High density lipoprotein cholesterol Assay Kit (HDL-C)

Method: Direct

Cat .No.	Size	Instrument
GB130Z	R1: 4×90 ml R2: 2×60 ml	For Hitachi 717& ShimadzuCL7200/8000
GB130Z/S	R1: 2×90 ml R2: 1×60 ml	For Hitachi 717& ShimadzuCL7200/8000
GS131Z	R1: 6×60 ml R2: 2×60 ml	For Hitachi917& OlympusAU640/400/600
GS131Z/S	R1: 3×60 ml R2: 1×60 ml	For Hitachi917& OlympusAU640/400/600
GH131Z	R1: 2×48 ml R2: 2×16 ml	For Hitachi902
GX131Z	R1: 2×60 ml R2: 2×20 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-800
GT131Z	R1: 5×42 ml R2: 2×35 ml	For TOSHIBA
GD131Z	R1:24×4.2 ml R2:12×2.9 ml	For DATE DEMENSION

INTENDED USE

For the *in vitro* quantitative determination of HDL-C in serum.

CLINICAL SIGNIFICANCE

High-density lipoproteins (HDL) are one of the major classes of plasma lipoproteins. They are composed of a number of heterogeneous particles, including cholesterol and vary with respect to size and content of lipid and apolipoprotein. HDL serve to remove cholesterol from the peripheral cells to the liver, where the cholesterol is converted to bile acids and excreted into the intestine. An inverse relationship between HDL-cholesterol (HDL-C) levels in serum and the incidence/prevalence of coronary heart disease (CHD) has been demonstrated in a number of epidemiological studies. The importance of HDL-C as a risk factor for CHD is now recognized[1].Accurate measurement of HDL-C is of vital importance when assessing patient risk from CHD. In this diagnostic test kit a method for direct measurement of HDL-C, without sample pretreatment, is presented. Direct measurement gives improved accuracy and reproducibility when compared to precipitation methods.

ASSAY PRINCIPLE

The direct HDL Cholesterol assay is a homogeneous method for directly measuring serum HDL-C levels without the need for any pretreatment and centrifugation steps. First step, substances with high affinity to LDL, VLDL, and chylomicrons block them involving to enzyme reaction. Second step, special surfactant that selectively accelerates reaction with the enzyme reagent with HDL cholesterol and determining them.

$$\text{HDL-C} \xrightarrow[\text{Cholesterol esterase, oxidase}]{\text{surfactant}} \text{cholestenone} + H_2O_2$$

$$2H_2O_2 + \text{4-AA} + \text{TOD} \xrightarrow{\text{POD}} \text{purple-blue pigment } (\lambda max=585\ nm)$$

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
Buffer (pH6.5)	10 mmol/L
TODB	1 mmol/L
Ascorbate oxidase	3.0 U/ml
PVS	2 mg/L
PEGME	0.2%
$MgCl_2$	2 mmol/L
Reagent 2 (R2)	
Buffer (pH6.5)	10 mmol/L
Cholesterol esterase	4 U/ml
Cholesterol oxidase	10 U/ml
Peroxidase	30 U/ml
4-aminoantipyrine	2.5 mmol/L
Detergent	0.5%

SAMPLE COLLECTION AND PREPARATION

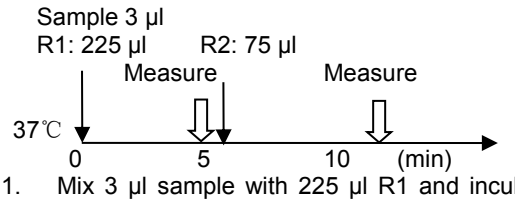
Serum samples or heparin, EDTA plasma samples. Samples may be taken from non-fasting or fasting individuals. Serum samples are stable for 6 day at 2-8℃ or 1 year when stored at -70 ℃.

STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.

ASSAY PROCEDURE

Test Procedure for Analyzers (HITACHI 917)
Assay Mode: 2 Point End, 16-34
Wave length (main/sub): 600 nm/700 nm



1. Mix 3 µl sample with 225 µl R1 and incubate at 37℃ for 5 minutes, then read initial absorbance A_1 at 600 nm.
2. Add 75 µl R2 into cuvette, mix and incubate for 5 minutes at 37℃, read final absorbance A_2.
3. Calculate the absorbance change $\Delta A=A_2-A_1$.

CALIBRATION

Recommend that this assay should be calibrated using Gcell calibrator GC-HDL.

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CALCULATION OF RESULTS

$$\text{Concentration} = \frac{\Delta A_{sample} - \Delta A_{blank}}{\Delta A_{calibrator} - \Delta A_{blank}} \times \text{Calibrator value}$$

QUALITY CONTROL

Gcell or Randox Lipid Control Sera, are recommended for daily quality control. The values for these controls should fall within specified limits. If the control values fall outside these ranges the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUES

≤ 30mg/dl.

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

CONVERSION FACTORS

mg/dl × 0.0259 = mmol/L

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The method is linear up to 2.59 mmol/L. The concentration in sample above this concentration should be diluted with 0.9% NaCl and reassay. Multiply the result by dilution factor.

PRECISION

The CV of this test should be less than 10%.

Intra assay precision			
N=20	Level1	Level 2	Level 3
Mean (mmol/L)	1.32	1.32	2.47
SD	0.06	0.003	0.033
CV(%)	4.51%	0.19%	1.34%
Inter assay precision			
N=3	Batch 1	Batch 2	Batch 3
Mean (mmol/L)	1.35	1.27	1.29
$\bar{x}$	1.30		
(Xmax-Xmin)/$\bar{x}$	(1.35-1.27)/1.30*100=6.14%		

INTERFERENCES

The following analytes were tested up to the levels indicated and found not to interfere:

Ascorbic acid up to 50 mg/dl
Bilirubin up to 20 mg/dl
Hemoglobin up to 500 mg/dl

SAFETY PRECAUTIONS AND WARNINGS

1. For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. Reagents contain Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious(HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

1. National Institutes of Health Consensus Development Conference Statement: Triglyceride, High Density Lipoprotein and Coronary Heart Disease. Washington D. C. Feb 26-28, 1992.
2. Izawa S., Okada M., Matsui H., and Horita Y.J.Medicine and Pharmaceutical Sci., 1385-1388, 37(1997).
3. Shih WJ, Bachorik PS, Haga JA, Myers GL, Stein EA; Clinical Chemistry, 2000; 46:3:351-364.
4. Third Report of the National Cholesterol Education Programme (NCEP) Expert Panel on Detection, Evaluation and treatment of High Blood Cholesterol in Adults(Adult Treatment Panel III). JAMA Publication, Vol 285,No.19, P2486-2497; 2001.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

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