LDH-P Kit

CliniQuant – FSR

DGKC Method, Kinetic

Meril Diagnostics

IVD For *in vitro* diagnostic use
Read this pack insert thoroughly before use

REF	Pack Size	R1 LDH-P Reagent	R2 LDH-P Reagent
LDHFSR-01	1 x 8 / 1 x 2ml	1 x 8ml	1 x 2ml

INTENDED USE

This reagent is intended for quantitative determination of LDH level in human serum.

CLINICAL SIGNIFICANCE

Lactate dehydrogenase (LDH) is present in high levels in kidneys, heart, lliver, and skeletal muscle. Elevated level of LDH is an index of myocardial infarction, renal failure, hepatitis, anemia, malignancies, and affections of skeletal muscles.

PRINCIPLE OF THE METHOD

$$\text{Pyruvate} + \text{NADH} \xrightarrow{\text{LDH}} \text{Lactate} + \text{NAD}$$

KIT COMPONENTS

Composition :

R1 - LDH-P Reagent : Sodium Pyruvate 2.0 mmol/l, Tris buffer 100 mmol/l

R2 - LDH-P Reagent : NADH 1 mmol/l, Sodium Bicarbonate 10 mmol/l

MATERIALS REQUIRED BUT NOT PROVIDED

Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath, controls, saline.

REAGENT PREPARATION, STORAGE & STABILITY

Mix reagent 1 & reagent 2 in ratio 4:1. Keep away from direct light sources.

Stability: up to expiration date on labels at 2-8 °C.

Stability of working reagent: 5 days at 2-8 °C.

REAGENT DETERIORATION

Discard the reagent if absorbance <1. 0 at 340 nm against distilled water.

WARNINGS AND PRECAUTIONS

1. Reagent may contain some non-reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
2. Specimens should be considered infectious and handled appropriately.
3. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

Use serum, plasma. LDH is stable for 3 days at 2-8 °C or 1 month at -20°C.

Programme Parameter for MERILYZER CliniQuant

Reading Mode	Rate
Factor	8095
Filter - 1 (nm)	340
Temperature	37 °C
Volume (µl)	500
Delay Time (Sec)	60
Test Time (Sec)	180
Unit	U/l
Reaction Direction	decrease
Reference Low	200
Reference High	450
Linearity Limit	2000

TEST PROCEDURE

Dispense in tube working reagent	1000 µl
Sample	20 µl
Mix, execute a first reading of absorbance after 1 minute, incubating at 37°C. Perform other 3 readings at 60 seconds intervals. Calculate the ΔA/min.	

RESULT CALCULATION

Perform calculations in units per litre, multiplying the ΔA/min by the factor.

Activity in U/l = ΔA/min x 8095

CE
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EXPECTED VALUES

200 - 450 U/l at 37°C

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

QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.

When using the recommended Calibrator (BioCal), calibrate the assay:

a. When using a new reagent or lot

b. When QC values are out of range

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TEST PERFORMANCE

1. Linearity

The linearity is up to 2000 U/l or 34 µkat/l.

2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 0.8 U/l.

The limit of quantification is 2.5 U/l.

3. Interferences

No interference has been observed for the following

Ascorbic up to 30 mg/dl; Bilirubin up to 40 mg/dl

Triglycerides up to 1000 mg/dl

4. Precision

Intra-assay precision

	Mean	SD	CV
n = 20	U/l	U/l	%
sample 1	71.81	0.71	0.99
sample 2	169.8	1.02	0.60

Inter-assay precision

	Mean	SD	CV
n = 20	U/l	U/l	%
sample 1	71.90	2.79	3.88
sample 2	173.72	2.69	1.55

5. Methods Comparison

Comparison was done between reference LDH-P Reagent and CliniQuant - FSR LDH-P Reagent (test).

N = 12 $y = 1.185x - 28.54$

$r^2 = 0.987$

LIMITATIONS

Samples with values above 2000 U/l should be diluted with 0.9% saline, re-run and multiply results by dilution factor.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

REFERENCES

1. Burtis, C.A., Ashwood, E.R., editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia, W.B. Saunders Company, 1994, p. 812 - 819.

2. Data on file: Meril Diagnostics.

IFU/LDHFSR01/00

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Symbols used on Meril Diagnostics labels:

REF	Catalogue No.		Attention See Instruction for Use
LOT	Batch No.	IVD	*In vitro* Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged

EC REP Authorized European Representative in the European Community