Low density lipoprotein cholesterol Assay Kit (LDL-C)

Method: Direct

Cat .No.	Size	Instrument
GB140Z	R1: 4×90 ml R2: 2×60 ml	For Hitachi 717 & ShimadzuCL7200/8000
GB140Z/S	R1: 2×90 ml R2: 1×60 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS141Z	R1: 6×60 ml R2: 2×60 ml	For Hitachi917 & OlympusAU640/400/600
GS141Z/S	R1: 3×60 ml R2: 1×60 ml	For Hitachi917 & OlympusAU640/400/600
GH141Z	R1: 6×60 ml R2: 2×60 ml	For Hitachi902
GX141Z	R1: 6×60 ml R2: 2×60 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-800
GT141Z	R1: 5×42 ml R2: 2×35 ml	For TOSHIBA
GD141Z	R1:24×4.2 ml R2:12×2.9 ml	For DATE DEMENSION

INTENDED USE

For the *in vitro* quantitative determination of LDL in serum.

CLINICAL SIGNIFICANCE[1, 2]

Low density lipoproteins (LDL) are synthesized in the liver by the action of various lipolytic enzymes on triglyceride rich very-low-density lipoproteins (VLDLs). Specific LDL receptors exist to facilitate the elimination of LDL from plasma by liver parenchymal cells. It has been shown that most of the cholesterol stored in atherosclerotic plaques originates from LDL. For this reason the LDL-Cholesterol concentration is considered to be the most important clinical predictor, of all single parameters, with respect to coronary atherosclerosis.Accurate measurement of LDL-Cholesterol is of vital importance in therapies which focus on lipid reduction to prevent atherosclerosis or reduce its progress and to avoid plaque rupture.In this diagnostic test kit an elimination method for the measurement of LDL-Cholesterol, without sample pretreatment, is presented which correlates well with precipitation and ultracentrifugation methods.

ASSAY PRINCIPLE[3, 4]

The assay consists of 2 distinct reaction steps:

1. Elimination of chylomicron, VLDL-Cholesterol and HDL-Cholesterol by cholesterol esterase, cholesterol oxidase.

$$\text{Cholesterol ester} \xrightarrow{\text{Cholesterol esterase}} \text{Cholesterol+ Fatty Acid}$$

$$\text{Cholesterol} + O_2 \xrightarrow{\text{Cholesterol oxidase}} \text{Cholestenone} + H_2O_2$$

2. Specific measurement of LDL-Cholesterol after release of LDL-Cholesterol by detergents in Reagent 2.

$$\text{Cholesterol ester} \xrightarrow{\text{Cholesterol esterase}} \text{Cholesterol + Fatty Acid}$$

$$\text{Cholesterol} + O_2 \xrightarrow{\text{Cholesterol oxidase}} \text{Cholestenone} + H_2O_2$$

$$2H_2O_2 + \text{4-AA} + \text{TODB} \xrightarrow{\text{Peroxidase}} \text{Quinone pigment} + 4H_2O$$

The intensity of the quinoneimine dye produced is directly proportional to the cholesterol concentration when measured at 600 nm.

SAMPLE COLLECTION AND PREPARATION[5]

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

REAGENT COMPOSITION

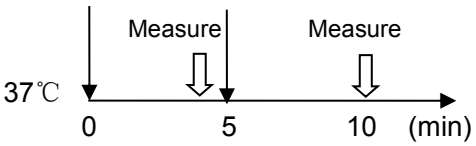
Contents	Concentration of Solutions
Reagent 1 (R1)	
Goods buffer	10 mmol/L
Cholesterol esterase	5 KU
Cholesterol oxidase	5 KU
Peroxidase	20 KU
4-aminoantipyrine	0.5 g/L
$MgCl_2$	2 mmol/L
Detergent	0.5 g/L
Preservative	0.5 g/L
Reagent 2 (R2)	
Goods buffer	10 mmol/L
TODB	2 mmol/L
Detergent	1%
Preservative	0.5 g/L

STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.
Once opened the reagent is stable for 1 month on-board the analyser at approximately 2-8°C.

ASSAY PROCEDURE

Test Procedure for Analyzers (HITACHI 7170/917)
Assay Mode: 2 Point End, 16-34
Wave length (main/sub): 600 nm/700 nm
Sample: 3 µl
R1: 225 µl R2: 75 µl



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 $\Delta A = A_2 - A_1$.

CALCULATION

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

CALIBRATION

Beijing Strong Biotechnologies, Inc.
Add: 5/F Kuang Yi Building, No.15 Hua Yuan Dong Lu, Haidian District, Beijing 100191 P. R. China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812

Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn

CE version 10 APR 2017

Recommend that this assay should be calibrated using Gcell calibrator (Cat .No. GC-HDL/LDL).
the calibrator trace to the international reference material NIST 1951b.

MATERIALS REQUIRED BUT NOT PROVIDED

Randox Lipid Control: Level 1 LE 2661
Level 2 LE 2662
Level 3 LE 2663

QUALITY CONTROL

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 VALUE

Normal: ≤ 3.35 mmol/L (129 mg/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 × 0.0258 = mmol/L

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The method is linear up to 18 mmol/L. Sample above this concentration should be diluted with 0.9% NaCl and reassay. Multiply the result by dilution factor.

PRECISION

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

Intra assay precision			
N=20	Level 1	Level 2	Level 3
Mean (mmol/L)	2.66	3.64	5.88
SD	0.02	0.03	0.09
CV	0.80%	0.71%	1.48%
Inter assay precision			
N=5	Level1	Level 2	Level 3
Mean (mmol/L)	2.62	4.15	5.77
SD	0.03	0.03	0.06
CV	1.06%	0.73%	1.08%

SENSITIVITY

The sensitivity of the assay is 0.03 mmol/L.

INTERFERENCE

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

Ascorbic acid: 50mg/dl
Bilirubin: 20mg/dl
Hemoglobin: 500mg/dl
Intralipid: 500mg/dl

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:
y=1.0116x , and a correlation coefficient of 0.9978
57 patient samples were analyzed.

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. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES

1. Naito H.K.,et al, Clin Chem, 41: 132-133,1995.
2. Seidel D., et al, Internist, 28: 606-314,1987
3. Weiland H. and Seidel D., J Lip Res, 24: 904-909,1983.
4. Friedewald W.F., et al, Clin Chem, 18:499-502,1972.
5. Clinical Laboratory Diagnostics: Use and Assesment of Clinical Laboratory Results:First Edition T-H Books, Germany; p 172.

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

Manufacture：Beijing Strong Biotechnology, Inc.
Address： No. 15, Yanqi North Second Street, Yanqi Economic Development Area, Huairou District, Beijing 101400, P. R. China
Tel：+86 10 61667168

EC REP :Lotus NL B.V.
Address：Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
E-mail：peter@lotusnl.com
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