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ISO 13485:2016 ISO 9001:2015

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High-Density Lipoprotein Cholesterol (HDL-C) Content

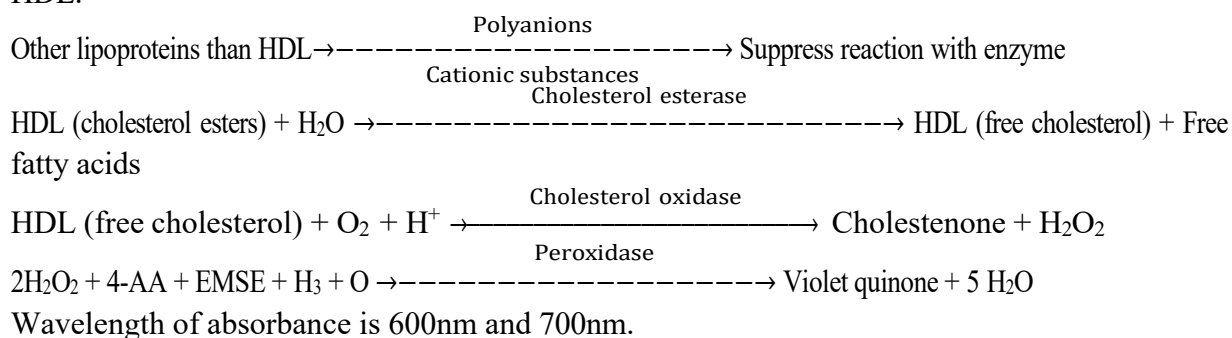
BC5320 (50Tests/48Samples)

FOR RESEARCH USE ONLY, DO NOT USE IT IN CLINICAL DIAGNOSIS

Product Description

Blood total cholesterol levels have long been known to be related to coronary heart disease (CHD). In recent years, in addition to total cholesterol, high density lipoprotein cholesterol (HDL-C) has become an important tool used to assess an individual risk of developing CHD since a strong negative relationship between HDL-C concentration and the incidence of CHD was reported.

The reaction between cholesterol other than HDL and the enzyme for cholesterol assay is suppressed by the electrostatic interaction between polyanions & cationic substances. Hydrogen peroxide is formed by the free cholesterol in HDL by cholesterol oxidase. Oxidative condensation of EMSE and 4-AA is caused by hydrogen peroxide in the presence of peroxidase, and the absorbance of the resulting red-purple Quinone is measured to obtain the cholesterol value in HDL.



Kit components

Reagent	Volume	Storage
Extraction Reagent	1 × 60mL	2-8°C
HDL –C Direct R1	2 × 30mL	2-8°C
HDL –C Direct R2	2 × 10mL	2-8°C
HDL –C Direct Calibrator (Concentration 65mg/dL)	1 × 3mL	2-8°C

Open Vial Stability

Once opened, the reagent is stable up to four weeks at 2-8°C, if contamination is avoided.

Reagent Deterioration

Turbidity or precipitation on in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Qualicheck Norm & Path control may also be an indication of reagent instability and associated results are invalid. Sample should be retested.

Reagent Preparation

The Reagent 1 & Reagent 2 are ready to use.

Calibrator: Reconstitute with 3mL of distilled water. Let it stand for 30minutes at room temperature. Dissolve the content of the vial by swirling gently to avoid the formation of foam.

Precaution

- To avoid contamination, use clean laboratory wares. Use clean, dry disposable pipette tips for dispensing. Close reagent bottles immediately after use.
- Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.

Operation Procedures

Sample Preparation

1. Bacteria or cells

Harvest the cells and wash twice with PBS. Ideal touse5millioncellsfortheassay.Add 1mL Extraction Reagent to 5 million cells and ultrasonicate (200W, work time 3second /interval 10 second repeat for 30 times) for complete lysis. Perform ultrasonication while keeping the cells in ice bath. Centrifuge at 8000 rpm, 4°C for 10 minutes and collect the supernatant. The supernatant should be kept on ice.

Note: Ideal proportion of Cells/Bacteria to Extraction Reagent is 1:5-10.

2. Tissue

Prepare 10% tissue homogenate by adding 1mL Extraction Reagent to 0.1g tissue. Grind completely to make a homogenate. Centrifuge at 8000 rpm, 4°C for 10 minutes and collect the supernatant.

3. Serum or Plasma

Directly use for the assay.

Interferences

No interference for

Bilirubin up to	40 mg/dL
Ascorbic acid up to	50 mg/dL
Haemoglobin up to	500 mg/dL
Triglyceride up to	1000 mg/dL

Materials Required but Not Provided

Pipettes & Tips, Test Tubes & racks, Timer, Incubator, Analyzer

Unit Conversion

Traditional Unit	SI Unit	Conversion from Traditional to SI
mg/dL	mmol/L	x 0.026

Procedure Notes

Reagent	Blank (B)	Calibrator (C)	Sample (S)
Reagent 1	450µL	450µL	450µL
Calibrator	-	5µL	-
Sample	-	-	5µL
Mix & incubate for 5 minutes at 37°C			
Reagent 2	150µL	150µL	150µL
Mix and incubate for 5 minutes at 37°C. Measure the absorbance (OD ₂) at 578nm/630 nm.			

Calculation

ΔA_S = Absorbance of Sample

ΔA_C = Absorbance of Calibrator

HDL-C Concentration (mg/dL) = $A_S \div A_C \times 64$

Calibrator concentration: 64 mg/dL

Performance

Linearity

This reagent is linear up to 150 mg/dL

If the concentration is greater than linearity (150 mg/dL), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

Sensitivity

Lower detection Limit is 1 mg/dL.