diatron

# APO A1

2°C 8°C

Specifically for use with Diatron PICTUS® 700 and PICTUS® 500 Analyzers

REF 1419-0550 **Packaging:** 6 x 8.1 mL (R1) + 6 x 2.7 mL (R2)

Σ 180

**INTENDED USE**

Reagents for In Vitro quantitative automated measurement of the concentration of Apolipoprotein A1 - ApoA1 in samples of human serum from the general patient population. Measurements of ApoA1 are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as a direct and indirect aid to screening, diagnosis, management and risk assessment of atherosclerotic cardiovascular disease (ACVD).

This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers.
For in vitro diagnostic use only by trained laboratory professionals.

**CLINICAL SIGNIFICANCE**

High Apo A1 concentrations in serum appear in familial α-lipoproteinemia and in reduction of body weight.
Low concentrations appear in the following cases: A-β-lipoproteinemia, lipoprotein lipase cofactor (Apo C-II) deficiency, cases of α-lipoproteinemia, hypertriglyceridemia, non-regulated diabetes, onset coronary disease, hepatocellular malfunctions, cholestasis, nephrotic syndrome, chronic renal failure, smoking, diet rich in hydrocarbon or poly-unsaturated fats

**METHOD PRINCIPLE**

The immunoturbidimetric method is applied. Addition of serum to a solution of anti-Apo A1 antibodies causes the formation of antigen-antibody aggregates, resulting to turbidity which is measured as an increase of absorbance at 550/700 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. Interference of other agents is described in the "Clinical Guide to Laboratory Tests". This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers. For additional information please contact customer support at Diatron or Medicon.

**REAGENT COMPOSITION**

| Reagent 1 (R1) | Reagent 2 (R2) |
|---|---|
| Polyethylene glycol in Tris buffer<br>Non-reactive ingredients, preservative | Goat anti-human Apo A1 antibodies<br>Non-reactive ingredients, preservative |

⚠ **WARNINGS – PRECAUTIONS**

- This reagent is designed for in vitro diagnostic use. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory techniques. Avoid inhalation and contact with eyes and skin.
- Samples should be considered as potentially infectious. Handle with special caution.
- The reagent contains NaOH ≤ 1.0 %. Avoid ingestion and contact with skin and mucous membranes.
- Any serious incident that may occur in relation to this device must be reported by the user to the manufacturer and the competent authority of the country in which the user and/or the patient is established!
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON upon request.

⚠ **PREPARATION**

Reagents R1 and R2 are liquid, ready to use when placed in the corresponding positions of the analyzer. The vials bear barcodes for automatic recognition by Diatron Pictus® P700 / P500 analyzers.

⚠ **REAGENT DETERIORATION**

The reagents should not be used:

- When they do not exhibit the specified linearity or control values lie outside the acceptable range after recalibration.
- After prolonged exposure to sunlight or high temperature.

⚠ **SHELF LIFE**

Unopened reagents are stable at 2°– 8°C up to the expiry date stated on the label. After opening, R1 and R2 remain stable for 1 month when stored in the cooled reagent tray of the Diatron Pictus® P700 or P500 analyzers.

⚠ **SAMPLE** Serum may be used as specimen. Use established Good Laboratory Practices for sampling, transport and separation from blood cells. Patients should be fasting for at least 12 hours before sampling. Do not use hemolyzed, contaminated or turbid sample specimens. Centrifuge sample as soon as possible, and store properly if analysis cannot take place right after sample separation. Apo A1 is stable in serum samples for at least 4 days when stored at 2 – 8°C, and for 1 year when stored at –20°C. Do not freeze thawed samples.

**CALIBRATION** Diatron offers MEDICON Apolipoprotein A1 & B Calibrator (1478-0550) traceable to the WHO Int. Ref. Material for APO-A1-SP1-01. Recalibrate the assay every 2 weeks on Pictus® P700 or P500 analyzers. Calibration should also be repeated after major maintenance is performed on the analyzer, after a critical part is replaced, or when a significant shift in control values occurs.

**QUALITY CONTROL** Diatron offers MEDICON APOA1/APO B Control Lev. 1 and Lev. 2 (1578-0553 and 1578-0554 respectively) for quality control. Control recovery should lie within the acceptable range. Results outside the acceptable range even after recalibration could be due to reagent deterioration, unsuitable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

**MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT**

- APO A1 Calibrator.
- Diatron Pictus® analyzer
- Quality control materials.
- Common laboratory equipment.

**REFERENCE INTERVALS**

Serum: 73 – 169 mg/dl
Reference values are based on current bibliography. Each laboratory should determine its own expected values as dictated by good laboratory practices.

**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**

The following values are representative of the reagent performance on Diatron Pictus® P700 or P500 analyzers. The reagent performance has been evaluated on other types of analyzers, covering all requirements of the 98/79 IVD Directive. A list of analyzers with the corresponding performance characteristics is available in the special leaflet accompanying the insert. The results taken in your laboratory may differ from these values.

**Linearity:** Up to 250 mg/dL
**Hook Effect:** >3000 mg/dL
**Lowest detection limit** 4.8 mg/dL

Lowest detection limit (LDL) 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**: Precision is estimated on two concentration levels of analyte according to CLSI protocol EP-5T (20 consecutive days, 2 runs per day, 2 repeats per run).

| Pictus® P700 and P500 | |
|---|---|
| **Level (mg/dL)** | **%CV** |
| 88.4 | 1.14 |
| 138 | 1.01 |
| **Level (mg/dL)** | **Total %CV** |
| 88.4 | 2.36 |
| 138 | 1.61 |

**INTERFERENCES -** Criterion: recovery within ±10% from target value

| **Serum** | (Insignificant up to) |
|---|---|
| Triglycerides | 1200 mg/dL |
| Hemoglobin | 500 mg/dL |
| Bilirubin | 20 mg/dL |
| Conj. Bilirubin | 20 mg/dL |
| Ascorbic acid | 3 mg/dL |

**Correlation:** A comparison was performed between this reagent on a Diatron Pictus® P700 and P500 analyzer and another commercially available product. The results were as follows:
Y = 0.989X + 2.738 R=0.9715 N=29 Sample range = 65.6 – 240 mg/dL

**BIBLIOGRAPHY**


1. Tietz, NW, ed. Clinical Guide to Laboratory Tests. 3rd. ed. Philadelphia: W.B. Saunders Company Ltd., 1995.
2. Burtis, CA and Ashwood, ER, ed. Tietz Textbook of Clinical Chemistry. 2nd. ed. Philadelphia: W.B. Saunders Company Ltd., 1994.
3. Jacobs, DJ, Demott, WR, Grady, HJ, Horvat, RJ, Huestis, DW and Kasten, BL, Jr, eds. Laboratory Test Handbook. 4th. ed. Ohio, Hudson: Lexi-Comp Inc., 1996.
4. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd. ed. Washington, DC: The American Association for Clinical Chemistry Press, 1997.


**SYMBOLS**

Manufacturer
IVD *In vitro* diagnostic medical device
Temperature Limit
REF Catalogue Number
Caution
Σ Contains sufficient for <n> tests




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