diatron

APO B

For use on Diatron Pictus® series analyzers
Method: Immunoturbidimetry
Product code: 1419-0562, 1419-0560
Package: 6x27 ml (R1) + 6x9 ml (R2), 6x8.1 ml (R1) + 6x2.7 ml (R2)
Store at: 2°– 8°C
For *in vitro* use only

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

CLINICAL SIGNIFICANCE
High concentrations are observed in type IIa, IIb, IV and V lipoproteinemia, β-apolipoproteinemia, (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 hypercalcemia, sphingolipodystrophy, Werner syndrome, emotional pressure induced stress.
Low concentrations are observed in lack of α-lipoprotein (Tangier disease), heterozygous β-hypolipoproteinemia, lecithin–cholesterol acyltransferase deficieny, 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 a-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".
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 B 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 (NaN_3) ≤ 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. Once opened, R1 and R2 remain stable for 28 days when stored in the cooled reagent tray of the Pictus® series analyzers.

SAMPLE
Specimens of non lipemic serum or plasma with EDTA must be used. Fasting is required for at least 12 hours prior to sampleing. When stored with preservative (thimerosal), Apo B is stable for 7 days at 2°– 4°C and for 3 years at –20°C.

CALIBRATION
Diatron provides Apolipoprotein A1 & B Calibrator (code 1478-0550), traceable to the WHO Int. Ref. Material SP3-08. Recalibrate the assay every 14 days on the 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 B calibrator
- Quality control materials
- Diatron Pictus® P400/P700/P500
- Common laboratory equipment

REFERENCE INTERVALS
Serum/Plasma: 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 (NaN_3), 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 220 mg/dL	Up to 220 mg/dL
Hook effect	> 2000 mg/dL	> 2000 mg/dL
Lowest detection limit	2.0 mg/dL	2.0 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		
	Within Run			Within Run	
Level (mg/dL)	CV%	Total CV%	Level (mg/dL)	CV%	Total CV%
51.7	2.10	3.18	51.8	2.00	2.98
80.1	2.03	3.45	80.3	1.90	3.15

Interference Criterion: recovery within ±20% from target value

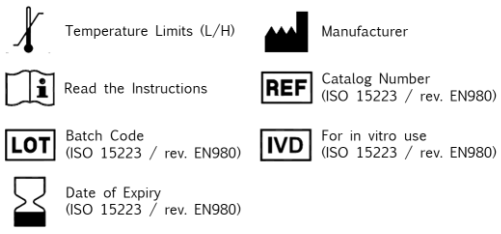
	Pictus® P400	Pictus® P700/P500
Lipemic	Insignificant up to Intralipid® 10 mg/dl	Insignificant up to Intralipid® 10 mg/dl
Haemoglobin	Insignificant up to 375 mg/dL	Insignificant up to 500 mg/dL
Non conj. Bilirubin	Insignificant up to 20 mg/dL	Insignificant up to 20 mg/dL
Conj. Bilirubin	Insignificant up to 20 mg/dL	Insignificant up to 20 mg/dL
Ascorbate	Insignificant up to 3 mg/dL	Insignificant up to 2.25 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 = 0.71X + 7.45	R=0.935	N=40	Sample range = 5.7 – 420.9 mg/dL
Pictus® P700/P500			
Y = 1.124X – 13.52	R=0.9854	N=59	Sample range = 40.8 – 155 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


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