Cat. No 9-450

DIAGNOSTIC KIT FOR DETERMINATION OF APOLIPOPROTIEN B CONCENTRATION

OS – APOLIPOPROTEIN B

INTRODUCTION

Lipids are transported in serum under the form of micelle known as lipoproteins. Lipoproteins are macromolecular complexes containing proteins (apolipoproteins), cholesterol and phospholipids in their outer layer, triglycerides and cholesterol esters in their inner structure. Lipoproteins are classified according to their increasing density respectively as chylomicrons, very low density lipoproteins (VLDL), low density lipoproteins (LDL) and high density lipoproteins (HDL). Apolipoprotein B is the major protein moiety of LDL. Apolipoprotein measurements are more discriminating than HDL and LDL cholesterol measurements in allowing to identify patients with coronary heart diseases and in assessing atherosclerotic risk.

METHOD PRINCIPLE

The apolipoprotein B presents in a sample form with the specific antibody an immunological complex. The increase of turbidity after the addition of antiserum measured at λ=340 nm is proportional to apolipoprotein B concentration in the sample.

REAGENTS

Package

1-Reagent	1 x 53.5 ml
2-Reagent	1 x 13 ml

Buffer (1-Reagent) stored at 2-8°C and antiserum (2-Reagent) stored at 2-8°C are stable until expiry date printed on the package. Store closed. Protect from light and avoid contamination!

Concentrations in the test

TRIS buffer (pH 8.0); PEG; sodium chloride; anti human apolipoprotein B antiserum; HEPES buffer (pH 7.4); stabilizers.

Warnings and notes

- Products for in vitro diagnostic use only.
- The reagents must be used only for the intended purpose, by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Products from human source have been tested for HBsAg and antibodies to HIV and HCV and found to be non-reactive. However this material should be handled as thought capable of transmitting infectious disease.
- Products contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN

Serum or plasma.
It is recommended to perform the assay with freshly collected samples!

PROCEDURE

These reagents may be used in automatic analysers Olympus AU400/AU640.
1-Reagent and 2-Reagent are ready to use.
For reagent blank 0.9% NaCl is recommended.

APPLICATION

Reagent ID: **043**

Specific Test Parameters

General | LIH | ISE | Range

Test name: **ApoB** Type: **Serum** Operation: **Yes**

Sample: Volume	3	µL	Dilution	0	µL	Pre-Dilution Rate:	1	
Reagents: R1 Volume	250	µL	Dilution	0	µL	Min OD	Max OD	
R2 Volume	50	µL	Dilution	0	µL	L -2.0000	H 2.5000	
						Reagent OD Limit:		
Wavelength: Pri.	340		Sec.	700		First L -2.0000	First H 2.5000	
Method:	END					Last L -2.0000	Last H 2.5000	
Reaction Slope:	+					Dynamic Range:		
Measuring Point 1: First	0		Last	27		L	H	
Measuring Point 2: First	0		Last	10		Correlation Factor:		
Linearity:		%				A 1.000	B 0.000	
No-Lag-Time:						On-board Stability Period:		

Specific Test Parameters

General | LIH | ISE | Range

Test name: **ApoB** Type: **Serum**

Value/Flag: # Level L: # Level H: #

Normal Ranges:

	Sex	Age L Year	Age L Month	Age H Year	Age H Month	L	H
1.	#	#	#	#	#	#	#
2.	#	#	#	#	#	#	#
3.	#	#	#	#	#	#	#
4.	#	#	#	#	#	#	#
5.	#	#	#	#	#	#	#
6.	#	#	#	#	#	#	#
7. None Selected						#	#
8 Out of Range						#	#

Panic Value: L # H # Unit: **g/l** Decimal Places: **2**

Calibration Specific

General | ISE

Test name: **ApoB** Type: **Serum**

Calibration Type: **6AB** Formula $Y=AX^3+BX^2+CX+D$ Counts: **1** Process: **CONC**

	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1:	#		**	-2.0000	2.5000
Point 2:	#		*	-2.0000	2.5000
Point 3:	#		*	-2.0000	2.5000
Point 4:	#		*	-2.0000	2.5000
Point 5:	#		*	-2.0000	2.5000
Point 6:	#		*	-2.0000	2.5000
Point 7:					

1-Point Cal.Point: with CONC-0 Slope Check: **None** Advanced Calibration: #

MB Type Factor: Calibration Stability Period:

\# User defined
* Calibrator value
** Saline should be used as calibrator 1

REFERENCE VALUES [3]

children (4-11 years)	0.56 – 1.13 g/l
children (12-19 years)	0.55 – 1.19 g/l
adults	0.59 – 1.73 g/l

It is recommended for each laboratory to establish its own reference ranges for local population. These ranges are sex and age dependent.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY APOLIPOPROTEIN CONTROL (Cat. No 4-293) with each batch of samples.
For the calibration of automatic analysers systems the CORMAY APOLIPOPROTEIN CALIBRATORS (Cat. No 4-289) is recommended.
The calibration curve should be prepared every 3 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using an automatic analyser Cobas Mira. Results may vary if a different instrument is used.

- **Analytical range:** 0.01 g/l – 4 g/l.

- **Specificity / Interferences**

Hemoglobin up to 0.32 g/dl, bilirubin up to 29,5 mg/dl, triglycerides up to 1000 mg/dl, heparin up to 0.5 g/l, sodium fluoride up to 4 g/l, EDTA up to 5 g/l, sodium citrate up to 5 g/l do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 10	Mean [g/l]	SD [g/l]	CV [%]
level 1	0.49	0.007	1.4
level 2	1.06	0.027	2.5
level 3	0.99	0.028	2.8

Reproducibility (day to day) n = 10	Mean [g/l]	SD [g/l]	CV [%]
level 1	0.50	0.014	2.8
level 2	1.01	0.038	3.8
level 3	1.11	0.041	3.7

- **Method comparison**

A comparison between CORMAY reagent (y) and commercially available assay (x) using 35 samples gave following results:
y = 0.92 x + 2.96 mg/dl;
R = 0,9508 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Marcovina, S.M., Albers, International Federation of Clinical Chemistry Standardization Project for Measurements of Apolipoproteins A1 and B. III.
2. Tietz, N.W. Fundamentals of Clinical Chemistry. Saunders, Philadelphia 1987.
3. Alan H.B. Wu, ed.: Tietz Clinical Guide to Laboratory Tests, 4th ed. W.B. Saunders Company., 146, (2006).
4. Burtis C.A., Ashwood E.R., ed. Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia, PA: WB Saunders, 1802, (1999).

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