

Apolipoprotein A1 FS*

Order Information

| Cat. No. | Kit size | | |
|------------------|--------------|---|--------------|
| 1 7102 99 10 021 | R1 5 x 25 mL | + | R2 1 x 25 mL |
| 1 7102 99 10 930 | R1 4 x 20 mL | + | R2 2 x 8 mL |
| 1 7102 99 10 935 | R1 2 x 20 mL | + | R2 1 x 8 mL |

Kits for use in conjunction with DiaSys CE applications.

Intended Use

Diagnostic reagent for quantitative in vitro determination of apolipoprotein A1 in human serum or heparin plasma on automated photometric systems.

Summary

Apolipoprotein A1 (Apo A1) is the principal protein component of high-density lipoprotein (HDL) which removes cholesterol from cells and thus has a protective effect to atherosclerosis, it also has long been considered a critical component for cholesterol metabolism and HDL synthesis. ApoA1 was one of the first apolipoproteins discovered. It is the most structurally and functionally important protein in HDL, accounting for roughly 70 % of the total HDL protein content. Epidemiological studies have shown an inverse relationship between levels of HDL respectively Apo A1 and the 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. [1,2,3]

Method

Immunoturbidimetric test

Determination of Apo A1 concentration by 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 and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 18 months until expiry date.

Warnings and Precautions

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 2 contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- In very rare cases, samples of patients with gammopathy might give falsified results [4].
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
- Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
- Please refer to the safety data sheets (SDS) 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.
- For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagents are ready to use.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [5]:

| | | |
|----------|----|-----------|
| 1 day | at | 20 – 25°C |
| 8 days | at | 4 – 8°C |
| 3 months | at | -20°C |

Only freeze once. Discard contaminated specimens.

Assay Procedure

Basic settings for BioMajesty®JCA-BM6010/C

| | |
|--------------------|---------------------------|
| Wavelength | 571/694 nm |
| Temperature | 37°C |
| Measurement | Endpoint |
| Sample/Calibrator | 1.0 µL |
| Reagent 1 | 100 µL |
| Reagent 2 | 20 µL |
| Addition reagent 2 | Cycle 19 (286 s) |
| Absorbance 1 | Cycle 17/18 (231 s/244 s) |
| Absorbance 2 | Cycle 41/42 (586 s/600 s) |
| Calibration | Logit Log 3 |

Calculation

The concentration of Apo 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.

Conversion Factor

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

Calibrators and Controls

DiaSys TruCal Apo A1/B is recommended for calibration. Calibrator values 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. Use DiaSys TruLab L Level 1 and Level 2 for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

| | Cat. No. | Kit size |
|------------------|------------------|----------|
| TruCal Apo A1/B | 1 7170 99 10 045 | 3 x 2 mL |
| TruLab L Level 1 | 5 9020 99 10 065 | 3 x 3 mL |
| TruLab L Level 2 | 5 9030 99 10 065 | 3 x 3 mL |

Performance Characteristics

Data evaluated on BioMajesty® JCA-BM6010/C

| | |
|---|-----------|
| Measuring range up to 250 mg/dL, depending on the concentration of the highest calibrator. Linearity is given within $\pm 5\%$. When values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2. | |
| Limit of detection** | 0.5 mg/dL |
| No prozone effect up to 500 mg/dL. | |

| Interference by | Interferences $\leq 10\%$ up to | Analyte concentration [mg/dL] |
|---|---------------------------------|-------------------------------|
| Ascorbic acid | 30 mg/dL | 192 |
| Bilirubin (conjugated) | 60 mg/dL | 193 |
| Bilirubin (unconjugated) | 60 mg/dL | 193 |
| Hemolysis | 500 mg/dL | 191 |
| Lipemia (triglycerides) | 2000 mg/dL | 154 |
| For further information on interfering substances, refer to the literature. [6,7] | | |

| Precision | | | |
|----------------------|----------|----------|----------|
| Repeatability (n=20) | Sample 1 | Sample 2 | Sample 3 |
| Mean [mg/dL] | 107 | 133 | 165 |
| CV [%] | 1.18 | 1.20 | 1.50 |
| Between day (n=20) | Sample 1 | Sample 2 | Sample 3 |
| Mean [mg/dL] | 130 | 286 | 468 |
| CV [%] | 2.13 | 1.51 | 2.04 |

| Method comparison (n=94) | |
|----------------------------|---|
| Test x | Competitor Apolipoprotein A1 (BioMajesty® JCA-BM6010/C) |
| Test y | DiaSys Apolipoprotein A1 FS (BioMajesty® JCA-BM6010/C) |
| Slope | 0.967 |
| Intercept | -3.05 mg/dL |
| Coefficient of correlation | 0.996 |

** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

Reference Range [8]

| | | |
|-------|-----------------|-------------------------------|
| Women | 120 – 190 mg/dL | 42.8 – 67.8 $\mu\text{mol/L}$ |
| Men | 110 – 170 mg/dL | 39.3 – 60.7 $\mu\text{mol/L}$ |

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

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

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