**APOLIPOPROTEIN A1**

**INTENDED USE**
Diagnostic reagent for in vitro quantitative determination of Apolipoprotein A1 in human serum by turbidimetric immunoassay.

**DIAGNOSTIC IMPLICATIONS**
Apo A1 is the main protein component of HDL (High Density Lipoprotein). Apo A1 activates lecithin cholesterol acyltransferase which catalyses the esterification of cholesterol. The resulting esterified cholesterol can then be transported to the liver, metabolised and excreted. Persons with atherosclerotic vascular changes frequently exhibit decreased levels of Apo A1. Even if the concentrations of apolipoprotein B are normal, a decreased Apo A1 level may be a risk factor for atherosclerotic processes.

Decreased levels of Apo A1 also occur in dyslipoproteinemias, acute hepatic cirrhosis and insulin-treated patients.

**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 A1 (variable).
Sodium azide (0.09 %)

**Calibrator**
Buffered human plasma, lyophilized and stabilized for 1 ml
Contains 0.08 % 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.
Invert gently to mix. Avoid foam formation and vigorous shaking.

**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 can not 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.

**USED SYMBOLS**

- **N/72/17/C/INT**
- **EN**
- **IVD**
- **Ce**
- **QUALITY SYSTEM CERTIFIED**
- **ISO 9001 ISO 13485**

**PERFORMANCES**
The performance characteristics for the Apolipoprotein A1 reagents were measured on a clinical chemistry analyzer.

- **Measuring Range:** 0 - 300 mg/dl
- **Detection Limit:** 4 mg/dl
- **Hook Effect:** > 5500 mg/dl
- **Sensitivity:** 0.00074 ABS units/concentration unit
- **Precision:**
  - **Intra-Run:** 3.05, 1.12, 1.48
  - **Inter-Run:** ND, 1.63, ND
- **Accuracy:**
  - **Control:**
    - **Assigned:** ERBA 109 (93 - 125)
    - **Measured:** 108
  - **Seronorm:**
    - **160 (135 - 183):** 169

**Specificity:**
Monospecific

**Interferences:**
- No interference for Hemoglobin (1000 mg/dl), Bilirubin (20 mg/dl) and Triglyceride (2000 mg/dl)

**Limitations:**
- None

**REFERENCES**

3. Polyethylene glycol is not biohazardous

4. Each donor unit used in the preparation of the calibrators and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA.