LDH P-L

Specifically for use with Diatron PICTUS® 700 and PICTUS® 500 Analyzers

2°C – 8°C

REF 1419-0110 **Packaging:** 6 x 16 mL (R1) + 6 x 4 mL (R2)

Σ 600

INTENDED USE

Reagents for In Vitro quantitative automated determination of Lactate Dehydrogenase -LDH (EC 1.1.1.27) in samples of human serum or plasma from the general patient population. Measurements of LDH are to be used as an aid for screening, diagnosis and management of conditions related to cell damage.

This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers.
For in vitro diagnostic use only by trained laboratory professionals.

CLINICAL SIGNIFICANCE

L-Lactate dehydrogenase is a NAD+ oxidoreductase, catalyzing the reverse oxidation of L-lactate to pyruvate using NAD+ as a hydrogen receptor. Total LDH activity in serum is expressed by 5 isoenzymes (LDH-1 to LDH-5) which are differentiated on their sub units composition. An LDH-1 level higher than the LDH-2 level (a "flipped pattern"), suggests myocardial infarction (damage to heart tissues releases into the bloodstream heart LDH, which is rich in LDH-1). LDH is often used as a marker of tissue breakdown. Generally, increased levels of LDH can be attributed to any cell damage that results in cytoplasm release (embolism, leukemias, hemolytic anemias, hepatitis (non-viral), sickle cell anemia, lymphoma, myocardial infarction or pulmonary embolism). Since LDH is abundant in red blood cells, it can also function as a marker for hemolysis. A blood sample that has been handled incorrectly can show false-positively high levels of LDH due to erythrocyte damage. LDH is used to follow-up cancer (especially lymphoma) patients, as cancer cells have a high rate of turnover, with destroyed cells leading to an elevated LDH activity. The enzyme is also found in cerebrospinal fluid where high levels of lactate dehydrogenase are often associated with bacterial or viral meningitis. Elevated LDH may also be seen in Aran-Duchenne and Kugelberg-Welander spinal muscular atrophy, dermatomyositis, polymyositis, and as a result of strenuous physical exercise, megaloblastic anemias, renal infarction, chronic glomerular disease, myoskeletal diseases.

METHOD PRINCIPLE

The SFBC method is applied. The kinetic determination of L-Lactate Dehydrogenase (LDH) according to the modified SFBC method is based on the following reaction:

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

LDH: Lactate Dehydrogenase
The rate of absorbance change at 340/380 nm is proportional to the LDH activity in the sample.

METHOD LIMITATIONS

Refer to the book "Effects of Preanalytical Variables on Clinical Laboratory Tests" for possible interference of other pharmaceutical agents in this particular test. Interference of other agents is described in the "Clinical Guide to Laboratory Tests". This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers. For additional information please contact customer support at Diatron or Medicon.

REAGENT COMPOSITION

Reagent 1 (R1)	Reagent 2 (R2)
Tris buffer (pH 7.2):100 mM Pyruvate: 2 mM Non-reactive ingredients, preservative.	NADH: 1.4 mM Non-reactive ingredients,

⚠ **WARNINGS – PRECAUTIONS**

- This reagent is designed for in vitro diagnostic use. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory techniques. Avoid inhalation and contact with eyes and skin.
- Samples should be considered as potentially infectious. Handle with special caution.
- This reagent contains sodium azide (NaN_3) ≤ 0.1%. Avoid swallowing and contact of the reagent with skin and mucous membranes.
- Any serious incident that may occur in relation to this device must be reported by the user to the manufacturer and the competent authority of the country in which the user and/or the patient is established!
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON upon request.

⚠ **PREPARATION**

Reagents R1 and R2 are liquid, and ready to use when placed in the corresponding positions of the analyzer. The vials bear barcodes for automatic recognition by Diatron Pictus® P700 / P500 analyzers.

⚠ **REAGENT DETERIORATION**

The reagents should not be used:

- When they do not exhibit the specified linearity or control values lie outside the acceptable range after recalibration.
- After prolonged exposure to sunlight or high temperature.

⚠ **SHELF LIFE**

Unopened, the reagent is stable at 2 – 8°C up to the expiry date stated on the label. Once opened, it remains stable for 1 month when stored in the cooled reagent tray of the Diatron Pictus® P700 or P500 analyzers.

⚠ **SAMPLE** Serum, or Li-heparin plasma may be used as specimen. Use established Good Laboratory Practices for sampling, transport and separation from blood cells. Do not use hemolyzed, contaminated or turbid sample specimens. Hemolysis will cause contamination from LDH released from the red blood cells. Anti-coagulants other than Li-heparin have not been tested and should not be used. Centrifuge sample as soon as possible and store at room temperature if analysis cannot take place right after sample separation. do not freeze or refrigerate samples. LDH is stable for up to 3 days at 15 - 25°C.

CALIBRATION Diatron offers MEDICON MEDI-CAL (1578-0891) traceable to Medicon Master Lot, for calibration. Calibrate the assay when a new lot of reagent is installed. The analyzer will automatically perform a Reagent Blank measurement every 2 weeks. Calibration should be repeated when a new lot of reagent is used, after major maintenance is performed on the analyzer, after a critical part is replaced, or when a significant shift in control values occurs.

QUALITY CONTROL Diatron offers MEDICON Clinical Chemistry Control Level 1 & 2 (1578-0901-12 & 1578-0902-12 respectively) for serum quality control. Control recovery should lie within the acceptable range. Results outside the acceptable range even after recalibration could be due to reagent deterioration, unsuitable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

- LDH calibrator
- Quality control materials
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS

Serum:	30°C	37°C
	140 – 280 U/L	170 – 480 U/L

Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practices.

⚠ **WASTE DISPOSAL**

This product contains sodium azide (NaN_3), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build up in the drain pipes.

SPECIFIC PERFORMANCE CHARACTERISTICS

The following values are representative of the reagent performance on Diatron Pictus® P700 or P500 analyzers. The reagent performance has been evaluated on other types of analyzers, covering all requirements of the 98/79 IVD Directive. A list of analyzers with the corresponding performance characteristics is available in the special leaflet accompanying the insert. The results taken in your laboratory may differ from these values.

Linearity Up to 1700 U/L

Lowest detection limit 0.53 U/L

The lowest detection limit (LDL) is defined as the lowest concentration of analyte that is distinguishable from zero. A sample free of analyte is assayed 20 times within the assay and the LDL is calculated as the absolute mean plus three standard deviations.

Precision: Precision is estimated on two concentration levels of analyte according to CLSI protocol EP-5T (20 consecutive days, 2 runs per day, 2 repeats per run).

Pictus® P700 and P500	
Level (U/L)	**Level (U/L)**
275	275
1027	1027
Level (U/L)	**Level (U/L)**
275	275
1027	1027

INTERFERENCES - Criterion: recovery within ±10% from target value

	(Insignificant up to)
Triglycerides	3000 mg/dL
Bilirubin	20 mg/dL
Conj. Bilirubin	20 mg/dL
Ascorbate	3 mg/dL

Correlation: A comparison was performed between this reagent on a Diatron Pictus® P700 and P500 analyzer and another, commercially available product. The results were as follows:

Y = 0.959X + 30.8 R=0.9952 N=40 Sample Range: 240-832 U/L

BIBLIOGRAPHY

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SYMBOLS

Manufacturer	IVD *In vitro* diagnostic medical device
Temperature Limit	REF Catalogue Number
Caution	Σ Contains sufficient for <n> tests

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