# TURBICHEM APOLIPOPROTEIN - B APO-B

# (Turbidimetry Method)

KIT NAME	KIT SIZE	CAT. NO
Turbichem - APO - B	1 x 40 ml	TAPB00040D

# INTRODUCTION

Apolipoprotein B (Apo B) is intended for Invitro quantitative determination of Apo B in human serum. Apolipoprotein B (APO B) is the major protein component of low density lipoprotein (LDL). It enables the reaction with LDL receptors in the liver and on cell walls and transports cholesterol from the liver to tissue cells. Studies have shown APO B to have a direct relationship to coronary artery disease and an inverse relationship with APO A1. APO B levels are useful in assessment of cardiovascular risk in addition to LDL cholesterol levels. Elevated levels of APO B can be an indication of increased cardiovascular risk even when total cholesterol and LDL cholesterol are within the normal range.

#### METHOD PRINCIPLE

The Kit utilizes latex-enhanced immunoturbidimetry to measure the Apo-B level in human serum or plasma. During the test, APO B in the sample binds with the specific anti APO-B antibody to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry, analyzer. The change in absorbance is proportional to the level of APO-B in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

### KIT CONTENTS

R1 - Apo - B Buffer	1 x 30 ml	
R2 - Apo - B antibody	1 x 10 ml	
R3 - Apo - B Calibrator	1 vial	

R3 Apo-B calibrator is in lyopholized form, which we can be reconstituted as per the instruction mentioned in the vial label

The reagents when stored at  $2-8^{\circ}\text{C}$  are stable up to expiry date printed on the package. The reagents are stable for 7-10 days on board the analyser at  $2-10^{\circ}\text{C}$ . Protect from light and avoid contamination.

# WORKING REAGENT PREPARATION AND STABILITY

Assay can be performed with use of separate R1-Apo-B and R2-Apo-B reagents of 3 parts of R1-Apo-B with 1 part of R2-Apo-B. Avoid foaming.

#### CONCENTRATIONS IN THE TEST

R1 - Glycine buffer solution. Sodium azide < 0.1%

R2 - Anti-APO B antibodies, glycine buffer, sodium azide < 0.1%

# WARNINGS AND NOTES

- The Kit is for in vitro diagnostic use only. Not for use in humans or animals.
- $2. \ The instructions \, must \, be \, followed \, to \, obtain \, accurate \, results.$
- 3. Do not use the reagents beyond the expiration date.
- Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed

# **ADDITIONAL EQUIPMENT**

- Automatic analyzer or photometer able to read at 340 nm
- Thermostat at 37ºC
- General laboratory equipment

# **SPECIMEN**

Follow standard laboratory procedures to collect serum samples. It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, store sample at  $2-4^{\circ}$  C for up to 3 days or at  $-20^{\circ}$  C for up to 6 months. Avoid repeated freezing and thawing.



#### PLOTTING OF MULTIPOINT CURVE

The Turbichem Apo-B is based on Non-Linear Reactions, hence it is strongly recommended to run Multi-standard mode to plot the Multi-point curve to have better accuracy and precise result.

## **Serial Dilution Step**

	1st	2nd	3rd	4th	5th
Calibrator	100 μl	50 μl from 1st Tube		50 μl from 3rd Tube	50 μl from 4th Tube
Normal Saline	0	50 µl	50 μl	50 μl	50 μl
Ratio of Dillution	Neat	1/2	1/4	1/8	1/16

#### **PROCEDURE**

These reagents may be used both for manual assay and in several automatic analyzers. Applications for them are available on request.

 $\begin{array}{lll} \text{Wavelength} & 340 \text{ nm} \\ \text{Temperature} & 37^{\circ}\text{C} \\ \text{Cuvette} & 1 \text{ cm} \end{array}$ 

# Pipette into the cuvette:

Reagent	Calibrator (C)	Test (T)		
R1 Apo - B Buffer	750 µl	750 µl		
Calibrator	10 μ1			
Sample	-	10 μ1		
Mix well and incubator for 5 mins. at 37° C				
R2 - Apo - B Anitbody	250 μl	250 μl		

Mix well & incubate for 5 min. at 37°C. Measure the absorbance of calibrator & sample

#### **CALCULATION**

Apo-B concentration = <u>Abs.Test</u> X Calibrator Concentration

Abs.Calibrator

#### REFERENCE VALUES

60 to 100 mg/dl

It is recommended for each laboratory to establish its own reference ranges for local population.

#### **OUALITY CONTROL**

To ensure adequate quality control, each run should include assayed normal and abnormal controls. If commercial controls are not available it is recommended that known value samples be aliquoted, frozen and used as controls

## PERFORMANCE CHARACTERISTICS

- Linearity: 30 to 200 mg/dL
- Precision : within Run  $CV \le 4\%$
- Specificity / Interferences

No interference detected for bilirubin upto 60 mg/dL and hemoglobin 10 q/L, triglycerides 1000 mg/dL

## WASTE MANAGEMENT

Please refer to local legal requirements.

#### **LITERATURE**

- 1. Raz, A., et al, J. Biol. Chem. 244: 12 (1969).
- 2. Kottke BA, et al. Mayo Clin. Proc. 1986; 61: 313.
- Ritchie, RF (ed). Serum Proteins in Clinical Medicine, Volume 1 aboratory Section. Scarborough, ME: Foundation for Blood Research; 12.01-5; 1996.
- 4. Snidermann AD. Can. J. Cardiol. 1988; 4 Suppl.: 24 A.
- 5. Sandkamp M. Diagnose & Labor 1990; 40: 37.

# SYSTEM PARAMETERS

Method	End Point	
Wavelength	340 nm	
Zero Setting	Reagent Blank	
Temperature Setting	37° C	
Incubation Temperature	37° C	
Incubation Time	5 mins + 5 mins	
Delay Time		
Read Time		
No. of Reading	2	
Interval Time		
Sample Volume	0.01 ml (10 ul)	
Reagent Volume	1.0 ml (1000 ul)	
Standard Concentration	Refer Callibrator vial	
Units	mg / dl	
Factor		
Reaction Slope	Increasing	
Linearity	200 mg/dl	





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