**INTENDED USE**
MEDICON HELLAS S.A. is a set of reagents for the enzymatic determination of LDH in human serum and plasma, with BECKMANN COULTER AU400/600/800/IVD40027005/400 and other discrete analyzers. For in vitro diagnostic use only.

**CLINICAL SIGNIFICANCE**
Lactate dehydrogenase is a NAD+ -cooxidoreductase, catalysing 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 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 the following:
- Cancer cells, where high levels of lactate dehydrogenase are often associated with cancer or viral metastasis.
- Elevated LDH may also be seen in laminated arteries and other causes of atherosclerosis.

**METHOD PRINCIPLE**
The kinetic determination of Lactate Dehydrogenase (LDH) according to the modified GSSC method is based on the following reaction:

Pyruvate + NADH + H+ Lactate + NAD+

**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 "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.

**REAGENT COMPOSITION**
Reagent 1:
- Tris buffer (pH 7.2): 100 mM
- Pyruvate: 2 mM
- Non-reading ingredients, preservative.

Reagent 2:
- NADH: 1.4 mM
- Non-reading 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) to 0.1%. Avoid swallowing and contact of the reagent with skin or 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 barcodes for recognition by BECKMANN COULTER AU Series analyzers.

**REAGENT DETERIORATION**
For in vitro use
- 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 up to the expiry date stated on the label at 2 – 8°C. After opening it remains stable for 1 month when stored refrigerated on the analyzer.

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

**CALIBRATION**
Determination 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 (1578-0981) or BECKMANN COULTER System Calibrator for Clinical Chemistry Analyzers Cat. No 66300 (MEDICON code: 4478-0891 for serum calibration, and MEDICAL-U (1579-0185) or BECKMANN COULTER Urine Calibrator ODC003 (MEDICON code: 4478-0960). A new calibrator 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 (1578-0961-12 & 1578-0902-12 respectively) or the BECKMANN COULTER Control Serum ODC003 & ODC004 (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 reaction deterioration, unstable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

**MATERIALS REQUIRED BUT NOT PROVIDED**
- LDH calibrator
- Quality control material
- Automated biochemistry analyzer
- Common laboratory equipment

**REFERENCE INTERVALS**
**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 (NaN₃), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of unlabelled reagent in order to avoid azide build up in the drain pipes.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

**Linearity**
The assay is linear within measuring range 17 – 2000 U/L. When values exceed this range samples should be diluted accordingly.

**Sensitivity**
The lowest detectable level of LDH is estimated at 3 U/L.

**Precision**

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<th>SD</th>
<th>%CV</th>
<th>Total SD</th>
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Precision is estimated on two concentration levels of analyte according to NCCLS protocol EP-S1 (20 consecutive days, 2 runs per day, 2 repeats per run).

**Interference**
- Lepem: insignificant up to 1000 mg/dL Intrapolad: insignificant up to 125 mg/dL.
- Non Cor. Bilirubin: insignificant up to 20 mg/dL.
- Con. Bilirubin: insignificant up to 20 mg/dL.
- Ascorbic acid: insignificant up to 3 mg/dL.

Refer to Young for further information on interfering substances.

**Method Comparison**
A comparison was performed between the reagent and another commercially available product. The results were as follows on a BECKMANN COULTER AU series analyzer:

Y = 0.9127X + 33.953
N=90 Sample range: 174.75 – 2315.2 U/L

**BIBLIOGRAPHY**

**SYMBOLS**

**LDH-P ➔ L**
LACTATE DEHYDROGENASE
For discrete analyzers

**Method: GSSC**

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**温度限制** (2°C-8°C) (ISO 15223/rev. EN980/ISO7000)

**N/CV**

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**IVD**

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