BIOBASE

High-density lipoprotein cholesterol (HDL-C) Test Kit

(Direct Method)

【NAME】

High-density lipoprotein cholesterol (HDL-C) Test Kit (Direct Method)

【INTEND USE】

The reagent is used to test High-density lipoprotein cholesterol (HDL-C) content in human serum or plasma. High-density lipoprotein cholesterol are the main physiological function transfer phospholipids and cholesterol, it is a kind of lipoprotein of atherosclerosis, coronary heart disease is the protection factor, high-density lipoprotein cholesterol levels and the degree of luminal stenosis was significantly negative correlation. Clinically in different kinds of lipoprotein ratio analysis as a different type of high lipoprotein disease in the differential diagnosis. High density lipoprotein abnormalities, found in the following diseases such as coronary heart disease, cerebrovascular disease, diabetes, hepatitis, liver cirrhosis, etc.

【METHODOLOGY】

In Reagent 1 have polyanion and surfactant, make polyanion selectively combine,With VLDL、LDL and restrain COD、CEH have effect on VLDL-CH、LDL-CH in Reagent 2, so selective effects on HDL – CH, through the CEH - COD - POD, testing 546 nm absorbance, and with HDL - C concentrations positively ratio.

【STABILITY AND STORAGE】

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

【SAMPLE REQUEST】

It is best to fresh serum or heparin anticoagulant blood plasma.
Sample stability: 2～8℃ for 3days, -20℃ for two weeks

【APPLICABLE INSTRUMENT】

Fully automatic biochemical analyzer.

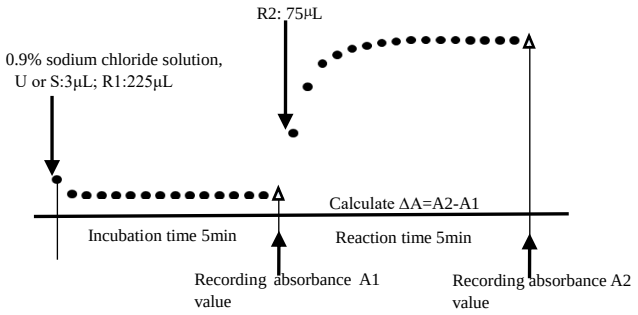
【TESTING SPECIFICATION】

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	3μL
Reagent1 Vol	225 μL
Reagent2 Vol	75 μL
Linearity	0～3.0mmol/L
Testing	Deducting the reagent blank

【OPERATION STEPS】

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



【CALCULATION】

Use the Calibrator

$$\text{Sample HDL-C concentration} = \frac{\text{Sample}\triangle A}{\text{Calibrator}\triangle A} \times \text{Calibrator concentration}$$

【REFERENCE RANGE】

0.77～2.25mmol/L（47～65mg/dl）

By clinical trials, choose no less than 100 women or men 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】

HDL-C testing from serum or plasma 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≤0.15,(546nm,lcm optical path).
2.Precision: repeatability CV≤5%; batch variations R≤8%.
3.Accuracy: relative deviation≤10%.
4.Linearity range: 0～3.0mmol/L, r≥0.990.

【ATTENTION】

1.Reagent contains sodium azide (toxic) preservatives, avoid to touch with skin and mucous membrane. If necessary preventive measures should be taken use of reagents, reagent touch with skin and mucous membrane, please rinse with water, please go to a doctor if necessary
2.This method linearity up limit is 3.0mmol/L. If sample value is more than limit, pls test again by use 0.9% sodium chloride solution to dilute, the result is multiplied the dilution ratio.
3.Application of double reagent method, should not be operated of single reagent method.
4.This reagent is potentially polluting, so should be treated carefully same as the patient samples.
5.Different batches reagents cannot mix, replacing reagents batch number, please calibrator again.

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