Apolipoprotein A1 – Page 1

Diagnostic reagent for quantitative in vitro determination of apolipoprotein A1 (Apo A1) in serum or plasma on photometric systems

Order Information

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Kit size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 7102 99 10 021</td>
<td>R1 5 x 25 mL + R2 1 x 25 mL</td>
</tr>
<tr>
<td>1 7102 99 10 930</td>
<td>R1 4 x 20 mL + R2 2 x 8 mL</td>
</tr>
<tr>
<td>1 7102 99 10 935</td>
<td>R1 2 x 20 mL + R2 1 x 8 mL</td>
</tr>
<tr>
<td>1 7170 99 10 045</td>
<td>3 x 2 mL TruCal Apo A1/B</td>
</tr>
</tbody>
</table>

Summary [1,2]

Apolipoprotein A1 (Apo A1) is the principal protein component of high density lipoprotein (HDL) which removes cholesterol from the cells and thus has a protective effect against atherosclerosis. Epidemiological studies have shown an inverse relationship between levels of HDL respectively Apo A1 and prevalence of coronary heart disease (CHD). While determination of total cholesterol and triglycerides is used for screening of coronary risk, measurement of Apo A1 beside lipoprotein (a) and apolipoprotein B provides further useful information in lipid disorders and can be an alternative to the measurement of HDL-cholesterol.

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

| R1 | TRIS pH 7.5 100 mmol/L |
| R2 | TRIS pH 7.5 100 mmol/L |

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 and contamination is avoided. Do not freeze the reagents! Protect reagents from light!

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. In very rare cases, samples of patients with gammopathy might give falsified results [6].
4. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
5. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum, heparin plasma or EDTA plasma [3]

Stability:
- 1 day at 20 – 25°C
- 3 days at 4 – 8°C
- 2 months at –20°C

Only freeze once!

Discard contaminated specimens.

Assay Procedure for Analyzers

Application sheets for automated systems are available on request.

Wavelength 580 nm (500 – 700 nm)

Optical path 1 cm

Temperature 37°C

Measurement Against reagent blank

\[
\Delta A = (A_2 - A_1) \text{ sample or calibrator}
\]

Calculation

The concentration of apolipoprotein A1 in unknown samples is derived from a calibration curve using an appropriate mathematical model such as logit/log. The calibration curve is obtained with 5 calibrators at different levels and distilled water or aqueous NaCl solution (9 g/L) for determination of the zero value. Stability of calibration: 4 weeks

Conversion factor

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

Calibrators and Controls

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

Performance Characteristics

Measuring Range

The test has been developed to determine concentrations of apolipoprotein A1 within a measuring range of 0.2 - 250 mg/dL, at least up to the concentration of the highest calibrator. When values exceed this range samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Prozone Limit

No prozone effect was observed up to an apolipoprotein A1 value of 500 mg/dL.
Specificity/Interferences
DiaSys Apolipoprotein A1 FS is through its antibodies a specific immunoassay for human Apo A1. No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 35 mg/dL, hemoglobin up to 500 mg/dL and lipemia up to 2000 mg/dL triglycerides. No cross reaction with apolipoprotein A2 or apolipoprotein B was observed under test conditions. For further information on interfering substances refer to Young DS [5].

Sensitivity/Limit of Detection
The lower limit of detection is 0.2 mg/dL.

Precision (n = 20)

<table>
<thead>
<tr>
<th>Precision type</th>
<th>Sample</th>
<th>Mean [mg/dL]</th>
<th>SD [mg/dL]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intra-assay precision</td>
<td>Sample 1</td>
<td>36.3</td>
<td>0.66</td>
<td>1.81</td>
</tr>
<tr>
<td></td>
<td>Sample 2</td>
<td>86.4</td>
<td>1.43</td>
<td>1.66</td>
</tr>
<tr>
<td></td>
<td>Sample 3</td>
<td>152</td>
<td>5.55</td>
<td>3.65</td>
</tr>
<tr>
<td>Inter-assay precision (daily calibration)</td>
<td>Sample 1</td>
<td>43.9</td>
<td>0.70</td>
<td>1.60</td>
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<tr>
<td></td>
<td>Sample 2</td>
<td>88.5</td>
<td>2.08</td>
<td>2.35</td>
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<td></td>
<td>Sample 3</td>
<td>146</td>
<td>2.80</td>
<td>1.92</td>
</tr>
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</table>

Method Comparison
A comparison of DiaSys Apolipoprotein A1 FS (y) with a commercially available test (x) using 53 samples gave following results: \( y = 1.15 \times x - 7.69 \text{ mg/dL} \); \( r = 0.994 \).

Reference Range
Women 120 – 190 mg/dL (42.8 – 67.8 µmol/L)
Men 110 – 170 mg/dL (39.3 – 60.7 µmol/L)

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. [2]

Literature

Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9  66598 Holzheim  Germany