LDH SYSTEM PACK

(P-> L KINETIC METHOD)

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200 , Beaconic chem 200, Beaconic B200, Beaconic analyzer 120 & Bonavera chem 100 (Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
BA273	LDH System Pack	1x20 + 1x5 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.

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

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= 1.113 X-43.37

r = 0.999

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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.

B Auto 200, Unicorn 230, Unicorn 120 ,Bonavera Chem 200, Beaconic chem 200, Beaconic B200, Beaconic analyzer 120& Bonavera chem 100
(Fully Auto Biochemistry Analyzer)

Test Name	LDH
Full Name	LDH
Pri Wave	340 nm
Sec Wave	630 nm
Assay/point	Kinetic
Start	20
End	30
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
Subsatrate 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, RIJ., 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 Analymatic 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

REF	Catalogue Number		Manufacturer
	See Instruction for Use	LOT	Lot Number
CONT	Content		Storage Temperature
	Expiry Date	IVD	In Vitro Diagnostics

BEA/24/LPL/SB/IFU Ver-00
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