LACTATE DEHIDROGENASE
LDH DGKC

Diagnostic reagent for determination of LDH activity.

Liquid. Dual Reagents, Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
A2260	5x100ML	K2261	1905 Tests	N2260	800 Tests	SIGE21	692 Tests
A2261	5x50ML	BY2260	6136 Tests	N2261	400 Tests	M2260	2386 Tests
A2262	5x25ML	BY2261	4091 Tests	R2260	1705 Tests	M2261	1591 Tests
DM2260	840 Tests	T2260	3474 Tests	R2261	568 Tests	L2260	3750 Tests
K2260	2857 Tests	T2261	1795 Tests	SIGE20	1246 Tests	L2261	2000 Tests

INTENDED USE

The test is applied for determination of LDH (Lactate Dehidrogenase) activity in human serum and plasma.

TEST PRINCIPLE

Lactate dehydrogenase (EC 1.1.1.27.; L-lactate: NAD^+ oxidoreductase; LDH) catalyzes the conversion of pyruvate to L-lactate in presence of NADH, which is converted to NAD^+. The rate of conversion of NADH/NAD^+, monitored at 340 nm, is proportional to LDH activity.

TEST PARAMETERS

Method : UV, Kinetic, Decreasing Reaction Optimized DGKC
Wavelength : 340 nm
Temperature : 37°C
Sample : Serum, EDTA-Plasma
Linearity : 30 U/L - 4000 U/L (37°C)

REAGENTS COMPOSITION

Composition in the test:

pH 7.50 phosphate buffer	≤ 60 mM,
Sodium pyruvate	≤ 0.70 mM,
NADH	≤ 0.20 mM.

REAGENTS PREPARATION

Working Reagents: add 4 ml of reagent 2 to a vial of reagent 1Stability of working reagent: 30 days at 2-8°C, away from light sources.

Working reagents are stable at 2-8ºC in case of closed vials and avoiding contamination after preparation.

For manual working procedures; if working reagent will be used; shake the Reagent 2 vial gently before pouring its contents into the Reagent 1 bottle. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

REAGENT STABILITY AND STORAGE

Once opened vials are stable minimum 30 days at 2-8°C at optimum conditions. On board stability is strongly related to auto analysers cooling specification and carry-over values.

SAMPLE

Serum, plasma heparinate or EDTA are by standard procedure. Avoid hemolysis.
LDH activity is stable 3 days in samples stored at 2-8°C, 7 days at 20 - 25°C, 6 weeks at -20°C.

TEST PROCEDURE

Sample Start
There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

Substrate Start
There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

Perform calculation in units per liter, multiplying the ΔA/min by the factor as it is indicated.

Calculation in U/L: ΔA/min x 16030 (sample starter)
Activity in µkat/L: U/L x 0.0167 = µkat/L

Unit Conversion

LDH µkat/L * 59.9 = LDH U/L

REFERENCE INTERVALS (NORMAL VALUES) (Based on rules CLSI C28-P Document)*

225 - 450 U/L (3.75 - 7.51 µkat/L)

* It is recommended that each laboratory establish its own normal range.

QUALITY CONTROL AND CALIBRATION

All control sera with LDH values determined by this method can be used. We recommend:

"ARCON N", Assayed Control Serum Normal
Cat.No. A3910

"ARCON P", Assayed Control Serum Abnormal
Cat.No. A3920

The use of a LDH Calibrator (for automated Systems) is optional. We recommend

ARCAL Calibrator
Cat. No. A39050

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 30 days in general.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

PERFORMANCE CHARACTERISTICS

Low Linearity: 30 U/L

High Linearity: The method is linear up to 4000 U/L.
If a ΔA/min of 0.100 is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatability (within run)(intra-assay):

Mean conc.	SD	CV	n
329.90 U/L	6.33 U/L	1.90%	10
531.90 U/L	7.75 U/L	1.50%	10

Reproducibility (run to run)(inter-assay):

Mean conc.	SD	CV	n
331.51 U/L	7.38 U/L	2.20%	20
546.04 U/L	11.76 U/L	2.20%	20

Sensitivity (LOD) (Based on CLSI EP17 document): The limit of detection (LOD) is 5 U/L.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Methods comparison: A comparison between Archem and a commercially available product gave the following results:
LDH Archem = x
LDH competitor = y
n = 99
$y = 0.99x + 2.41$ U/l $r^2 = 0.99$.

Interferences: No interference was observed by the presence of:

Hemoglobin	≤ 150 mg/dL
Bilirubin	≤ 40 mg/dL
Lipids	≤ 500 mg/dL

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1 & R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.

S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
IU : International Unit
LDH : Lactate Dehydrogenase
mA : miliabsorbance
mL : mililiter
NAD^+ : Nicotinamide Adenine Dinucleotide
NADH : Reduced NAD
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

REFERENCES

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2. HU Bergmeyer - Methods of enzymatic analysis, Vol. III (1987).
3. DGKC - Eur.J.Clin.Chem.Clin.Biochem., 31 (1993).
4. Kreutzer H.H. et al. - Clin. Chim. Acta 9,64 (1964)
5. Young D.S., et al. - Clin. Chem. 21 ID, 432D (1975)

SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
R2	Reagent 2
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

CE

Archem Diagnostics Industry LTD. ŞTİ.
Organize Sanayi Bölgesi, Mutsan Sanayi Sitesi
M8 Blok No: 48 Başakşehir / ISTANBUL TURKEY
Tlf: + 90 212 444 08 92
Fax: +90 212 629 98 89
info@archem.com.tr
www.archem.com.tr