

LDH SYSTEM PACK

(P-> L KINETIC METHOD)

B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic chem 400 (Fully Auto Biochemistry Analyzer)



Code	Product Name	Pack Size
UNI73	LDH System Pack	2x40 + 2x10 ml

INTENDED USE

Diagnostic reagent for quantitative *in vitro* determination of LDH in human serum.

CLINICAL SIGNIFICANCE

This enzyme is found in all organ cells, but especially plentiful in cardiac & skeletal muscle, liver, kidney & RBC. LDH is found in the form of iso-enzymes based on their electrophoretic mobility with each iso-enzymes being primarily from different organs.

Elevated levels are found in myocardial infarction, liver diseases, hemolytic anaemias, pernicious anaemia, Leukemia & Pulmonary diseases. Elevations in acute MI reaches a peak in 48-72 hrs. belonged elevations, (10-14 days) are useful in the late diagnosis of the condition.

PRINCIPLE

Kinetic determination of lactate dehydrogenase according to the following reaction.



REAGENT COMPOSITION

Reagent 1: Buffer Reagent

Tris Buffer (pH 7.4) 80 mmol/L
Pyruvate 1.6 mmol/L
Sodium chloride 200 mmol/L

Reagent 2: Starter Reagent

NADH 240 mmol/L

REAGENT PREPARATION

Reagent are liquid ,Ready to use

REAGENT DETERIORATION

Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Beacon Control Norm & Path control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using a fresh vial of reagent.

STABILITY AND STORAGE

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at +2-+8°C and protected from light.

On board stability: Min. 20days if refrigerated (+8-+14°C) and not contaminated.

SPECIMEN COLLECTION AND HANDLING

Use Serum / plasma (free of hemolysis)..

It is recommended to follow NCCLS procedures (or similar standardized conditions).

CALIBRATION

Calibration with the Beacon Multicalibrator is recommended.

QUALITY CONTROL

It's recommended to run normal and abnormal control sera to validate reagent performance.

EXPECTED VALUES

The following values may be used as guide line.

Serum /Plasma :1- 3 years	:490-730 U/L
4 - 9 years	:320-520 U/L
10 - 13 years	:250-500 U/L
Adults	:225-450 U/L

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

PERFORMANCE DATA

Data contained within this section is representative of performance on Beacon system.

Data obtained in your laboratory may differ from these values.

Limit of quantification:	7 U/L
Linearity:	2400 U/L
Measuring range:	7 - 2400 U/L

PRECISION

Intra-assay precision Within run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	456.7	3.52	0.77
Sample 2	764.3	3.57	0.47

Inter-assay precision Run to run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	661.2	3.82	0.58

COMPARISON

A comparison between LDH System Pack (y) and commercially available test (x) using 20 samples gave following results:

$$y = 1.113X - 43.37 \text{ U/L}$$
$$r = 0.999$$

INTERFERENCES

Following substances do not interfere:
Bilirubin up to 20 mg/dL. Significant hemolysis may increase LDH concentration because of high levels of LDH in the erythrocytes.

WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. To be handles by entitled and professionally educated person. MSDS will be provided on request.

WASTE MANAGEMENT

Please refer to local legal requirements.

Parameter For B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic chem 400 (Fully Auto Biochemistry Analyzer)

Test Name	LDH
Full Name	LDH
Pri Wave	340 nm
Sec Wave	630 nm
Assay/point	Kinetic
Start	15
End	33
Decimal	0
Unit	U/L
Linearity Range Low	7
Linearity Range High	2400
Sample Volume	2 µl
Reagent 1 (R1) Volume	160 µl
Reagent 2 (R2) Volume	40 µl
Substrate Depleted	-
Linearity	2400 U/L
Out Of Linearity Range	-
Calibration Type	2 Point linear
Points	2
Blank Type	Reagent
Concentration Blank	0.00
Concentration Std	Refer calibrator value sheet

NOTE









The program is made as per the in house testing, it can be modified as per requirements.
Clinical diagnosis should not be made on findings of a single test results, but both clinical and laboratory data.

REFERENCES

1. Searcy, R L., Diagnostic Biochemistry, McGraw-Hil, New york, NY, 1969.
2. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. Burtis, C.A, Ashwood, E-R., Bruns, D.E.; 5th edition, WB Saunders Comp., 2012.
3. Henry, RJ., Chiamori N., Golub O.J., And Berkman S., Am. J. Ciin. Path. 34(341)

4. Lum, G., Gambino, S.R., Am.J.Clin.Pathal. 61(108), 1974.
5. Bergmeyer, HW., Methods of Enzymatic Analytatic Analysis, Ed.2, Verlog Chemie, 1965.
6. Young DS, Effects of Drugs on Clirical Laboratory Tests. Third Edition. 1990;3:221-4.

Symbols Used On Labels

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|---|-------------------------|---|----------------------|
|  REF | Catalogue Number |  | Manufacturer |
|  | See Instruction for Use |  | Lot Number |
|  | Content |  | Storage Temperature |
|  | Expiry Date |  | In Vitro Diagnostics |

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