

## Apolipoprotein B (APOB) Test Kit (Immunoturbidimetry)

### 【NAME】

Apolipoprotein B (APOB) Test Kit (Immunoturbidimetry)

### 【INTEND USE】

This reagent is intended for the in vitro quantitative determination of Apolipoprotein B (APOB) in human serum. ApoB is the main structural protein of LDL. The hyperlipidemia and arteriosclerotic disease was positively correlated with ApoB levels.

### 【METHODOLOGY】

APOB and super sensitized APOB antibody latex particle reagent is reaction, And generate immune complex. Detection of the turbidity of change at 340nm, the degree of change is proportional to the APOB levels in the samples.

### 【STABILITY AND STORAGE】

Unopened, avoid light preservation in 2~8℃, valid for 12 months;  
Opened, avoid contamination preservation in 2~8℃, valid for 1 month.  
Reagent is not allowed frozen.

### 【SPECIMEN COLLECTION AND HANDLING】

It is best to fresh Serum, heparin anticoagulant blood plasma.  
Sample stability: 15~25℃ preservation stability in 3 days.  
2~8℃ preservation stability in 1 week.

Do not use the contaminated samples.

When the ascorbic acid concentration of sample  $\leq 1704 \mu\text{mol/L}$ ; bilirubin concentrations  $\leq 598 \mu\text{mol/L}$ ; hemoglobin  $\leq 5.00\text{g/L}$ , TG  $\leq 22.6\text{mmol/L}$ , was not observed clearly disturbance.

### 【APPLICABLE INSTRUMENT】

Fully automatic biochemical analyzer.

### 【SYSTEM PARAMETERS】

The following system parameters are recommended. Individual instrument applications are available upon request from the Technical Support Group

Temperature	37℃
Cuvette light path	1.0cm
Primary Wavelength	340nm
Secondary Wavelength	700nm
Assay Type	Two Point End
Direction	Increase
Sample : Reagent 1: Reagent 2 Ratio	2:225:75
eg : Sample Vol	2 $\mu\text{L}$
Reagent1 Vol	225 $\mu\text{L}$
Reagent2 Vol	75 $\mu\text{L}$
Linearity	0~2.5g/L
Testing	Deducting the reagent blank

### 【OPERATION STEPS】

R1: Reagent 1    R2: Reagent 2    S: Calibrator    U: Sample

### 【CALCULATION】

$$\Delta\text{Abs} = [ (A2 - A1) \text{ Calibrator or Sample} ] - [ (A2 - A1) \text{ Blank} ]$$

According to the calibration requirements, with different levels of calibration solution, together with 9 g/L sodium chloride solution as the blank. After measurement, the instrument automatic synthesize calibration curve for the calibration response quantity through the appropriate mathematical model (such as Logit/ Spline). Using APOB calibration values to calibrate instrument, within the scope of the reportable results, the instrument directly report reliable test results.

### 【REFERENCE RANGE】

Female: 0.75~1.50g/L    Male: 0.60~1.00g/L

By clinical trials, choose no less than 100 newborn or adults blood specimens, tested by automatic biochemical analyzer, and then processing the testing value with statistical method, calculating out the reference range.

**Recommendation: The laboratory set up its own reference range!**

### 【THE LIMITATION OF TEST RESULTS】

Apolipoprotein B (APOB) testing is just one of the standard that clinician diagnose the patient. Clinical physicians should according to patients' bodies, history and other diagnostic program, to get comprehensive judgment.

### 【THE INTERPRETATION OF TEST RESULTS】

Human error, the processing of specimen, analysis instrument deviation, etc. all can affect the measurement result; When one sample deviates from the expected value too far, need to be tested again.

### 【PERFORMANCE INDEX】

1. Reagent blank absorbance  $\leq 0.3$  (340nm, 1cm optical path).
2. Precision: repeatability CV  $\leq 5\%$ ; batch variations R  $\leq 8\%$ .
3. Accuracy: relative deviation  $\leq 10\%$ .
4. Linearity range: 0~2.50g/L,  $r \geq 0.990$ .
5. Stability: All package reagent, non corrosive gas and avoid light, preservation in 2~8℃, stable 12 months.

### 【ATTENTION】

1. Reagent contains sodium azide (toxic) preservatives, avoid contact with skin and mucous membrane. If necessary preventive measures should be taken use of reagents, reagent contact with skin and mucous membrane, please rinse with water, please go to a doctor if necessary.
2. The maximum linearity is 2.50g/L. If testing results is upper limit, dilute with 0.9% sodium chloride solution before test, results multiplied by the dilution ratio.
3. Liquid waste disposal: Suggest follow local regulations.
4. This specification is applied to the double reagent.
5. Different batches reagents cannot mix, when replacing reagents batch number, please calibration again.

