CE IVD

LDL-C Reagent Kit-2 (Direct Method)

Instructions for Use

REF CC1056

PRODUCT NAME

LDL-C Reagent Kit-2 (Direct Method)

PACKAGE SPECIFICATION

R1: 1×15mL	R2: 1×5mL	R1: 1×30mL	R2: 1×10mL
R1: 1×30mL	R2: 1×12mL	R1: 1×45mL	R2: 1×15mL
R1: 1×60mL	R2: 1×20mL	R1: 2×30mL	R2: 2×10mL
R1: 2×45mL	R2: 2×20mL	R1: 2×55mL	R2: 2×20mL
R1: 2×60mL	R2: 1×40mL	R1: 2×60mL	R2: 1×45mL
R1: 2×60mL	R2: 2×20mL	R1: 2×90mL	R2: 1×60mL
R1: 3×40mL	R2: 3×15mL	R1: 4×30mL	R2: 2×20mL
R1: 4×45mL	R2: 2×30mL	R1: 4×45mL	R2: 4×15mL
R1: 4×55mL	R2: 4×20mL	R1: 4×60mL	R2: 2×40mL
R1: 4×60mL	R2: 2×45mL	R1: 4×60mL	R2: 4×20mL
R1: 4×90mL	R2: 2×60mL	R1: 6×250mL	R2: 6×97mL
500T (R1: 1×80mL R2: 1×28mL)			
2×230T (R1: 2×60mL R2: 2×20mL)			
12×52T (R1: 12×16.8mL R2: 12×5.8mL)			

INTENDED USE

This reagent kit is intended for the *in vitro* quantitative determination of low-density lipoprotein cholesterol concentration in human serum and plasma.
Clinically, it is mainly used for the auxiliary diagnosis of hypercholesterolemia, coronary heart disease, and atherosclerosis.
For professional and laboratory use.

TEST PRINCIPLE

[Reaction 1]

$$HDL + VLDL + CM \xrightarrow{Surfactant} Micronized\ cholesterol \xrightarrow{CE.CO} H_2O_2$$

$$H_2O_2 + 4\text{-}AAP \xrightarrow{POD} Colorless$$

$$LDL \xrightarrow{Surfactant} LDL\ (soluble)$$

[Reaction 2]

$$LDL \xrightarrow{Surfactant} Micronized\ cholesterol \xrightarrow{CE.CO} H_2O_2$$

$$H_2O_2 + 4\text{-}AAP + ESPMT \xrightarrow{POD} Color\ reaction$$

As each type of lipoprotein has different physicochemical properties and reacts differently with surfactants, this reagent kit uses two surfactants. In reaction 1, the surfactant alters the structure of lipoproteins other than low-density lipoprotein cholesterol (LDL), such as chylomicron (CM), very low-density lipoprotein cholesterol (VLDL), and high-density lipoprotein cholesterol (HDL), and reacts with cholesterol oxidase and cholesterol esterase. LDL does not participate in the reaction, whereas CM, VLDL, and HDL do. Thus, lipoproteins other than LDL are eliminated under the action of the surfactant. In reaction 2, the surfactant promotes the enzymatic reactions of lipoproteins. LDL that was not eliminated in reaction 1 produces a color-presentation reaction in the presence of the surfactant.

MAIN COMPONENTS

Kit composition	Reagent components	Content
Reagent 1	Piperazine-1,4-bis (2-ethanesulfonic acid)	11 g/L
	Cholesterol oxidase	5 KU/L
	Cholesterol esterase	3 KU/L
	Tween-80	10 mL/L
	Peroxidase	3 KU/L
Reagent 2	Piperazine-1,4-bis (2-ethanesulfonic acid) (pH7.0)	11 g/L
	TritonX-100	10 mL/L
	4-Aminoantipyrine	0.5 g/L
	N-Ethyl-N-(3-propylsulfonyl)-3-methylaniline	0.3 g/L

The components in different batches of a multi-component kit are not interchangeable.
Calibrator traceability: traceable to National Reference Material GBW09180b.

STORAGE AND SHELF LIFE

The unopened reagents are stable for a shelf life of 18 months when stored away from direct sunlight at 2-8°C. Opened reagents are stable for 42 days when stored at 2-8°C.
Refer to the label on the reagent kit for the manufacturing date and the expiry date.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

Serum and plasma should be stored for 1 days at 15-25°C, for 7 days at 2-8°C and for 12 months at -20°C.

TEST PROCEDURE

1. The dual reagent is ready for use directly.
2. Test conditions:

Primary/Secondary Wavelength	546 nm/660 nm	**Calibration Type**	Linearity
Sample/R1/R2	3/300/100 μL	**Time of Mixture of Serum and R1**	5min
Method	Two-point endpoint method	**Reaction time after addition of R2**	5min
Calibration Method	Two-point calibration	**Direction**	Upward

Operating procedures:
Operation using two reagents

Temperature	37˚C
Sample	3 μL
Reagent 1	300 μL
Mix well, incubate at 37˚C for 5min, and read the absorbance A_0 of each tube	
Reagent 2	100 μL
Mix well, incubate at 37˚C for 5min, read the absorbance A_1 of each tube, and calculate $\Delta A = A_1 - A_0$	

3. Calibration procedure: A calibrator from Getein is recommended, and a calibration serum from Randox can also be used.
4. Quality control procedure: Use the quality control serum from Randox, and its measured value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:
   4.1 Check whether the parameter settings and light source are correct.
   4.2 Check whether the cuvettes and sample probes are clean.
   4.3 Check whether water is contaminated, and bacterial growth will cause incorrect results.
   4.4 Check reaction temperature.
   4.5 Check the expiration date of the kit.
5. Result calculation
   LDL Concentration (mmol/L) = LDL standard concentration × $\triangle A_{test\ sample}$ / $\triangle A_{standard}$

REFERENCE RANGE

	Total Cholesterol	LDL-cholesterol
Normal Value Range of Cholesterol	≤ 5.17 mmol/L	≤ 3.10 mmol/L
Critical Value Range of Cholesterol	5.17 - 5.68 mmol/L	3.10 - 3.61 mmol/L
Hypercholesterolemia	≥ 5.69 mmol/L	≥ 3.62 mmol/L

The provided reference range is for reference only, and it is recommended that each laboratory establish its own reference range.

RESULT INTERPRETATION

Hemolysis can interfere with the measurement, and it should be avoided during the operation.
The storage duration of the sample can also affect the measurement results.

LIMITATIONS

There is no interference with the measurement when hemoglobin is ≤ 500 mg/dL, ascorbic acid is ≤ 20 mg/dL, bilirubin is ≤ 20 mg/dL and triglycerides is ≤ 500 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Reagent 1 in the kit is a colorless or slightly yellow clear liquid, which may contain a small number of insoluble particles that do not affect determination. Reagent 2 is a colorless or slightly yellow clear liquid, which may contain a small number of insoluble particles that do not affect determination.
2. Reagent blank absorbance
   Test with a blank sample added to the reagent, and the reagent blank absorbance A_{546nm} < 0.05.
3. Accuracy
   The relative deviation should be within ± 10%.
4. Linear Range
   Linear correlation coefficient (r) should be ≥ 0.995 in the range of [0.05, 11.6] mmol/L.
   a) Within the range of [0.05, 1] mmol/L, the linear absolute deviation should not exceed ± 0.2 mmol/L;
   b) Within the range of (1, 11.6] mmol/L, the linear relative deviation should not exceed ± 10%.
5. Analytical sensitivity
   When testing a 1.00mmol/L sample, the absorbance difference (ΔA) should be > 0.03.
6. Precision
   6.1 Repeatability
   When repeatedly testing samples with concentrations of (2.50 ± 0.50) mmol/L and (5.00 ±1.00) mmol/L, the coefficient of variation (CV) of results should not be greater than 3%.
   6.2 Between-run precision
   When testing a (2.50 ± 0.50) mmol/L sample, the relative range (R) between batches should not be greater than 10.0%.

PRECAUTIONS

1. General precautions
   1.1 This product is for *in vitro* diagnostic use only.
   1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
   1.3 Please use this product according to the user manual.
2. Precautions for operation
   2.1 Treat the specimens as dangerous materials that may cause infection with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
   2.2 If the reagents get into the eyes or mouth, or touch the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
3. Precautions for use
   3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
   3.2 Please do not use expired reagents whose test results may be inaccurate.
   3.3 Please avoid adding reagents halfway during a test.
   3.4 Please avoid direct sunlight during operation.
   3.5. Avoid using the reagent if it displays any signs of turbidity.
4. Precautions for waste disposal
   Samples, waste liquids, etc. are potentially biologically hazardous. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
   5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
   5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
   5.3 Please do not use the reagent bottles for other purposes.
   5.4. A result calculated with the k value is not as reliable as that obtained using the calibration result.
   5.6 Please do not mix reagents in different batches.

REFERENCE

Shang Hong, et al. National Standard Operating Procedure for Clinical Testing (4th Edition). People's Medical Publishing House, 2015: 323-326.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on the reagent kit are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

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