LDH L → P
For discrete analyzers
Method: IFCC
Product code: 1418-0118  4 x 40 mL + 4 x 40 mL
1418-0119  4 x 8 mL + 4 x 8 mL
Store at 2 – 8°C
For in vitro use

INTENDED USE
Reagent for the enzymatic determination of LDH-L in human serum with BECKMAN COULTER AU400/480/600/609/640/680/2700/5400 and other discrete analyzers mentioned in the special leaflet accompanying the insert. For in vitro diagnostic use only.

CLINICAL SIGNIFICANCE
Lactate dehydrogenase levels are increased in megablastic and malignant anemia, spread carcinoma, viral hepatitis, shock, cirrhosis, renal infarction, several types of renal disease, myoskeletal diseases. In general, elevated levels are explained by any cellular injury that results into cytoplasmic leak because of a heart attack or pulmonary embolism, by leukemia, hemolytic anemia, hepatitis (non-viral), sickle cell anemia, and lymphoma.

METHOD PRINCIPLE
The kinetic determination of L-Lactate Dehydrogenase (LDH-L) according to the IFCC method is based on the following reaction:

L-Lactate + NAD+ $\rightarrow$ Pyruvate + NADH + H+

LDH: Lactate Dehydrogenase

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”.

The reagent is designed especially for use with discrete analyzers. For chemistry protocols and further information contact the customer support unit at MEDICON.

COMPOSITION
Lactate 70 mmol/L
NAD+ 7 mmol/L
Non-reacting 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 (NaN3) ≤ 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 MEDICON upon request

PREPARATION
Reagents are liquid, ready-to-use, and are placed in the corresponding positions on the analyzer. Vials bear bar-code for recognition by BECKMAN COULTER AU 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, reagents are stable up to the expiry date stated on the label, at 2 – 8°C. Once opened, they remain stable for 1 month when stored well capped and refrigerated on the analyzer.

SAMPLE
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
Calibration takes place in MB Calibration Mode. The calibration factor is derived by the mean of at least 3 separate analyses series, on different days, in single point calibration mode (AB). MEDICON provides MEDICAL-CAL (1578-0891) or BECKMAN COULTER System Calibrator for Clinical Chemistry Analyzers Cat. No 60300 (MEDICON code: 4478-0891) for serum calibration, and MEDICAL-U (1578-0185) or BECKMAN COULTER Urine Calibrator OCD0025 (MEDICON code: 4478-0950). A new calibration vial should be used for each series of series of analyses. Recalibration should be repeated after major maintenance is performed on the analyzer or after a critical part is replaced or when a significant shift in control values occurs.

QUALITY CONTROL
MEDICON provides the MEDICON Clinical Chemistry Control Level 1 & 2 (1578-0901-12 & 1578-0902-12 respectively) or the BECKMAN COULTER Control Serum OCD0003 & OCD0004, (MEDICON code: 4478-0941 & 4478-0942 respectively) for serum/plasma/urine/CSF 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 NEEDED BUT NOT PROVIDED WITH THE KIT
LDH calibrator
Quality control material
Automated biochemistry analyzer
Common laboratory equipment

REFERENCE INTERVALS
The normal values for LDH, when that is measured with lactate as a substrate, are:

Women < 247 U/L
Men < 248 U/L
Infants 0 – 4 days 290 – 775 U/L
Infants 4 – 10 days 545 – 2000 U/L
Infants 10 days – 24 months 180 – 430 U/L
Children 2 - 12 years 110 – 295 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
This product contains sodium azide (NaN3), 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 BECKMAN COULTER AU400/600/609/640/680/2700/5400 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: 5 to 1200 U/L

Within Run
Precision: Precision is estimated on two concentration levels of analyte according to NCCLS protocol EP5-A (20 consecutive days, 2 runs per day, 2 repeats per run).

Mean U/L SD CV% SD CV% Total
144.7 1.1 0.76 2.1 1.43
530.8 2.5 0.48 6.0 1.13

The lowest detection limit (LDL) is defined as the lowest concentration of LDH 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.

Interferences: Criterion: recovery within ±10% from target value

Lipemic: Insignificant up to Htralipop® 1000 mg/dl
Bilirubin: Insignificant up to 20 mg/dl

Correlation: A comparison was performed between this reagent, and another, commercially available, product on a BECKMAN COULTER AU analyzer. The results were as follows:

Y = 0.972X + 5.2
R² = 0.995
N = 99
Sample range = 147 – 848 U/L

BIBLIOGRAPHY

SYMBOLS
- Temperature limits (°C/F)
- NIST/STANDARD
- Manufacturer
- Batch Code (ISO 15223/ EN 980 / rev.):
- Catalogue Number (ISO 15223/ EN 980 / rev.):
- Date of Expire (ISO 15223/ EN 980 / rev.):
- EXP
- PROD DATE
- FOR IN VITRO USE
- CE MARKING

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