

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

Product name

High Density Lipoprotein-Cholesterol (HDL-C)
Diagnostic Reagent Kit (Direct-selective Inhibition
Method)

Abbreviation: HDL-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

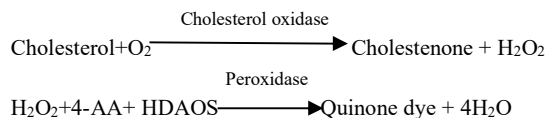
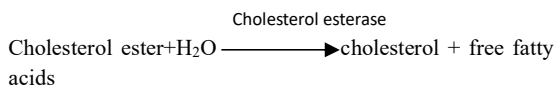
HDL-Cholesterol (HDL-C) diagnostic reagent is used for quantitative in vitro determination of HDL-Cholesterol in human serum on photometric systems.

Clinical significance

High density lipoproteins (HDL) are responsible for the reverse transport of cholesterol from the peripheral cells to the liver. Here, cholesterol is transformed to bile acids which are excreted into the intestine via the biliary tract. Monitoring of HDL-cholesterol in serum is of clinical importance since an inverse correlation exists between serum HDL-cholesterol concentrations and the risk of atherosclerotic disease. Elevated HDL-cholesterol concentrations are protective against coronary heart disease, while reduced HDL-cholesterol concentrations, particularly in conjunction with elevated triglycerides, increase the cardiovascular risk. Strategies have emerged to increase the level of HDL-cholesterol to treat cardiovascular disease.

Principle

The low-density lipoprotein (LDL) and very low-density lipoprotein (VLDL) in the serum are blocked through a chemical reaction, and the esterified high-density lipoprotein cholesterol (HDL) is oxidized by cholesterol oxidase. The generated H₂O₂ reacts with 4-aminoantipyrine and HDAOS to form a quinone dye (Trinder reaction). The dye has maximum light absorption at 600nm, and the color intensity is proportional to the HDL content in the serum.



Main ingredient

Name	Ingredient	Concentration
R1	MOPS Buffer	100mmol/L
	MgCl ₂	10mmol/L
	Triton	5%
	Preservative	0.1%
R2	PBS Buffer	25 mmol/L
	Cholesterol esterase	1 KU/L
	Cholesterol oxidase	1 KU/L
	Peroxidase	4 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	3μl
Subwavelength	800 nm	Reagent 1	225μl
Reaction 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°C for 5 minutes, absorbance A1; incubate at 37°C for 5 minutes, absorbance A2 ΔA= A2-A1	

Calculations

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

Reference interval

≥0.9 mmol/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:

0.2mmol/L - 3.9mmol/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	40mg/dl
Total Bilirubin	40mg/dl
Haemoglobin	500mg/dl
Intralipid	1.6 %

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 or (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	3.9
Correlation Factor A	1.0
Correlation Factor B	0.0
Calibration Type	AB
Formula	*
STD(1) Conc.#	*
Unit	mmol/L

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