Lp(a) 21 FS*

Diagnostic reagent for quantitative in vitro determination of lipoprotein (a) [Lp(a)] in serum or plasma on DiaSys respons®920

Order Information
Cat. No. 1 7139 99 10 921
4 twin containers for 100 determinations each

Method
Particle enhanced Immunoturbidimetric test

Principle
Determination of the Lp(a) concentration by photometric measurement of antigen-antibody-reaction between antibodies against Lp(a) bound to particles and Lp(a) present in the sample.

Reagents
Components and Concentrations
R1: Glycine-buffer pH 8.3 <1.5%
R2: Glycine-buffer pH 8.2 <1.5%
Latex particles coated with anti-human lipoprotein (a) antibody (rabbit)

Storage Instructions and Reagent Stability
The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions
1. The reagents contain sodium azide (0.9 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
2. The reagents contain biological material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
3. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
1. In very rare cases, samples of patients with gammopathy might give falsified results [8].
2. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient’s medical history, clinical examinations and other findings.
3. For professional use only!

Waste Management
Please refer to local legal requirements.

Reagent Preparation
The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Specimen
Serum, heparin plasma or EDTA plasma

Stability [1]:
2 days at 20 – 25°C
2 weeks at 4 – 8°C
3 months at −20°C
Discard contaminated specimens. Freeze only once!

Calibrators and Controls
DiaSys TruCal Lp(a) 21 calibrator set is recommended for calibration. The assigned values of the calibrator in nmol/L have been made traceable to the WHO/IFCC SRM®-2B reference material and the assigned values of the calibrator in mg/dL have been made traceable to a reference preparation. For internal quality control a DiaSys TruLab Lp(a) control should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics
Measuring range up to 110 mg/dL (260 nmol/L) Lp(a), depending on the concentration of the highest calibrator (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).

Limit of detection** 2 mg/dL Lp(a)
No prozone effect up to 400 mg/dL (800 nmol/L) Lp(a)
On-board stability 6 weeks
Calibration stability 4 weeks

Interferences < 10% by
- Bilirubin up to 40 mg/dL
- Hemoglobin up to 500 mg/dL
- Rheumatoid factor up to 500 IU/mL
- Lipemia (triglycerides) up to 2000 mg/dL

For further information on interfering substances refer to Young DS [2].

Precision
Within run (n=20) Sample 1 Sample 2 Sample 3
Mean [mg/dL] 29.3 46.0 83.9
Coefficient of variation [%] 2.31 1.42 2.97
Between run (n=20) Sample 1 Sample 2 Sample 3
Mean [mg/dL] 28.2 31.1 67.7
Coefficient of variation [%] 3.64 3.55 1.98

Method comparison (n=130)
Test x DiaSys Lp(a) 21 FS (Hitachi 917)
Test y DiaSys Lp(a) 21 FS (respons®920)
Slope 1.015
Intercept 0.50 mg/dL
Coefficient of correlation 0.998

Reference Range
< 30 mg/dL [4]
< 75 nmol/L for Caucasians [7]

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.


## Lp(a) 21 FS
### Application for serum and plasma

<table>
<thead>
<tr>
<th>Test Details</th>
<th>Test Volumes</th>
<th>Reference Ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test</td>
<td>LPA</td>
<td>Auto Rerun</td>
</tr>
<tr>
<td>Report Name</td>
<td>Lipoprotein (a)</td>
<td>Online Calibration</td>
</tr>
<tr>
<td>Unit</td>
<td>mg/dL</td>
<td>Decimal Places</td>
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<td>Secondary</td>
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<tr>
<td>Assay Type</td>
<td>2-Point</td>
<td>Curve Type</td>
</tr>
<tr>
<td>M1 Start</td>
<td>19</td>
<td>M1 End</td>
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<tr>
<td>M2 Start</td>
<td>33</td>
<td>M2 End</td>
</tr>
<tr>
<td>Sample Replicates</td>
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<td>Standard Replicates</td>
</tr>
<tr>
<td>Control Replicates</td>
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<td>Control Interval</td>
</tr>
<tr>
<td>Reaction Direction</td>
<td>Increasing</td>
<td>React. Abs. Limit</td>
</tr>
<tr>
<td>Prozone Limit %</td>
<td>97</td>
<td>Prozone Check</td>
</tr>
<tr>
<td>Linearity Limit %</td>
<td>0</td>
<td>Delta Abs./Min.</td>
</tr>
<tr>
<td>Technical Minimum</td>
<td>*</td>
<td>Technical Maximum</td>
</tr>
<tr>
<td>Y = aX + b</td>
<td>a = 1.0000</td>
<td>b = Calibrator 5</td>
</tr>
</tbody>
</table>

### Sample Volumes

| Normal        | 3.00 µL | Dilution Ratio | 1 X |
| Increase      | 10.00 µL| Dilution Ratio | 1 X |
| Decrease      | 2.00 µL | Dilution Ratio | 1 X |
| Standard Volume | 3.00 µL |

### Reagent Volumes and Stirrer Speed

| RGT-1 Volume | 120 µL | R1 Stirrer Speed | High |
| RGT-2 Volume | 60 µL  | R2 Stirrer Speed | High |

### Reference Range

<table>
<thead>
<tr>
<th>Lower Limit (mg/dL)</th>
<th>Upper Limit (mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>0.00</td>
</tr>
<tr>
<td>Panic</td>
<td>0.00</td>
</tr>
</tbody>
</table>

### Sample Types

- Serum
- Urine
- CSF
- Plasma
- Whole Blood
- Other