Apolipoprotein B Assay Kit (APOB)

Method: Immunoturbidimetric

INTENDED USE

Cat . No.	Size	Instrument
GB170Z	R1: 4×45 ml R2: 4×15 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS171Z	R1: 3×60 ml R2: 3×20 ml	For Hitachi917 & OlympusAU640/400/600
GX171Z	R1: 2×60 ml R2: 2×20 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-800

For the *in vitro* quantitative determination of apolipoprotein B (Apo B) in serum. For use as an aid in assessing the risk of cardiovascular disease.

CLINICAL SIGNIFICANCE

Lipids are synthesised in the intestine or liver but must be transported to tissues and organs. However this is not possible without hydrophilic adaptation. Lipids are therefore transported by a series of micellar structures. These structures consist of an outer monolayer of protein (an apolipoprotein) and polar lipids (phospholipids and unesterified cholesterol) plus an inner core of neutral lipids (triglycerides and cholesterol esters). The apolipoproteins interact with a series of enzymes and tissue receptors and are therefore responsible for further metabolism and catabolism of the micelle.

The B apolipoproteins are the main form of protein found in low density lipoproteins (LDL). Two forms of apo B are found in humans. The most common form is apo B-100 (or large B) which constitutes the apo B found in lipoproteins synthesised in the liver. The other form is apo B-48 (or small B), thought to be synthesised in the intestinal wall. Apo B is the main cholesterol carrying protein in the blood and is the ligand concerned with the uptake of cholesterol into cells by the LDL-receptor pathway. Apo B shows atherogenic signs and is thus useful for the evalution of coronary risk. Studies have shown that there is an inverse relationship between APO A-1 and coronary artery disease and a direct relationship with APO B such that pateints with CAD have generally reduced levels of APO A-1 and increased levels of APO B.

ASSAY PRINCIPLE

This method is based on the reaction of a samplecontaining human apo B and a specific antiserum to form an insoluble complex which can be measured turbidimetrically at 340 nm. By constructing a standard curve from the absorbances of standards the concentration of apo B can be determined.

REAGENT COMPOSITION

Contents	Concentrations of reagents
R1. Buffer	
Polyethylene glycol	maximum 4%
Tris/HCl buffer	17 mmol/L
Sodium Chloride	125 mmol/L
R2. Antibody Reagent	
Anti-human-apo B	
Calibrator	lot specific

SPECIMEN COLLECTION AND PREPARATION

Serum samples.

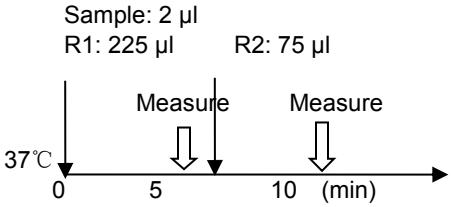
Apo B is stable for 7 days at 15 -25℃, 4 weeks at 2-8℃ or 2 months at - 20℃.

STABILITY AND PREPARATION OF REAGENTS

Reagents are stable until expiry date when stored unopened at 2-8℃.

ASSAY PROCEDURE

Wavelength(main/sub) : 340 nm/700 nm



CALIBRATION

Apolipoprotein Calibrator (value is lot specific) provided with the kit is recommended for calibration.

Recalibration is recommended for each series of samples run. The Apolipoprotein B concentration was determined using a WHO/IFCC reference standard.

CALCULATIONS OF RESULTS

Plot calibrator concentrations against the corresponding-A values using graph paper. The concentration of Apo B in the sample is obtained by reading off -A value from the calibration curve. Exploration above or below the range of calibrators, must not be attempted.

QUALITY CONTROL

Specific Protein Controls are recommended.Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE

Adults: 63 - 114 mg/dl

It is recommended that each laboratory should assign its own normal range as this is dependent upon geographical location.

MAIN PERFORMANCE CHARACTERISTICS

LINEARITY

The method is linear up to 230 mg/dl. If the concentration is above 230mg/dl,plaese dilute it with 0.9% NaCl and reassay. Multiply the result by dilution factor.

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CE Revised2014 version 0801

PRECISION

The CV of the test should be less than 5%.

Intar assay precision		
N=20	level 1	level 2
Mean(mg/dl)	59.35	61.11
SD	0.84	1.00
CV(%)	1.42	1.64

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(mg/dl)	57.45	59.01	59.20
$\bar{x}$	58.55		
(Xmax-Xmin)/$\bar{x}$	(59.2-57.45)/58.55*100=2.99%		

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

Hemoglobin up to 500 mg/dl
Intralipid up to 500 mg/dl
Bilirubin up to 40 mg/dl

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

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INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

Manufacture：Beijing Strong Biotechnology, Inc.
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