LDL DIRECT CHOLESTEROL

En

REF 02R05-31 3130 Tests
REF 02R05-21 1532 Tests

FOR USE WITH
ARCHITECT

Test for the quantitative determination of LDL-Cholesterol in human serum.
Liquid. Dual reagents. Store at 2°C - 8°C. Do not freeze. For in Vitro Diagnostic Use.

02R05-31 / 02R05-21 Ref Number Products are Produced Specifically for Abbott Architect Chemistry Analyzer Series.
Note: REF 02R05-21 is not available in Poland.

INTENDED USE

The test is applied for the quantitative determination of LDL (Low Density Lipoprotein)-cholesterol in human serum.

TEST PRINCIPLE

The assay consists of distinct reaction steps:

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-colour 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 colour formation.

TEST PARAMETERS

Method	: Colorimetric
Wavelength	: Main: 604 – 700 nm
Temperature	: 37 °C
Sample	: Serum.
Linearity	: 5-600 mg/dL

REAGENT COMPOSITION

Reagent 1:
Polyanion detergent 1

Cholesterol esterase	:	≤ 200.000 U/L
Cholesterol oxidase	:	≤ 200.000 U/L
Peroxidase	:	≤ 200.000 U/L

4-aminoantipyrine
TOOS

Reagent 2:
Detergent 2
TOOS
Tris Buffer

REAGENT PREPARATION

Reagents are ready to use, liquid.

REAGENT STABILITY AND STORAGE

On board stability:
Once opened vials are stable 30 days at 2-8ºC at optimum conditions. There is a strong relation between on board stability and auto analyzer's cooling specification and carry-over values.
Store at 2-8ºC. Reagents are stable until the expiry date stated on the label when stored in closed vials and avoiding contamination during their usage.
Indications of deterioration:
Reagent blank OD values ≥ 0.3.

SAMPLE[2]

Samples: Fresh Serum on an empty stomach is the recommended specimen.

Note: Separate the serum as soon as possible after collection (within 3 hours). Store serum no more than 12 hours at room temperature, no more than 7 days at 2-8 ºC. Serum is stable for 30 days at (-60)-(-80) °C. [7, 8]

PROCEDURE

Materials Provided
LDL Direct Cholesterol, REF 02R05-31 or REF 02R05-21

Materials Required but not Provided
Archem Lipids (HDL-LDL) Calibrator
REF**:** 01R95-01

REFERENCE INTERVALS (NORMAL VALUES)

Optimal	: < 100 mg/dL (< 2.59 mmol/L)
Near optimal, above optimal	: 100 – 129mg/dL (2.59 – 3.34 mmol/L)
Borderline high	: 130 - 159 mg/dL (3.37 – 4.12 mmol/L)
High	: 160 – 189 mg/dL (4.14 – 4.89 mmol/L)
Very high	: ≥ 190 mg/dL (≥ 4.92 mmol/L) [14, 15]

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

QUALITY CONTROL

Commercially available control material with established values determined by this method may be used.

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

CALIBRATION

Calibrator:

Lipids HDL/LDL Calibrator (Standard) **REF: 01R95-01**

Calibration Stability:
Calibration stability is 30 days in ARCHITECT c Systems.

Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low Linearity (LOQ) (LOQ values are based on CV% ≤ 20%): 5 mg/dL.

High Linearity: The test is linear up to 600 mg/dL.

Precision Studies (Based on CLSI EP05A3):

Repeatability (within run)(intra-assay):

Mean conc.	SD	CV	N
35.9 mg/L	0.32	0.89 %	20
58.5 mg/L	0.81	1.39 %	20

Reproducibility (day to day) (inter-assay)

Mean conc.	SD	CV	N
55.3 mg/L	2.19	3.96 %	80
184.2 mg/L	8.09	4.39 %	80

Correlation: Correlation with a reference reagent is: r=0.985 (Range 19.5 mg/dL to 153.2 mg/dL)
According to Passing-Bablok Fit:
Slope: 0.96
Intercept: 1.6
Sensitivity (LOD): 4.5 mg/dL.

Interferences: [1]

The acceptable interference limit is set 10% below the highest interferent concentration that is within ±10% recovery of the target.

Hemoglobin up to 6.3 g/L, bilirubin up to 13.5 mg/dL, lipemia (Triglycerides) up to 2250 mg/dL do not interfere. Other drugs and substances may interfere.

Significant interference may be observed with hemolyzed samples. Reference observed results in the table below. [10, 11]

Interferent and Concentration	LDL Direct Cho.Target (mg/dL)	N	Observed Recovery %
Bilirubin Total 15 mg/dL	48.7	3	92
	70.2	3	108
Triglyceride 2500 mg/dL	47	3	101
	98.5	3	98
Hemoglobin 7 g/L	44.4	3	109
Hemoglobin 10 g/L	104	3	108

The effect of interfering substances has only been evaluated for those listed in this labeling.

An analyzer has been used to obtain these performance characteristics. Usage of different analyzer or a manual procedure may cause the variance in results.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1&R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The reagents contain sodium azide (< 0.1%) as a preservative.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general GLP guidelines.
R32: Contact with acids liberates very toxic gas.
EUH032: Contact with acids liberates very toxic gas.
H300: Fatal if swallowed
H400: Very toxic to aquatic life

H410: Very toxic to aquatic life with long lasting effects.
Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
NCEP : National Cholesterol Education Program
IU : International Unit
mL : milliliter
QC : Quality Control
mg : milligram
L : liter
g : gram
dL : deciliter

REFERENCES

1. Young DS. Effects of drugs on clinical laboratory tests, 4th ed. AACC Press, 1995.
2. Tietz NW. Clinical guide to laboratory tests, 2nd ed. Saunders Co, 1991.1988;26:783-790
3. Rifai N, Warnick GR, McNamara JR, Belcher JD, Grinstead GF, Expected Values Handbook of Laboratory Medicine, Li-hua Zhu 1998
4. Frantz Jr ID. Measurement of Low-Density-Lipoprotein Cholesterol in Serum: a Status Report. Clin Chem 1992;38:150-160.
5. Kannel, W.B., Castelli W.P., Gordon, T., Cholesterol in the Prediction of Artheriosclerotic Disease; New Perspectives Based on the Framingham Study, Am. Intern. Med., 90:85 (1979).
6. Bachoric P. Measurement of Low-Density-Lipoprotein. 245-263. In: Handbook of Lipoprotein Testing (eds. Rifai, Warnick and Dominiczak), 2nd edition, AACC press, 2000.
7. Stability study of 81 analytes in human whole blood, in serum and in plasma Christiane Oddoze , Elise Lombard, Henri Portugal Clinical Laboratory, Department of Clinical Biology, CHU Timone, Marseille, France.
8. Effect of Storage Time and Temperature on some Serum Analytes Ahmed M Dirar, Daleel A Abdallah and Kamal Eldin A Abdelsalam. International Journal of Pathology; 2010; 8(2): 68-71
9. National Committee for Clinical Laboratory Standards, National Evaluation Protocols for Interference Testing, Evaluation Protocol Number 7, Vol. 4, No. 8, June 1984.
10. Wieland H, Seidel D. Quantitative Lipoprotein Electrophoresis. In: Handbook of Electrophoresis, Vol III, ed. Lewis A., Boca Raton: CRC Press, 83-102, 1983.
11. Westgard, J.O., Carey, R.N., Wold, S., Criteria for judging precision and accuracy in method development and evaluation. Clinical Chemistry 1974:20:825-833.
12. Armstrong V, Seidel D. Evaluation of a Commercial Kit for the Determination of LDL-Cholesterol in Serum Based on Precipitation of LDL with Dextran Sulfate. Ärztl. Lab. 1985;31:325-330.
13. National Institutes on Health Publication no. 93-3095, September 1993.
14. 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 2001;285:2486-97.
15. Tietz Fundamentals of Clinical Chemistry and Molecular Diagostics, 7th Edition Page:405(ELSEVIER) Editors:Carl A. Burtis,Ph.D.(Author) 2015 By Saun.

SYMBOLS

IVD	In Vitro Diagnostic Medical Device
LOT	Lot number
R1	Reagent 1
R2	Reagent 2
GTIN	Global Trade Item Number
REF	Reference Number
GLP	Good Laboratory Practices
FOR USE WITH	Identifies products to be used together
PRODUCT OF TURKEY	Product of Turkey
	Manufacturer
	Expiration date
	Temperature limitation
	Consult instructions for use
	Caution
	Sufficient for

Archem Diagnostics Industry LTD.ŞTİ.
Organize Sanayi Bölgesi, Mutsan Sanayi Sitesi
M8 Blok No: 48 34490 ISTANBUL TURKEY
Tlf: + 90 212 444 08 92
Fax: +90 212 629 98 89
info@archem.com.tr
www.archem.com.tr