

APO B

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

REF 1419-0560

Packaging: 6 x 8.1 mL (R1) + 6 x 2.7 mL (R2)

180



INTENDED USE

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

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 concentrations are observed in type IIa, IIb, IV and V lipoproteinemia, β -apoproteinemia, (normal LDL-C, high LDL-Apo-B), onset coronary disease, diabetes, hypothyroidism, nephrotic syndrome, renal failure, hepatic disease, Cushing syndrome, dysglobulinemia, porphyria, pregnancy, anorexia nervosa, pituitary dwarfism, children hypercalcaemia, sphingolipidystrophies, Werner syndrome, emotional pressure induced stress. Low concentrations are observed in lack of α -lipoprotein (Tangier disease), heterozygous β -hypolipoproteinemia, lecithin-cholesterol acyltransferase deficiency, type I hyperlipoproteinemia, lipoprotein lipase cofactor (Apo C-II) deficiency, hyperthyroidism, malnutrition, enteric malabsorption, chronic anemias, severe hepatocellular malfunctions, Reye's syndrome, inflammation of the joints, chronic lung diseases, myeloma, weight loss. Apolipoprotein B is absent in α - β lipoproteinemia, and homozygous β -hypolipoproteinemia. Measuring the concentration of Apo-B in serum acts as a confirmation test in these cases.

METHOD PRINCIPLE

The immunoturbidimetric method is applied. Addition of serum to a solution of anti-Apo B antibodies causes the formation of antigen-antibody aggregates resulting to turbidity in the test solution. The absorbance at 340/700 nm is proportionate to the concentration of Apo B.

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 Non-reactive ingredients, preservative	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.
- 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 B 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. A slight increase may be seen with freezing. Do not freeze thawed samples.

CALIBRATION Diatron offers MEDICON Apolipoprotein A1 & B Calibrator (1478-0550) traceable to the WHO Int. Ref. Material SP3-08 for calibration. 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 B Calibrator.
- Diatron Pictus® analyzer
- Quality control materials.
- Common laboratory equipment.

REFERENCE INTERVALS

Serum: 58–138 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 220 mg/dL

Hook Effect: >2000 mg/dL

Lowest detection limit 2.0 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
51.8	1.00
80.3	0.90
Level (mg/dL)	Total %CV
51.8	1.98
80.3	2.15

INTERFERENCES - Criterion: recovery within $\pm 10\%$ from target value

Serum	(Insignificant up to)
Hemoglobin	500 mg/dL
Bilirubin	20 mg/dL
Conj. Bilirubin	20 mg/dL
Ascorbic acid	2.25 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 = 1.124X – 13.52 R=0.9854 N=59 Sample range = 40.8 – 155 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

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