BIOBASE

Low -density lipoprotein cholesterol (LDL-C) Test Kit

(Direct Method)

【NAME】

Low-density lipoprotein cholesterol (LDL-C) Test Kit (Direct Method)

【INTEND USE】

This reagent is intended for the in vitro quantitative determination of Low-density lipoprotein cholesterol (LDL-C) in human serum. Coronary heart disease and atherosclerosis can be diagnosed by the content of Low-density lipoprotein cholesterol (LDL-C). Precipitated lipid in Atherosclerosis (AS) plaque primarily is LDL. In all kinds of lipids, LDL is considered to the main risk factors, and high density lipoprotein (HDL) may play a protective role. Serum total cholesterol (TC) reflects approximately LDL-cholesterol (LDL-CHO) level, but also affected by HDL-C levels, so in AS lipid risk factors discrimination, if TC is high, the determination of LDL-C has important clinical significance.

【METHODOLOGY】

Polyanion and LDL combine into complex and shelter LDL - C, in serum HDL, VLDL and CM under the effect of surfactants with enzymes reagent have incomplete Trinder reaction, the reaction H2O2 in the absence of coupling agent is consumed without color. When add R2, surfactant containing have a specific effect on LDL can hydrolyze LDL, release the cholesterol, participate in the complete Trinder reaction, determine the absorbance at 546 nm was positively ratio with LDL-C.

【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. do not use EDTA plasma.

Sample stability:-20℃ preservation stability in 1 week .

Do not use the contaminated samples.

【APPLICABLE INSTRUMENT】

Fully automatic biochemical analyzer.

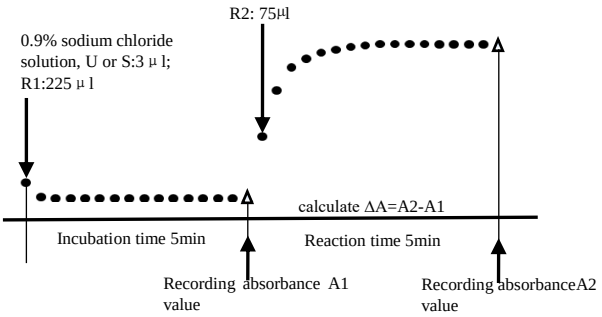
【SYSTEM PARAMETERS】

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

Temperature	37° C
Cuvette light path	1.0cm
Primary Wavelength	546 nm
Secondary Wavelength	700nm
Assay Type	Two Point End
Direction	Increase
Sample : Reagent 1: Reagent 2 Ratio	3:225:75
eg : Sample Vol.	3 μL
Reagent1 Vol.	225 μL
Reagent2 Vol.	75 μL
Linearity	0～11.6 mmol/L
Testing	Deducting the reagent blank

【OPERATION STEPS】

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



【CALCULATION】

$$\text{Sample LDL-C concentration} = \frac{\text{Sample}\triangle\text{Abs}}{\text{Calibrator}\triangle\text{Abs}} \times \text{Calibrator concentration}$$

【REFERENCE RANGE】

1.27～4.13mmol/L（80～120mg/dl）

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】

Low-density lipoprotein cholesterol (LDL-C) testing is just one of the standard that clinicist 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 ≤0.4,(546 nm,lcm optical path).

2.Precision: repeatability CV≤5%;batch variations R≤5%.

3.Accuracy: relative deviation ≤10%.

4.Linearity range: 0～11.6 mmol/L, r≥0.990.

【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.Different batches reagents cannot mix, when replacing reagents batch number, please calibration again.

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