BIOGENIX
INC. PVT. LTD.

Direct LDL Cholesterol Assay （Clearance）

Cat.No.	Contents	ROCHE HITACHI 902/911/912/917/ COBAS/ MODULAR P	BECKMAN COULTER AU400/560/600/2700/5400	ABBOTT ARCHITECT c4000/c8000/c16000	SYSMEX 180
000020248 000025748	R1：60ml×4 R2：20ml×4 Calibrator：1ml×1	•	•	•	•
		TOSHIBA TBA-40/120 FR	MINDRAY BS120/200/300/380/400	URIT 200/8020/8030/8060	BIOSINO ZS200/ZS310/320/330 /ZS400/ZS800
		•	•	•	•

●Indicates analyzer(s) on which kit(s) can be used.

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【Intended Use】

In vitro test for the quantitative determination of low-density lipoprotein cholesterol (LDL-C) in human serum from adults on automated clinical chemistry analyzers for clinical laboratories.

【Summary and Explanation】

Lipoproteins are spherical-shaped particles that contain varying amounts of cholesterol, triglycerides, phospholipids and proteins. The relative amounts of the protein and lipid constituents determine the density of the lipoprotein particles. The studies all point to low-density lipoprotein (LDL) cholesterol as the key factor in the pathogenesis of artherosclerosis and coronary artery disease (CAD). Even within the normal range of total cholesterol concentrations, an increase in LDL cholesterol can occur with an associated risk for CAD.

【Principle】

1. The LDL complexes with polyanion. The detergent 1 in Reagent 1 is soluble only in the non-LDL lipoprotein particles (CM、HDL、VLDL). The cholesterol released will be used up by enzymatic reagent and be in a non-color forming reaction without the chromogenic coupler.
2. The cholesterol released from LDL-C by detergent 2 in Reagent 2 reacts with chromogenic coupler for the color formation. .

【Components】

Reagent	Component	Concentration
R1	Detergent 1 Cholesterol esterase (CE) Cholesterol oxidase (COD) Peroxidase (POD) MES (pH=6.5)	0.5% ≥800U/L ≥400U/L ≥5000U/L 100mmol/L
R2	Detergent 2 MES (pH=6.5)	2% 100mmol/L
Calibrator	LDL-C	106.10mg/dL

【Storage and Stability】

1. Unopened reagent: stable for 12 months at 2～8℃, protect from light.
2. Opened reagent: stable up to 30 days at 2～8℃, protect from light.
3. Unopened calibrator: stable for 36 months at 2～8℃, protect from light.
4. Dissolved calibrator: stable for 5 days at 2～8℃, sealed, protect from light.

【Specimen Collection and Handling】

Only the specimens listed below were tested and found acceptable.

For specimen collection and preparation, only use suitable tubes or collection containers.

Specimen: Serum samples on an empty stomach are the recommended specimens.

Serum: Collect fresh serum using standard sampling tubes. If processing samples in primary tubes, follow the instructions of the tube manufacturer.

For samples with Absorbance interference, including samples of hemolysis and turbidity, may affect the test results. Sample recollection is recommended.

Stability：Store serum less than 7 days at 2～8℃, 1 month at -20℃～-15℃. Protected from light and avoid repeated freeze thaw cycles.

Centrifuge samples containing precipitate before performing the assay.

【Procedure】

Reaction type: Endpoint

Reagent preparation:

R1: Ready for use; R2: Ready for use.

Wavelength：600nm (540～620nm)

Temperature：37℃

Cuvette: 1cm

	Blank tube	Calibrator tube	Sample tube
Sample	—	—	0.003ml
Calibrator	—	0.003ml	—
Deionized water	0.003ml	—	—
R1	0.3ml	0.3ml	0.3ml
Mix well separately, incubate at 37℃ for 5 minutes, read the absorbance A.			
R2	0.1ml	0.1ml	0.1ml
Mix well separately, incubate at 37℃ for 5 minutes, read the absorbance A again, set zero for blank tube, calculate the $\triangle A_{calibrator}$ and $\triangle A_{sample.}$			

Calibration Calibration

Traceability: This method has been standardized against the a secondary reference material（SRM1951）.

Use Biogenix Direct LDL Calibrator (inside the kit) for calibration.

Calibration Period: 30 days.

Recalibration is recommended:

- as reagent lot changes
- as quality control drifts
- after the analyzer maintenance or change the spare parts

Calibration verification: Not necessary

Quality control

It is recommended to use Sekisui control or Roche PreciControl ClinChem Multi 1 and 2 for daily quality control.

Two levels of controls should be assayed at least once a day.

Values obtained should fall within a specified range.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Calculation：

The analyzer automatically calculates the analyte concentration of each sample.

D-LDL-C Conc. = $\Delta A_{sample}/ \Delta A_{calibrator} \times C_{calibrator}$

【Expected Value】

Middle-aged and elder people	2.7~3.1 mmol/L	105~120 mg/dl
Expected values	＜3.12 mmol/L	＜120 mg/dl
Verge level	3.15～3.61 mmol/L	121～139 mg/dl
Increase	＞3.64 mmol/L	＞140 mg/dl

The reference range should be determined by each laboratory based on the characteristics of the region being tested.

【Limitations and Interference】

1. Lipemia (Intralipid): no interference up to 250mg/dl.
2. Hemolysis: no interference up to 1000mg/dl.

3. Vc: no interference up to 50mg/dl.
4. Bilirubin: no interference up to 10mg/dl.
The result may vary with different analyzers or calibrations. For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

【Performance Characteristics】

The following performance data was obtained using analyzer at 37℃. Results obtained in individual laboratories may differ.

Reagent blank absorbance A≤0.08

Accuracy ≤±10%

Measuring range

0.3mmol/L～10.34mmol/L (12mg/dl～400mg/dl)

Determine the samples with higher concentrations via the rerun function.

Analytical sensitivity

2.59mmol/L(100mg/dl) LDL-C（ΔA: 0.080～0.350)

Precision

Within Run Precision≤5%

Between Run Precision≤5%

Method comparison

The method (Y) was compared to another commercially availavle method (X). 64 patient samples with values spanning the range 17.7 to 368.6 mg/dl were subjected to linear regression analysis giving the following equation:
Y= 0.954x+3.713 with a correlation coefficient r=0.995

【Precautions and Warnings】

1. For in vitro diagnostic use.
2. Avoid skin and eye contact. Avoid ingestion.
3. Disposal of the used material in accordance with local guidelines. Avoid pollution and reuse.
4. Do not use the product if interior package is damaged during shipment.
5. The possibility of reagent instability or deterioration may be considered if there is precipitation, visible exudate, turbidity, microorganism growth, calibration results do not meet the appropriate standard specification, or control values out of range.
6. Exercise the normal precautions required for handling all laboratory reagents.
7. Wear protective clothing and disposable gloves while handling the kit reagents.
8. Wash hands thoroughly after performing the test.
9. Use in ventilated area.
10. For acids, include appropriate warnings for spills such as "wipe up spills immediately and flush with water" and "should the reagent contact eyes or skin, flush with copious amounts of water and consult a physician".
11. For biological spills, indicate appropriate disinfectants and disinfection procedure.
12. Dispose of all specimens and components of the kit as potentially infectious agents.
13. Do not use the kit or any kit component past the indicated expiry date.
14. Do not use any other reagents from different lots in this test, unless the reagent is designated to be used with other lots of the same kit.
15. Avoid microbial contamination of reagents.
16. The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

【Definition of Symbols】

USE BY (LAST DAY OF THE MONTH)	
BATCH CODE	
DATE OF MANUFACTURE	
TEMPERATURE LIMITS	
CONSULT INSTRUCTIONS FOR USE	
HANDLE WITH CARE	
UPWARDS LAY	
KEEP DRY	
KEEP AWAY FROM SUNLIGHT	
IN VITRO DIAGNOSTIC MEDICAL DEVICE	
CATALOGUE NUMBER	
SUFFICIENT FOR	
MANUFACTURER	

【Bibliography】

1. Castelli, W.P. et al., Circulation, 1977;55:767
2. National Institute on Health publication No. 93-3095, September 1993.
3. Kannel, W.B. et al, Am. Intern. Med., 1979;90:85.

【Manufactured By:】

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