APOLIPOPROTEIN B

**INTENDED USE**
Diagnostic reagent for in vitro quantitative determination of Apolipoprotein B in human serum by turbidimetric immunoassay.

**DIAGNOSTIC IMPLICATIONS**
Apolipoprotein B is the main protein component of LDL (Low Density Lipoprotein). Apolipoprotein B is necessary for the reaction with LDL receptors in the liver and on cell walls and is thus involved in transporting cholesterol from the liver to the vessel cells. Elevated levels of Apolipoprotein B are frequently found in atherosclerotic vascular changes and are a risk factor for atherosclerosis.

**METHOD**
Measurement of antigen-antibody reaction by the end-point method.

**REAGENTS PROVIDED**
- **Buffer**
  - Phosphate buffered saline (pH 7.43).
  - Polyethylene glycol (60 g/l).
  - Detergent (0.1%).
  - Sodium azide (0.09 %).

- **Antiserum**
  - Phosphate buffered saline (pH 7.43).
  - Polyclonal goat anti-human Apolipoprotein B (variable).
  - Sodium azide (0.09 %).

- **Calibrator**
  - Buffered human plasma, lyophilized and stabilized for 1 ml.
  - Contains 0.09 % sodium azide as preservative.
  - Concentration: See bottle label.

**PREPARATION OF REAGENTS**
Dissolve the calibrator vial contents in exactly 1 ml distilled water and let stand at + 15 to + 25°C for 30 minutes.

**STABILITY AND STORAGE**
The reagents are stable until expiry date when kept at 2-8°C. Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

**REAGENTS REQUIRED BUT NOT SUPPLIED**
Saline (9 g/l NaCl)

**SAMPLE COLLECTION**
Use fresh serum. If the test cannot be carried out on the same day, the serum may be stored at 2-8°C for 48 hours. If stored for a longer period, the sample should be frozen.

**AUTOMATION**
Application procedures on clinical chemistry analyzers are available upon request.

**MANUAL PROCEDURE**
Sample/Control: dilute 1:10 in saline 9 g/l.

**REFERENCE CURVE**
Generate a reference curve by diluting the Apolipoprotein A1/B calibrator 1:10, 1:20, 1:40, 1:80, 1:160 in saline 9 g/l. Use saline 9 g/l as zero point.

**TEST**
Mix 40 µl diluted calibrators, controls and samples with 900 µl buffer. Read optical density (OD1) of samples and calibrators at 340 nm. Add 80 µl antiserum, mix and incubate for 5 minutes at room temperature. Read optical density (OD2) of samples, controls and calibrators at 340 nm.

Calculate ∆OD’s, plot a calibrator curve and read the concentration of controls and samples.

**REFERENCE VALUES**
- **Men:** 60 – 138 mg/dl (IFCC)
- **Women:** 52 – 129 mg/dl

This range is given for orientation only. Each laboratory should establish its own reference values.

**PERFORMANCES**
The performance characteristics for the Apolipoprotein B reagents were measured on a clinical chemistry analyzer.

- **Measuring Range:** 0 - 330 mg/dl
- **Detection Limit:** 8 mg/dl
- **Hook effect:** No risk
- **Sensitivity:** 0.00049 ABS units/concentration unit

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Low (%)</th>
<th>Medium (%)</th>
<th>High (%)</th>
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<tbody>
<tr>
<td>Intra-Run</td>
<td>5.24</td>
<td>1.16</td>
<td>0.91</td>
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<tr>
<td>Inter-Run</td>
<td>ND</td>
<td>1.02</td>
<td>ND</td>
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<table>
<thead>
<tr>
<th>Control</th>
<th>Assigned</th>
<th>Measured</th>
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<tbody>
<tr>
<td>ERBA</td>
<td>121 (1.03 - 139)</td>
<td>120</td>
</tr>
<tr>
<td>Seronorm</td>
<td>97 (82 - 112)</td>
<td>89</td>
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</table>

**SPECIFICITY**
Monospecific

**INTERFERENCES**
No interference for Hemoglobin (1000 mg/dl), Bilirubin (20 mg/dl) and Triglyceride (2500 mg/dl)

**LIMITATIONS**
None

**COMPARISON WITH NEPHELOMETRY**
\[ y = 0.8384x + 24.362 \]
\[ r = 0.9886 \]

**REAGENTS**
<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Description</th>
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<tbody>
<tr>
<td>BLT20006</td>
<td>APO B</td>
<td>2 x 25 ml APO A1 Buffer</td>
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<tr>
<td></td>
<td></td>
<td>1 x 5 ml APO B Antiserum</td>
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<tr>
<td></td>
<td></td>
<td>1 x 1 ml APO B Calibrator</td>
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**CONTROL**
Control with an appropriate control is recommended.

**REFERENCES**

**USED SYMBOLS**
- Lot Number
- IVD: In vitro Diagnostics
- Manufacturer
- Storage Temperature

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Date of revision: 24. 11. 2017