mAbs/10

Blank measurement

Blank measurement: Disable reagent blank and S1 blank

Measurement of Reagent Blank during Run: None

Reagent blank measurement at calibration: Reagent blank (No sample)

The number of measurement: Duplicate

Reagent blank limit checks:

✓ Duplicate Limit 20 mAbs/10

Instrument Factor

a 1.00 b 0.00

LDH FS IFCC

Chemistry Code 100 56

Registration Calibration

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method: * Name: LDH

Sample: Serum

Sampling: Duplicate

Check Interval: 7 days

Auto: Change Lot Full Calibration

Auto Interval: hours

Type: Linear Lot: New

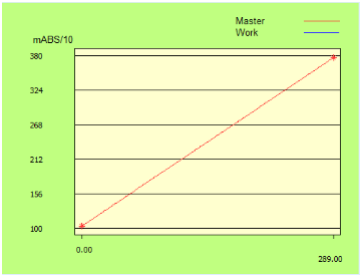
Material Name: TruCal U

	Conc.	WORK	MASTER	Lot No. (S) ☐ All
S1	0	Automatic entry	Automatic entry	
S2	*	Automatic entry	Automatic entry	
S3	*			
S4	*			
S5	*			
S6	*			
S7	*			

K: Automatic entry ☐ S1 Blank ☐ Reagent Blank for S1

***Entered by user**

R Lot No. R1: * R2: * Last:



The calibration curve is lot dependent

Reagent blank: mAbs/10 Last:

Blank: Automatic entry mAbs/10 Last:

Type: Conc.:

Absorbance: mAbs/10 Recalculation