LDH SYSTEM PACK

(L->P METHOD)

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

| Code	Product Name	Pack Size
UNI24	LDH System Pack	2 x 50 + 2 x 10 ml

BEACON

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

CLINICAL SIGNIFICANCE
Increased levels of LDH are associated with myocardial infarction. Levels reach a maximum approxixmately 48 hours after the onset of pain and persist about ten days. The degree of elevation is of value in assessing the extent of damage and in developing a prognosis. LDH elevations are also observed in liver disease, pernicious anemia, in some cases of renal disease, and in some cases of skeletal muscle trauma.

PRINCIPLE

$$L\text{-Lactate} + NAD^+ \xrightarrow{\ LDH\ } Pyruvate + NADH + H^+$$
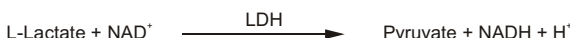
Lactate dehydrogenase catalyzes the oxidation of lactate to pyruvate with simultaneous reduction of NAD to NADH. The rate of NAD reduction can be measured as an increase in absorbance at 340 nm. This rate is directly proportional to LDH activity in serum

REAGENT COMPOSITION
Reagent 1 : Buffer Reagent

Buffer	>25 mmol/l
L-Lactate	<100 mmol/l

Reagent 2 : Starter Reagent

NAD	<15 mmol/L

REAGENT PREPARATION
Ready to use

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.

On board stability: Min. 21 days if refrigerated +8-+14°C and not contaminated

SPECIMEN COLLECTION AND HANDLING
Use unheamolytic serum.
It is recommended to follow NCCLS procedures (or similar standardized conditions).

Loss of activity:	within 24 hours	at +15-+25 °C	< 2 %
	within 3 days	at +2-+8°C	< 8 %
	Stability at least 6 weeks at -20°C.		
	Discard contaminated specimens.		

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
At 37°C: Male   - 80 - 285 U/L
          Female - 103 - 227 U/L

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: 1200 U/L
Measuring range: 7 – 1200 U/L

PRECISION

Intra-assay precision Within run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	228	4.48	1.97
Sample 2	470	4.96	1.06

Inter-assay precision Run to run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	251	1.10	0.44

COMPARISON
A comparision between LDH System Pack (y) and commercially available test (x) using 20 samples gave folioing results:

Y = 1.0027x - 1.7002 U/L
 r = 0.999

INTERFERENCES
Following substances do not interfere:
Bilirubin up to 20 mg/dl, triglycerides up to 500 mg/dl, haemoglobin up to 5.0 g/l. Significant hemolysis may increase LD concentration because of high levels of LD in the erythrocytes.

WARNING AND PRECAUTIONS
For *in vitro* diagnostic use. To be handles by entitled and professionally educated person.

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	16
END	33
DECIMAL	1
UNIT	U/L
LINEARITY RANGE LOW	7
LINEARITY RANGE HIGH	1200
SAMPLE VOLUME	3 µl
REAGENT 1 (R1) VOLUME	150 µl
REAGENT 1 (R2) VOLUME	30 µl
SUBSTRATE DEPLETED	-
LINEARITY	1200 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.

REFERENCES

1. Searcy, R.L., Diagnostic Biochemistry, McGraw-Hill, 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, RlJ., Chiamori N., Golub O.J., And Berkman S., Am. J. Clin. Path. 34(341)
4. Lum, G., Gambino, S.R., Am.J.Clin.Pathol. 61(108), 1974.
5. Bergmeyer, H.W., Methods of Enzymatic Analymatic Analysis, Ed.2, Verlog Chemie, 1965.
6. Young DS, Effects of Drugs on Clinical 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/LDH/UN/IFU Ver-02
23/04/2025