Apolipoprotein A1 FS*

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Apolipoprotein A1 FS* is a reagent for quantitative in vitro determination of apolipoprotein A1 (Apo A1) in serum or plasma on DiaSys respons®920.

**Order Information**
Cat. No. 1 7102 99 10 921
4 twin containers for 100 determinations each

**Method**
Immunoturbidimetric test

**Principle**
Determination of Apo A1 concentration via photometric measurement of antigen-antibody-reaction between antibodies to human Apo A1 and Apo A1 present in the sample.

**Reagents**

**Components and Concentrations**

<table>
<thead>
<tr>
<th>Reagent</th>
<th>Component</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1: TRIS</td>
<td>pH 7.5</td>
<td>100 mmol/L</td>
</tr>
<tr>
<td>R2: TRIS</td>
<td>pH 7.5</td>
<td>100 mmol/L</td>
</tr>
</tbody>
</table>

Anti-human apolipoprotein A1 antibody (goat) ≤ 1%

**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, protected from light and contamination is avoided. DiaSys reagents provide protection from light. Do not freeze the reagents!

**Warnings and Precautions**
1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow. Avoid contact with skin and mucous membranes!
2. Reagent 2 contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
3. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys response®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.
4. In very rare cases, samples of patients with gammapathy might give falsified results [6].
5. 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.
6. 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]:**
- 1 day at 20 – 25°C
- 3 days at 4 – 8°C
- 2 months at 20°C
- Discard contaminated specimens. Freeze only once.

**Calibrators and Controls**
DiaSys TruCal ApoA1/B calibrator set is recommended for calibration. The assigned values of the calibrator have been made traceable to a commercially available measurement procedure, standardized against IFCC reference standards (WHO-RRP October 1992). For standardization of Apo A1 the reference standard SP1-01 was used. For internal quality control, DiaSys TruLab-L control should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

### Conversion factor
Apo A1 [mg/dL] x 0.357 = Apo A1 [µmol/L]

### Reference Range
- Mean values according to data reported in [3]

### Clinical Interpretation
Several studies indicate that increased concentrations of Apo B (> 150 mg/dL in women and > 155 mg/dL in men) and decreased concentrations of Apo A1 (< 120 mg/dL in women and < 110 mg/dL in men) may be good predictors of risk of CHD [4].

### Performance Characteristics
- Measuring range up to 250 mg/dL Apo A1, at least up to 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 the rerun function).
- Limit of detection** 0.8 mg/dL Apo A1
- No prozone effect up to 500 mg/dL Apo A1
- On-board stability 4 weeks
- Calibration stability 4 weeks
- Interferences < 10% by
  - Ascorbate up to 30 mg/dL
  - Bilirubin up to 60 mg/dL
  - Hemoglobin up to 1000 mg/dL
  - 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
    - Mean [mg/dL]: 49.4
    - Coefficient of variance [%]: 1.83
  - Sample 2
    - Mean [mg/dL]: 87.0
    - Coefficient of variance [%]: 1.75
  - Sample 3
    - Mean [mg/dL]: 137
    - Coefficient of variance [%]: 1.83
- Between run (n=20)
  - Sample 1
    - Mean [mg/dL]: 50.1
    - Coefficient of variance [%]: 3.22
  - Sample 2
    - Mean [mg/dL]: 118
    - Coefficient of variance [%]: 1.42
  - Sample 3
    - Mean [mg/dL]: 200
    - Coefficient of variance [%]: 1.51

### Method comparison (n=126)
- Test x: DiaSys Apo A1 FS (Hitachi 917)
- Test y: DiaSys Apo A1 FS (respons®920)
- Slope: 1.022
- Intercept: 0.624 mg/dL
- Coefficient of correlation: 0.996

**Lowest measurable concentration which can be distinguished from zero mean ± 3 SD (n=20) of an analytic free specimen"**

### Literature
2. Young WS. Effects of Drugs on Clinical Laboratory Tests. 5th ed.
# Apolipoprotein A1 FS

Application for serum and plasma

<table>
<thead>
<tr>
<th>Test</th>
<th>Test Volumes</th>
<th>Reference Ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test</td>
<td>APOA1</td>
<td>Auto Rerun</td>
</tr>
<tr>
<td>Report Name</td>
<td>Apolipoprotein A1</td>
<td>Online Calibration</td>
</tr>
<tr>
<td>Unit</td>
<td>mg/dL</td>
<td>Decimal Places : 2</td>
</tr>
<tr>
<td>Wavelength-Primary</td>
<td>578</td>
<td>Secondary : 060</td>
</tr>
<tr>
<td>Assay Type</td>
<td>2-Point</td>
<td>Curve Type : Polynomial</td>
</tr>
<tr>
<td>M1 Start</td>
<td>15</td>
<td>M1 End : 15</td>
</tr>
<tr>
<td>M2 Start</td>
<td>33</td>
<td>M2 End : 33</td>
</tr>
<tr>
<td>Sample Replicates</td>
<td>1</td>
<td>Standard Replicates : 3</td>
</tr>
<tr>
<td>Control Replicates</td>
<td>1</td>
<td>Control Interval : 0</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 : Lower</td>
</tr>
<tr>
<td>Linearity Limit %</td>
<td>0</td>
<td>Delta Abs./Min. : 0.0000</td>
</tr>
<tr>
<td>Technical Minimum</td>
<td>*</td>
<td>Technical Maximum : *</td>
</tr>
</tbody>
</table>
| **Technical limits are automatically defined by the software via the upper and lower calibrator level.** **Enter calibrator value.**

<table>
<thead>
<tr>
<th>Test Details</th>
<th>Test Volumes</th>
<th>Reference Ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test</td>
<td>APOA1</td>
<td>Serum</td>
</tr>
<tr>
<td>Category</td>
<td>Male</td>
<td>Male</td>
</tr>
</tbody>
</table>

## Test Details

### Test Volumes

<table>
<thead>
<tr>
<th>Test</th>
<th>Test Volumes</th>
<th>Reference Ranges</th>
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</thead>
<tbody>
<tr>
<td>Normal</td>
<td>2.00 µL</td>
<td>Dilution Ratio : 1</td>
</tr>
<tr>
<td>Increase</td>
<td>6.00 µL</td>
<td>Dilution Ratio : 1</td>
</tr>
<tr>
<td>Decrease</td>
<td>2.00 µL</td>
<td>Dilution Ratio : 2</td>
</tr>
</tbody>
</table>

### Sample Volumes

| RGT-1 Volume | 200 µL |
| RGT-2 Volume | 40 µL |

### Reagent Volumes and Stirrer Speed

<table>
<thead>
<tr>
<th>RGT-1 Volume</th>
<th>R1 Stirrer Speed : Medium</th>
</tr>
</thead>
<tbody>
<tr>
<td>RGT-2 Volume</td>
<td>R2 Stirrer Speed : High</td>
</tr>
</tbody>
</table>

## Reference Range

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<tr>
<th>Test</th>
<th>Test Volumes</th>
<th>Reference Ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower Limit (mg/dL)</td>
<td>Normal : 110.00</td>
<td>Panic : 0.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample Types</th>
<th>Serum</th>
<th>Urine</th>
<th>CSF</th>
<th>Plasma</th>
<th>Whole Blood</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
<td>Male</td>
<td>Male</td>
<td>Male</td>
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