

APO A1

For use on Diatron Pictus® series analyzers

Method: **Immunturbidimetry**

Product code: **1419-0552, 1419-0550**

Package: **6 x 27 ml (R1) + 6 x 9 ml (R2), 6 x 8.1 ml (R1) + 6 x 2.7 ml (R2)**

Store at: **2° – 8°C**

For **in vitro** use only

INTENDED USE

Ready to use reagents for the determination of Apolipoprotein A1 (Apo A1) in human serum or plasma specifically for use with Diatron Pictus® series analyzers. For in vitro diagnostic use only.

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 immunturbidimetric 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".

The reagent is designed especially for use with the Diatron Pictus® series of chemistry analyzers. For chemistry protocols and further information please contact the customer support unit at Diatron.

REAGENT COMPOSITION

Reagent 1 (R1)

Polyethylene glycol in Tris buffer
Non reactive ingredients, preservative

Reagent 2 (R2)

Goat anti-human Apo A1 antibodies
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.
- This reagent contains sodium azide (NaN₃) ≤ 0.1%. Avoid swallowing and contact of the reagent with skin and mucous membranes.
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON HELLAS (manufacturer) upon request.

REAGENT 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 Pictus® series 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 28 days when stored in the cooled reagent tray of the Pictus® series analyzers.

SAMPLE

Serum or plasma with EDTA specimens must be used. Fasting is required for at least 12 hours prior to sampling. The concentration of Apolipoprotein A1 is stable at 2° – 8°C for 4 days and at –20°C for 6 months.

CALIBRATION

Diatron provides the Apolipoprotein A1 & B Calibrator (1478-0550) traceable to the WHO Int. Ref. Material for APO-A1-SP1-01. Recalibrate the assay every 14 days on Pictus® series 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 provides APOA1/APO B Control Lev. 1 and Lev. 2 (1578-0553 and 1578-0554 respectively). 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 SUPPLIED WITH THE KIT

- Apo A1 calibrator
- Quality control materials
- Diatron Pictus® P400/P700/P500
- Common laboratory equipment

REFERENCE INTERVALS

Serum/Plasma: 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® series 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.

	Pictus® P400	Pictus® P700/P500
Linearity	Up to 250 mg/dL	Up to 250 mg/dL
Hook effect	> 3000 mg/dL	> 3000 mg/dL
Lowest detection limit	4.8 mg/dL	4.8 mg/dL

The 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 5-A (20 consecutive days, 2 runs per day, 2 repeats per run).

Pictus® P400			Pictus® P700/P500		
Level (mg/dL)	Within Run CV%	Total CV%	Level (mg/dL)	Within Run CV%	Total CV%
74.2	2.60	3.40	88.4	2.34	3.46
138.3	2.65	2.85	138	2.41	2.71

Interference: Criterion: recovery within ±20% from target value

	Pictus® P400	Pictus® P700/P500
Lipemic	Insignificant up to Intralipid® 100 mg/dl	Insignificant up to 400 mg/dl Intralipid®
Hemoglobin	Insignificant up to 500 mg/dL	Insignificant up to 500 mg/dL
Non conj. Bilirubin	Insignificant up to 20 mg/dL	Insignificant up to 20 mg/dL
Conj. Bilirubin	Insignificant up to 20 mg/dL	Insignificant up to 20 mg/dL








Correlation: A comparison was performed between this reagent on a Pictus® series analyzer, and a BECKMAN COULTER AU-series system. The results were as follows:

Pictus® P400	Y = 0.981X + 2.765	R=0.969	N=40	Sample range = 58.2 – 234.5 mg/dL
Pictus® P700/P500	Y = 0.989X + 2.738	R=0.9715	N=29	Sample range = 65.6 – 240 mg/dL

BIBLIOGRAPHY

- Tietz, NW, ed. Clinical Guide to Laboratory Tests. 3rd. ed. Philadelphia: W.B. Saunders Company Ltd., 1995.
- Burtis, CA and Ashwood, ER, ed. Tietz Textbook of Clinical Chemistry. 2nd. ed. Philadelphia: W.B. Saunders Company Ltd., 1994.
- 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.
- Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd. ed. Washington, DC: The American Association for Clinical Chemistry Press, 1997.

SYMBOLS

	Temperature Limits (L/H)		Manufacturer
	Read the Instructions		Catalog Number (ISO 15223 / rev. EN980)
	Batch Code (ISO 15223 / rev. EN980)		For in vitro use (ISO 15223 / rev. EN980)
	Date of Expiry (ISO 15223 / rev. EN980)		

