APOLIPOPROTEIN B
For discrete analyzers
Method: Immuno-turbidimetry
Product code: 1418-0560
4 x 3.25 ml (R1) + 4 x 1.75 ml (R2)
1418-0567
4 x 6.5 ml (R1) + 4 x 3.5 ml (R2)
Store at 2 – 8°C
For in vitro use

INTENDED USE
MEDICON apo-B is a set of immunoturbidimetric reagents for the quantitative determination of apo-B in human serum and plasma, with BECKMAN COULTER AU400/600/800-ID/640/700/5400 and other discrete analyzers. For in vitro diagnostic use only.

CLINICAL SIGNIFICANCE
Elevated levels are observed in type IIa, IIb, IV and V types of lipoproteinemia, β-apoproteinemia (normal LDL-C, high Lp(a)-apo-B), early coronary disease, diabetes, hypothyroidism, nephrotic syndrome, kidney failure, hepatic disease. Cushing syndrome, dysgalubinephria, porphyria, pregnancy, anorexia nervosa, pulitary dwarfinism, childhood hyperacemia, splenophagodystrophies, Werner syndrome, emotional changes. Apo-B deficiency is observed at a lipoprotein deficiency. Tangier’s disease), heterozygous hypo-β-lipoproteinemia, lipoproteinemic lipase cofactor deficiency (Apo C-II), hyperthyroidism, malnutrition, hyperthyroidism, malnutrition, intestinal malabsorption, chronic anemia, severe hepatocellular dysfunction. Reye syndrome, joint inflammations, chronic lung conditions, myeloma, or weight loss. Apo-B is absent in cases of a β-lipoproteinemia and homozygous β-hypoproteinemia. In such cases, measurement of Apo-B concentration in serum acts as confirmation.

METHOD PRINCIPLE
The immunoturbidimetric method is applied. Addition of anti-Apo A1 antibodies causes the formation of antigen-antibody complexes, resulting in an increase of turbidity, which is measured as increase of absorbance at 340 nm.

METHOD LIMITATIONS
Refer to the book "Effects of Preanalytical Variables on Clinical Laboratory Tests" for possible interference of other pharmaceutical agents in this particular test. Interest of other agents is described in the "Clinical Guide to Laboratory Tests". The reagent is designed for in vitro diagnostic use only. In vitro diagnostic tests can be hazardous. They should be handled according to good laboratory practices and techniques. Avoid inhalation and contact with eyes and skin.

REAGENT COMPOSITION
Reagent 1 (R1)
Polyethylene glycol in Tris buffer
Non reagent components and preservatives
Reagent 2 (R2)
Goat anti-apo-B
Non reagent components and preservatives

WARNINGS – PRECAUTIONS
- Samples should be considered as potentially infectious. Handle according to the universal precautions and good laboratory practices.
- The reagent contains sodium azide (NaN₃ < 0.1%). Avoid swallowing and contact of the reagent with skin and mucous membrane.
- Antibodies are raised in clinically healthy animals in monitored facilities under constant surveillance.
- Dispose all waste according to national laws.
- MSDS is available by MEDICON upon request.

PREPARATION
Reagent 1 and 2 are ready to use. Vials bear barcode for recognition by BECKMAN COULTER AU Series analyzers.

REAGENT DETERIORATION
The reagent should not be used:
- When it does not exhibit the specified linearity or recovery of control values lies outside the acceptable range after recalibration.
- After prolonged exposure to high temperature or sunlight.

SHELF LIFE
Unopened, reagents are stable up to the stated expiry date when stored at 2 – 8°C. Once opened, they can be stored refrigerated on the instrument for 1 month.

SAMPLE
Use serum or EDTA-plasma as specimen. Use serum or EDTA-plasma as specimen. Patients should be fasting for at least 12 hours before sampling. Apo-B is stable for serum for 8 days when stored at 2 – 8°C and for 3 years when stored at -20°C.

CALIBRATION
MEDICON Apolipoprotein A1 & B Calibrator (1478-0550), traceable to WHO International Reference material for apo-B SP3-07, or BECKMAN COULTER Apolipoprotein A1 & B Calibrator ODR3035 (MEDICON code: 4478-0537) can be used for calibration. Calibrate the assay every 1 week. Recalibrate following preventive maintenance or replacement of a critical part, when using a new reagent kit or a new reagent lot number, or when Quality Control results are out of range.

QUALITY CONTROL
MEDICON provides the following products for quality control: APO A1 / APO B Control Level 1 (code: 1578-0553) and APO A1 / APO B Control Level 2 (code: 1578-0554), and BECKMAN COULTER CONTROL SERUM ODC0003 and ODC0004 (MEDICON code: 4478-0941 and 4478-0942).
Control target values and limits should fall within acceptable intervals adjusted to the requirements of each laboratory. Target values for apo-B should be verified with the corresponding working protocol. Results outside the specified values even after recalibration could be due to potential deterioration, unsuitable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT
Apo-B calibrator
Quality control material
Automated biochemistry analyzer
Common laboratory equipment

REFERENCE INTERVALS
Serum, plasma: 58 – 138 mg/dl
Each laboratory should determine its own expected values as dictated by good laboratory practice.

CALCULATIONS
During manual use of the reagent, the absorbance (A) of sample and reagent blank are measured before the reaction begins and after its completion (time values 1 and 2 respectively). The pure change in absorbance of the sample is afterwards calculated according to:
\[ \Delta A = A_{blank} - A_{sample} \] (A1(blank) – A2(blank) - A1(sample) - A2(blank))

A calibration curve is formed, transferring the ΔA of standard solutions on the Y axis, and the concentrations they refer to on the X axis. By placing the ΔA(sample) on the curve, the concentration of the sample is calculated.

WASTE DISPOSAL
This product contains sodium azide (NaN₃), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build up in the drain pipes.

SPECIFIC PERFORMANCE CHARACTERISTICS
Linearity
The assay is linear within measuring range 4 – 250 mg/dL.

Prozone Tolerance
No hook effect is observed up to 3000 mg/dL.

Sensitivity
The lowest detectable level of Apo-B is estimated at 1 mg/dL.

The lowest detection limit (DL) is defined as the lowest concentration of analyte that is distinguishable from zero. A sample free of analyte is assayed 20 times within the assay and the LDL is calculated as the absolute mean plus three standard deviations.

Precision

<table>
<thead>
<tr>
<th>Level (mg/dL)</th>
<th>Within Run CV%</th>
<th>Total CV%</th>
</tr>
</thead>
<tbody>
<tr>
<td>49</td>
<td>1.33</td>
<td>2.97</td>
</tr>
<tr>
<td>82</td>
<td>1.45</td>
<td>2.51</td>
</tr>
</tbody>
</table>

Precision is estimated on two concentration levels of analyte according to NCLLS protocol EP-57 (20 consecutive days, 2 runs per day, 2 repeats per run).

Interference
Lipemic
Hemoglobin
Non Cor. Bilirubin
Cor. Bilirubin
Ascorbic Acid

Method Comparison
A comparison was performed between this reagent and another commercially available product.

The results were as follows:

\[ Y = 1.1429X - 12.715 \]

R=0.9749

Sample range: 77 – 150 mg/dL

BIBLIOGRAPHY

SYMBOLS

- Temperature Unit: °C/°F (R1)

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Unit</th>
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<tbody>
<tr>
<td>2°C</td>
<td>°C/°F</td>
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- Ascorbic Acid

- Manufacturing Date (ISO 15223 / rev. EN980 / ISO7000)

- Ceiling Value (ISO 15223 / rev. EN980 / ISO7000)

- Production Date (ISO 15223 / rev. EN980 / ISO7000)

- For in vitro use (ISO 15223 / rev. EN980)

CE IVD