LD reagent, when used in conjunction with SYNCHRON LX® System(s), UniCel® DxC 600/800 System(s), is intended for the quantitative determination of lactate dehydrogenase activity in human serum or plasma.

Lactate dehydrogenase measurements are used in the diagnosis and treatment of liver diseases such as acute viral hepatitis, cirrhosis, and metastatic carcinoma of the liver, cardiac diseases such as myocardial infarction, and tumors of the lung or kidneys.

LD reagent is used to measure lactate dehydrogenase activity by an enzymatic rate method. In the reaction, LD catalyzes the reversible oxidation of L-lactate to pyruvate with the concurrent reduction of β-nicotinamide adenine dinucleotide (NAD) to reduced β-nicotinamide adenine dinucleotide (NADH).

The SYNCHRON® System(s) automatically proportions the appropriate sample and reagent volumes into a cuvette. The ratio used is one part sample to 20 parts reagent. The system monitors the change in absorbance at 340 nanometers. This change in absorbance is directly proportional to the activity of lactate dehydrogenase in the sample and is used by the System to calculate and express the lactate dehydrogenase activity.

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SPECIMEN

TYPE OF SPECIMEN

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum or plasma are the preferred specimens. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood or urine are not recommended for use as a sample.

SPECIMEN STORAGE AND STABILITY

1. Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.
2. Refrigerated or frozen samples are not recommended.

ADDITIONAL SPECIMEN STORAGE AND STABILITY CONDITIONS AS DESIGNATED BY THIS LABORATORY:

Refer to “Sample Integrity in Chemistry” write up in “Policies and Procedures” manual

SAMPLE VOLUME

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

CRITERIA FOR UNACCEPTABLE SPECIMENS

Refer to the PROCEDURAL NOTES section of this chemistry information sheet for information on unacceptable specimens.
CRITERIA FOR SAMPLE REJECTION AS DESIGNATED BY THIS LABORATORY:

Refer to “Sample Integrity in Chemistry” write up in “Policies and Procedures” manual

PATIENT PREPARATION

SPECIAL INSTRUCTIONS FOR PATIENT PREPARATION AS DESIGNATED BY THIS LABORATORY:

Refer to “Sample Integrity in Chemistry” write up in “Policies and Procedures” manual

SPECIMEN HANDLING

SPECIAL INSTRUCTIONS FOR SPECIMEN HANDLING AS DESIGNATED BY THIS LABORATORY:

Refer to “Sample Integrity in Chemistry” write up in “Policies and Procedures” manual

REAGENTS

CONTENTS

Each kit contains the following items:
Two LD Reagent Cartridges (2 x 200 tests) or (2 x 300 tests)

VOLUMES PER TEST

<table>
<thead>
<tr>
<th>Component</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Volume</td>
<td>13 µL</td>
</tr>
<tr>
<td>ORDAC Sample Volume</td>
<td>3 µL</td>
</tr>
<tr>
<td>Total Reagent Volume</td>
<td>260 µL</td>
</tr>
<tr>
<td>Cartridge Volumes</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>251 µL</td>
</tr>
<tr>
<td>B</td>
<td>--</td>
</tr>
<tr>
<td>C</td>
<td>9 µL</td>
</tr>
</tbody>
</table>

REACTIVE INGREDIENTS

REAGENT CONSTITUENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>L-Lactate Acid</td>
<td>50 mmol/L</td>
</tr>
<tr>
<td>NAD</td>
<td>11 mmol/L</td>
</tr>
</tbody>
</table>

Also non-reactive chemicals necessary for optimal system performance.
Avoid skin contact with reagent. Use water to wash reagent from skin.

EUROPEAN HAZARD CLASSIFICATION

Lactate Dehydrogenase Reagent, Lactate → Pyruvate (Compartment A)

Xn;R22 Harmful if swallowed.
S28 After contact with skin, wash immediately with plenty of water.

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

At least two levels of control material
Saline

REAGENT PREPARATION

No preparation is required.

ACCEPTABLE REAGENT PERFORMANCE

The acceptability of a reagent is determined by ensuring that quality control results are within your facility's acceptance criteria.

REAGENT STORAGE AND STABILITY

LD reagent, when stored unopened at +2°C to +8°C, will remain stable until the expiration date printed on the cartridge label. Once opened, the reagent cartridge is stable for 30 days unless the expiration date is exceeded. DO NOT FREEZE.

REAGENT STORAGE LOCATION:

Chemistry section, room L568. Refer to reagent “map” on Chemistry refrigerator #6.

CALIBRATION

CALIBRATOR REQUIRED

Calibration is not required.
TRACEABILITY

This measurand (analyte) is traceable to the manufacturer’s selected Measurement Procedure as described in the Methodology section.

QUALITY CONTROL

At least two levels of control material should be analyzed daily. In addition, these controls should be run with each new reagent cartridge and after specific maintenance or troubleshooting procedures as detailed in the appropriate system manual. More frequent use of controls or the use of additional controls is left to the discretion of the user based on good laboratory practices or laboratory accreditation requirements and applicable laws.

The following controls should be prepared and used in accordance with the package inserts. Discrepant quality control results should be evaluated by your facility.

<table>
<thead>
<tr>
<th>CONTROL NAME</th>
<th>SAMPLE TYPE</th>
<th>STORAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitrol levels 1 and 2 vials in use kept refrigerated after thawing. Unopened Monitrol kept frozen until just before use. Refer to “DXC 800 Control Analysis” in DXC 800 procedure manual for other control material used and storage. Control preparations and acceptance of QC results are in “Policies and Procedures” manual</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

TESTING PROCEDURE(S)

1. If necessary, load the reagent onto the system.
2. Program samples and controls for analysis.
3. After loading samples and controls onto the system, follow the protocols for system operations.

For detailed testing procedures, refer to the SYNCHRON LX Operations Manual, or the UniCel DxC 600/800 System Instructions For Use (IFU) manual.

CALCULATIONS

The SYNCHRON® System(s) performs all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

REPORTING RESULTS

Equivalency between the SYNCHRON CX, SYNCHRON LX, and UniCel DxC 600/800 Systems has been established. Chemistry results between these systems are in agreement and data from representative systems may be shown.

REFERENCE INTERVALS

Each laboratory should establish its own reference intervals based upon its patient population. The following reference intervals were taken from literature and a study performed on SYNCHRON Systems.
### TABLE 2 REFERENCE INTERVALS

<table>
<thead>
<tr>
<th>INTERVALS</th>
<th>SAMPLE TYPE</th>
<th>CONVENTIONAL UNITS</th>
<th>S.I. UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Literature</td>
<td>Serum or Plasma</td>
<td>100 – 190 IU/L</td>
<td>1.6 – 3.1 µkat/L</td>
</tr>
<tr>
<td>SYNCHRON</td>
<td>Serum or Plasma</td>
<td>98 – 192 IU/L</td>
<td>1.6 – 3.2 µkat/L</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>INTERVALS</th>
<th>SAMPLE TYPE</th>
<th>AGE</th>
<th>BOTH GENDERS</th>
<th>MALE</th>
<th>FEMALE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory</td>
<td>Serum or Plasma</td>
<td>0-30d</td>
<td>125-735 U/L</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td>31d-&lt;1y</td>
<td>170-450 U/L</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1y-&lt;5y</td>
<td>--</td>
<td>140-304 U/L</td>
<td>142-297 U/L</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5y-&lt;10y</td>
<td>--</td>
<td>155-290 U/L</td>
<td>142-261 U/L</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10y-&lt;15y</td>
<td>--</td>
<td>115-257 U/L</td>
<td>122-234 U/L</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;15 yr</td>
<td>102-199 U/L</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Refer to References (6, 7, 8) for guidelines on establishing laboratory-specific reference intervals.

2. Normal range for children 1 to less than 15 years old adapted from Beckman Coulter’s “Pediatric Reference Range Guidelines for Synchron Systems” Bulletin 9345
3. Normal range for adults was determined by testing 271 male and female healthy blood donors at UCSF. Adult range used for pediatric patients >15 years.

### ADDITIONAL REPORTING INFORMATION AS DESIGNATED BY THIS LABORATORY:

Refer to “DXC800 Linearity and Reportable Range” chart in Technical notes section of DXC800 Procedure manual

### PROCEDURAL NOTES

### ANTICOAGULANT TEST RESULTS

1. If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of 20 healthy volunteers:

#### TABLE 3 COMPATIBLE ANTICOAGULANTS

<table>
<thead>
<tr>
<th>ANTICOAGULANT</th>
<th>LEVEL TESTED FOR IN VITRO INTERFERENCE</th>
<th>AVERAGE PLASMA-SERUM BIAS (IU/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ammonium Heparin</td>
<td>14 Units/mL</td>
<td>NSI²</td>
</tr>
<tr>
<td>Lithium Heparin</td>
<td>14 Units/mL</td>
<td>NSI</td>
</tr>
<tr>
<td>Sodium Heparin</td>
<td>14 Units/mL</td>
<td>NSI</td>
</tr>
</tbody>
</table>

2. The following anticoagulants were found to be incompatible with this method:

#### TABLE 4 INCOMPATIBLE ANTICOAGULANTS

<table>
<thead>
<tr>
<th>ANTICOAGULANT</th>
<th>LEVEL TESTED FOR IN VITRO INTERFERENCE</th>
<th>PLASMA-SERUM BIAS (IU/L)³</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDTA</td>
<td>1.5 mg/mL</td>
<td>-27</td>
</tr>
<tr>
<td>Potassium Oxalate/Sodium Fluoride</td>
<td>2.0 / 2.5 mg/mL</td>
<td>-140</td>
</tr>
</tbody>
</table>
LIMITATIONS
None identified.

INTERFERENCES
1. The following substances were tested for interference with this methodology:

TABLE 5 INTERFERENCES

<table>
<thead>
<tr>
<th>SUBSTANCE</th>
<th>SOURCE</th>
<th>LEVEL TESTED</th>
<th>OBSERVED EFFECT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin (unconjugated)</td>
<td>Bovine</td>
<td>30 mg/dL</td>
<td>NSI</td>
</tr>
<tr>
<td>Lipemia</td>
<td>Intralipid$^d$</td>
<td>500 mg/dL</td>
<td>NSI</td>
</tr>
</tbody>
</table>

2. Samples showing evidence of hemolysis should not be used. Hemolysis may cause falsely elevated results.

3. Refer to References (9,10,11) for other interferences caused by drugs, disease and preanalytical variables.

PERFORMANCE CHARACTERISTICS

Analytic Range
The SYNCHRON® System(s) method for the determination of this analyte provides the following analytical ranges:

TABLE 6 ANALYTICAL RANGE

<table>
<thead>
<tr>
<th>SAMPLE TYPE</th>
<th>CONVENTIONAL UNITS</th>
<th>S.I. UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum or Plasma</td>
<td>5 – 750 IU/L</td>
<td>0.1 – 12.5 µkat/L</td>
</tr>
<tr>
<td>Serum or Plasma ORDAC$^a$</td>
<td>600 – 2700 IU/L</td>
<td>10.0 – 45.0 µkat/L</td>
</tr>
</tbody>
</table>

Samples with activities exceeding the high end of the analytical range should be rerun with ORDAC enabled or diluted with saline and reanalyzed.

REPORTABLE RANGE (as determined on site):

TABLE 7 REPORTABLE RANGE

<table>
<thead>
<tr>
<th>SAMPLE TYPE</th>
<th>CONVENTIONAL UNITS</th>
<th>S.I. UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum or Plasma ORDAC$^a$</td>
<td>5 - 2700 IU/L</td>
<td>n/a</td>
</tr>
</tbody>
</table>

SENSITIVITY
Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for LD determination is 5 IU/L (0.08 µkat/L).

EQUIVALENCY
Equivalency was assessed by Deming regression analysis of patient samples to accepted clinical methods.

Serum or plasma (in the range of 5 to 787 IU/L):

\[ Y \text{ (SYNCHRON LX Systems)} = 1.018X + 0.17 \]
Serum or plasma (in the range of 5 to 787 IU/L):

- \( N = 80 \)
- \( \text{MEAN (SYNCHRON LX Systems)} = 171.8 \)
- \( \text{MEAN (SYNCHRON CX® 7 DELTA)} = 168.5 \)
- \( \text{CORRELATION COEFFICIENT (r)} = 0.9993 \)

Refer to References (12) for guidelines on performing equivalency testing.

**PRECISION**

A properly operating SYNCHRON® System(s) should exhibit precision values less than or equal to the following:

**TABLE 8 MAXIMUM PERFORMANCE LIMITS**

<table>
<thead>
<tr>
<th>TYPE OF PRECISION</th>
<th>SAMPLE TYPE</th>
<th>1 SD</th>
<th>CHANGEOVER VALUE</th>
<th>% CV</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>IU/L</td>
<td>µkat/L</td>
<td>IU/L</td>
</tr>
<tr>
<td>Within-run</td>
<td>Serum/Plasma</td>
<td>5.0</td>
<td>0.08</td>
<td>143</td>
</tr>
<tr>
<td></td>
<td>Serum/Plasma (ORDAC)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Total</td>
<td>Serum/Plasma</td>
<td>7.5</td>
<td>0.12</td>
<td>143</td>
</tr>
<tr>
<td></td>
<td>Serum/Plasma (ORDAC)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

Comparative performance data for a SYNCHRON LX® System evaluated using the NCCLS Proposed Guideline EP5-T2 appears in the table below. Each laboratory should characterize their own instrument performance for comparison purposes.

**TABLE 9 NCCLS EP5-T2 PRECISION ESTIMATE METHOD**

<table>
<thead>
<tr>
<th>TYPE OF IMPRECISION</th>
<th>SAMPLE TYPE</th>
<th>No. Systems</th>
<th>No. Data Points</th>
<th>Test Mean Value (IU/L)</th>
<th>EP5-T2 Calculated Point Estimates</th>
<th>SD</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within-run</td>
<td>Serum Control 1</td>
<td>1</td>
<td>80</td>
<td>49.9</td>
<td>1.6</td>
<td>3.2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Serum Control 2</td>
<td>1</td>
<td>80</td>
<td>363.5</td>
<td>3.4</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>Serum Control 1</td>
<td>1</td>
<td>80</td>
<td>49.9</td>
<td>2.0</td>
<td>4.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Serum Control 2</td>
<td>1</td>
<td>80</td>
<td>363.5</td>
<td>5.3</td>
<td>1.5</td>
<td></td>
</tr>
</tbody>
</table>

**NOTICE**

These degrees of precision and equivalency were obtained in typical testing procedures on a SYNCHRON LX® System and are not intended to represent the performance specifications for this reagent.

**ADDITIONAL INFORMATION**

For more detailed information on SYNCHRON LX Systems or UniCel DxC Systems, refer to the appropriate system manual.

**SHIPPING DAMAGE**

If damaged product is received, notify your Beckman Coulter Clinical Support Center.
REFERENCES


Beckman Coulter, Inc., 250 South Kraemer Blvd., Brea, CA 92821
ENDNOTES

a  NSI = No Significant Interference (within ±10.0 IU/L or 7%).

b  Bias is based on worst case instead of average. Plus (+) or minus (-) signs in this column signify positive or negative bias.

c  NSI = No Significant Interference (within ±10.0 IU/L or 7%).

d  Intralipid is a registered trademark of KabiVitrum, Inc., Clayton, NC 27250.

e  Overrange Detection and Correction. Refer to the SYNCHRON LX Operations Manual, or the UniCel DxC 600/800 System Instructions For Use (IFU) manual for more details on this function.

f  When the mean of the test precision data is less than or equal to the changeover value, compare the test SD to the SD guideline given above to determine the acceptability of the precision testing. When the mean of the test precision data is greater than the changeover value, compare the test % CV to the guideline given above to determine acceptability. Changeover value = (SD guideline/CV guideline) x 100.

g  NA = Not applicable.

h  The point estimate is based on the data from one system, run for twenty days, two runs per day, two observations per run on an instrument operated and maintained according to the manufacturer’s instructions.