Low Density Lipoprotein-Cholesterol (HDL-C) Diagnostic Reagent Kit (Direct-selective Inhibition Method) Product Instruction

Product name

Low density lipoprotein-cholesterol (LDL-C) diagnostic reagent kit (direct-selective inhibition method)
Abbreviation: LDL-C

Package Specifications

R1	R2
60ml×1	20ml×1
45ml×1	15ml×1
60ml×2	20ml×2

Calibrator (lyophilized):
Specification 1 (1.0mL×1; 1 level).

Intended use

LDL-Cholesterol (LDL-C) diagnostic reagent is used for quantitative in vitro determination of LDL-Cholesterol in human serum on photometric systems.

Clinical significance

Numerous clinical studies have shown that the different lipoprotein classes have varied effects. The studies all point to LDL cholesterol as the key factor in the pathogenesis of atherosclerosis and coronary artery disease (CAD), while HDL cholesterol has often been observed to have a protective effect. Even within the normal range of total cholesterol concentrations, an increase in LDL cholesterol can occur with an associated risk for CAD.

Principle

In the cholesterol determination system with the presence of cholesterol lipase (CHER) and cholesterol oxidase (CHOD), a specific surfactant is added to selectively dissolve LDL-C to measure LDL-C. Other lipoproteins (HDL, VLDL, chylomicrons) do not react due to being hindered by surfactants and saccharides, and remain in the form of lipoproteins in the reaction system. Based on this principle, LDL-C can be measured.

$$\text{Cholesterol esters} + H_2O \xrightarrow{\text{Cholesterol esterase}} \text{Cholesterol} + \text{free fatty acids}$$

$$\text{Cholesterol} + O_2 \xrightarrow{\text{Cholesterol oxidase}} \text{Cholestenol} + 4H_2O_2$$

$$H_2O_2 + \text{4-AA} + \text{HDAOS} \xrightarrow{\text{Peroxidase}} \text{Benzoquinone dye} + 5H_2O$$

Main ingredient

Name	Ingredient	Concentration
R1	MES Buffer	50mmol/L
	MgCl2	100mmol/L
	Surfactant	0.3%
	Cholesterol esterase	2.5KU
	Cholesterol oxidase	1.5KU
	Preservative	0.1%
R2	MES buffer	50 mmol/L
	4-Aminoantipyrine	10 mmol/L
	N-(2-Hydroxy-3-sulfo propyl)-3'5-dimethox yaniline sodium salt (HDAOS)	1 mmol/L
	Peroxidase	5 KU/L
	Preservative	0.1%

Storage and stability

This kit stays stable for 18 months when stored in a dark condition at 2-8°C (do not freeze). After being opened for the first time, the kit can be stored at 2-8°C in an anti-pollution environment and stays stable for 14 days.

Specimen preparation

Fresh serum.
2-8°C, stable for 3 days.
-70°C, stable for 3 months.

Assay procedure

1. Reagent preparation

This reagent is liquid and can be used directly.

Main wavelength	600nm	Sample(S)	3μl
Subwavelength	800nm	Reagent 1	225μl
Reation temperature	37°C	Reagent 2	75μl
Cuvette light path	1cm	Reaction type	Two Point End

2. Operation steps

Add to the cuvette:	
Sample (S)	3μl
R1	225μl
Mix well, incubate at 37°C for 5 minutes, then add	
R2	75μl
Mix well, incubate at 37°Cfor 5 minutes, absorbance A1; incubate at 37°Cfor 5 minutes, absorbance A2 △A= A2-A1	

Calculations

$$\text{Conc. of HDL-C} = \frac{A(\text{sample}) - A(\text{blank})}{A(\text{Cal.}) - A(\text{blank})} \times \text{conc. of Cal.}$$

Reference interval
≤3.36mmol/L
It is recommended that each laboratory should establish its own reference interval.

Quality control
The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Performance characteristics
Measuring range
0.8mmol/L - 20.0mmol/L
Samples above this concentration should be diluted 1+1 with 0.9% NaCl solution and the result multiplied by 2.

Interference
The effect of the following substances can be neglected if the concentrations of the following substances are at or below the given values.

Substances	Concentrations
Direct Bilirubin	24mg/dl
Total Bilirubin	16mg/dl
Haemoglobin	500mg/dl
Intralipid	1.6 %
VC	50mg/dl

Automation
Special adaptations for automatic analyzers can be made on request.

General precautions
For in vitro diagnostic use only.
Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.

Precautions for measurement
Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
Reagents with different lot numbers should not be interchanged or mixed.
For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Material safety data sheet available for professional user on request.

Instrument settings

HITACHI	
Model	7180
Assay Code	2 Point End
Reaction Time	10
Assay Point	16-34
Wave Length Sec	800
Wave Length Prim	600
ABS. Limit	32000
Sample Volume（uL）	3
R1 Volume（uL）	225
R2 Volume（uL）	0
R3 Volume（uL）	75
Calibration Type	Linear
Calibration Point	2
Span Point	2
SD Limit	999
Duplicate Limit	1000 或（0%-1000Abs）
Sensitivity Limit	0
Prozone Limit	32000

OLYMPUS 400	
Sample Volume（uL）	3
Sample DIL. VOL.	/
R1 Volume（uL）	225
R2 Volume（uL）	75
Reagent DIL. VOL.	800
Measure Wave 1	600
Measure Wave 2	/
METHOD	END
SLOPE	-
Method Point	9-27
Linear Limit	-
NO LAG TIME	Yes
OD L	-
OD H	-
Reagent OD Limit	
FIRST	-2.0-+2.5
LAST	-2.0-+2.5
Dynamic Range L	0

Dynamic Range H	26.0
Correlation Factor A	1.0
Correlation Factor B	0.0
Calibration Type	AB
Formula	*
STD(1) Conc.#	*
Unit	mmol/L

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