

## LDH P → L

For use on Diatron Pictus® series analyzers

**Method:** SFBC  
**Product code:** 1419-0112, 1419-0110  
**Package:** 6 x 32 ml (R1) + 6 x 8 ml (R2), 6 x 16 ml (R1) + 6 x 4 ml (R2)  
**Store at:** 2°– 8°C  
**For *in vitro* use only**

### INTENDED USE

Ready to use reagents for the quantitative determination of L-Lactate dehydrogenase in human serum and plasma samples specifically for use with Diatron Pictus® series analyzers. For *in vitro* diagnostic use only.

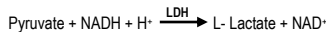
### CLINICAL SIGNIFICANCE<sup>1,3</sup>

L-Lactate dehydrogenase is a NAD<sup>+</sup> oxidoreductase, catalyzing the reverse oxidation of L-lactate to pyruvate using NAD<sup>+</sup> as a hydrogen receptor.

Total LDH activity in serum is expressed by 5 isoenzymes (LDH-1 to LDH-5) which are differentiated on their subunits 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 kinetic determination of L-Lactate Dehydrogenase (LDH) according to the modified SFBC method is based on the following reaction:



LDH : Lactate Dehydrogenase

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

### METHOD LIMITATIONS<sup>2,5</sup>

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".

The reagent is designed especially for use with the Diatron Pictus® series of chemistry analyzers. For chemistry protocols and further information please contact the customer support unit at Diatron.

### REAGENT COMPOSITION

#### Reagent 1:

Tris buffer (pH 7.2): 100 mM  
 Pyruvate: 2 mM

Non reactive ingredients, preservative.

#### Reagent 2:

NADH: 1.4 mM

Non reactive ingredients, preservative.

### 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<sub>3</sub>) ≤ 0.1%. Avoid swallowing and contact of the reagent with skin and mucous membranes.
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON HELLAS (manufacturer) upon request.

### REAGENT PREPARATION

Reagents R1 and R2 are liquid, ready-to-use when placed in the corresponding positions of the analyzer. The vials bear barcodes for automatic recognition by Pictus® series 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 28 days when stored in the cooled reagent tray of the Pictus® series analyzers.

### SAMPLE<sup>4</sup>

Non hemolyzed serum or plasma with heparin. Do not use hemolyzed samples due to contamination by LDH released from the red blood cells. LDH is stable for 2 – 3 days at room temperature. Liver LDH is destroyed after freezing-thawing of the samples.

### CALIBRATION

Diatron provides MEDI-CAL (1578-0891) for calibration. Calibrate the assay when a new lot of reagent is installed. The analyzer will automatically perform a Reagent Blank measurement every 14 days. 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 provides the 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 SUPPLIED WITH THE KIT

- LDH calibrator
- Quality control materials
- Diatron Pictus® P400/P700/P500
- Common laboratory equipment.

### REFERENCE INTERVALS<sup>1</sup>

Serum: 30°C 140 – 280 U/L 37°C 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<sub>3</sub>), 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® series 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.

	Pictus® P400	Pictus® P700/P500
<b>Linearity</b>	Up to 1700 U/L	Up to 1700 U/L
<b>Lowest detection limit</b>	12 U/L	0.4 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® P400			Pictus® P700/P500		
	Level (U/L)	Within Run CV%	Total CV%	Level (U/L)	Within Run CV%	Total CV%
	329	2.97	3.56	275	2.48	3.37
	1168	2.08	2.63	1027	2.12	3.10

**Interferences:** Criterion: recovery within ±20% from target value

	Pictus® P400	Pictus® P700/P500
Lipemia	Insignificant up to 1000 mg/dL Intralipid®	Insignificant up to 1000 mg/dL Intralipid®
Non conj. Bilirubin	Insignificant up to 20 mg/dL	Insignificant up to 20 mg/dL
Conj. Bilirubin	Insignificant up to 20 mg/dL	Insignificant up to 20 mg/dL
Ascorbate	Insignificant up to 3 mg/dL	Insignificant up to 3 mg/dL

**Correlation:** A comparison was performed between this reagent on a Pictus® series analyzer, and a BECKMAN COULTER AU-series system. The results were as follows:

#### Pictus® P400

Y = 0.934X + 16.0 R=0.9940 N=60 Sample range = 198 – 870 U/L

#### Pictus® P700/P500

Y = 0.959X + 30.8 R=0.9952 N=40 Sample range = 240 – 832 U/L

### BIBLIOGRAPHY

- Thomas L. Lactate dehydrogenase (LDH). In Thomas L, ed. Clinical laboratory diagnostics. Use and assessment of clinical laboratory results. Frankfurt/Main: TH-Books Verlagsgesellschaft 1998,89-94.
- Tietz NW, ed. Clinical guide to laboratory tests, 3<sup>rd</sup> ed. Philadelphia WB Saunders Company, 1995:385pp.
- Moss DW, Henderson RA. Clinical Enzymology. In Burtis CA, Ashwood ER, eds. Tietz textbook of clinical chemistry. Philadelphia WB Saunders Company, 1999:668-673.
- Ehret W, Heil W, Schmitt Y, Topfer G, Wisser H, Zawta B, et al. Use of anticoagulants in diagnostic laboratory investigations and stability of blood, serum and plasma samples. WHO/DIL/LAB/99.1 Rev.2:26pp.
- Young DS. Effects of drugs on clinical laboratory tests, 5<sup>th</sup> ed. AACCPress, 2000.

### SYMBOLS ON THE LABEL



Temperature Limits (L/H)



Manufacturer



Read the Instructions



Catalog Number (ISO 15223 / rev. EN980)



Batch Code (ISO 15223 / rev. EN980)



For in vitro use (ISO 15223 / rev. EN980)



Date of Expiry (ISO 15223 / rev. EN980)

