LDL CHOLESTEROL (2-8°C)

(DIRECT WITH CALIBRATOR)

CATALOGUE NUMBER	KIT SIZE (mL)
MPRLDL5	1x60ml / 1x20ml / 1x3ml

Intended Use:

For ***In Vitro*** diagnostic use by professionals only.

This reagent is intended for the quantitative determination of LDL Cholesterol in human serum or plasma.

Clinical Significance:

Low Density Lipoproteins (LDL) play a key role in causing and influencing the progression of atherosclerosis and coronary sclerosis in particular. The LDLs are derived from VLDLs (Very Low Density Lipoproteins) rich in triglycerides by the action of various lipolytic enzymes and are synthesized in the liver. The elimination of LDL from plasma takes place mainly by liver parenchymal cells via specific LDL receptors.

Elevated LDL concentrations in blood and an increase in their residence time coupled with an increase in the biological modification rate results in the destruction of the endothelial function and a higher LDL-cholesterol uptake in the monocyte / macrophage system as well as by smooth muscle cells in vessel walls. The majority of cholesterol stored in atherosclerotic plaques originates from LDL. The LDL-cholesterol value is the most powerful clinical predictor among all of the single parameters with respect to coronary atherosclerosis. Therefore, therapies focusing on lipid reduction primarily target the reduction of LDL-cholesterol which is then expressed in an improvement of the endothelial function, prevention of atherosclerosis and reducing its progression as well as preventing plaque rupture.

Test Principle:

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

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

$$2H_2O_2 + \text{4-AA} + \text{HDAOS} \xrightarrow{\text{Peroxidase}} \text{Quinone Pigment} + 4\,H_2O$$

Reagent Composition

REAGENT	COMPONENT	CONCENTRATION
Reagent R1	Buffer pH 7.0	100 mmol/l
	HDAOS	0.9 mmol/l
	Dextran Sodium Sulphate	1 mg/dl
	Ascorbate Oxidase	3000 U/l
Reagent R2	Buffer	100 mmol/l
	Cholesterol Esterase	4700 U/l
	Cholesterol Oxidase	930 U/l
	POD	20 kU/l
	4 Amino Antipyrine	2.5 mmol/l
HDL / LDL Calibrator	HDL / LDL	Lot Specific – Value on vial label

Reagent Preparation and Stability:

R1: Liquid, ready to Use

R2: Liquid, ready to Use

Calibrator: Reconstitute with 3 ml distilled/deionised water and stand for 30 minutes. Swirl gently to mix.

R1 and R2 are stable to the stated expiry date when stored unopened at 2 - 8°C and protected from light.

Dispose of reagents carefully in line with local guidelines.

Sample Collection, Preparation and Stability:

Collect serum and heparin or plasma by standard venepuncture technique. Stable up to 6 days at 2 - 8°C and 1 month at -20°C.

Assay Procedure:

WAVELENGTH	600 (578 – 620) nm
TEMPERATURE	37°C
CUVETTE	1cm Path Length
BLANK	Reagent Blank

	Calibrator	Sample
Sample	-	3 µl
Calibrator	3 µl	-
Reagent R1	225 µl	225 µl
Mix, incubate for 5 minutes at 37 °C, then read Absorbance 1 (Abs 1)		
Reagent R2	75 µl	75 µl
Mix, incubate for 5 minutes at 37 °C, then read Absorbance 2 (Abs 2)		

ΔAbs = A2 – A1

Calculation:

$$\text{LDL Concentration} = \frac{\Delta\text{Abs Sample}}{\Delta\text{Abs Calibrator}} \times \text{Concentration of Calibrator}$$

Conversion Factor: mg/dl x 0.0259 = mmol/l

Performance Characteristics:

Measuring range:

0.13 to 6.48 mmol/l (5 - 250 mg/dl)

Dilute samples with higher concentrations using Normal saline 1+1 and rerun the assay. Multiply the result by the dilution factor (2).

Imprecision

Intra-Assay Precision:

Sample	Mean (mmol/l)	SD (mmol/l)	CV %
Level 1	2.66	0.02	0.80
Level 2	5.88	0.09	1.48

Inter-Assay Precision:

Sample	Mean (mmol/l)	SD (mmol/l)	CV %
Level 1	2.62	0.03	1.06
Level 2	5.77	0.06	1.08

Method Comparison:

The AMS LDL Cholesterol Direct kit (y) was compared with another commercially available reagent (x) and gave the following results:

y = 1.0116 x, r = 0.9978

Interferences:

The following analytes were tested up to the levels indicated and found not to interfere in the LDL Direct assay:

Ascorbic Acid at 100 mg/dl

Bilirubin at 40 mg/dl

Haemoglobin at 500 mg/dl

Triglycerides: at 1200 mg/dl

Reference Range:

	Adult
Low Risk	< 3.37 mmol/l (< 130 mg/dl)
Standard Risk Level	3.37 – 4.12 mmol/l (130-159 mg/dl)
High Risk	> 4.14 mmol/l (160 mg/dl)

Each laboratory should establish its own mean reference range according to the population.

Automated systems:

Contact AMS Technical Department for applications on a wide range of automated analysers.

Quality Control Material:

Human Assayed Control Normal: **QCCHAN1 / QCCHAN2**

Human Assayed Control Elevated: **QCCHAE1 / QCCHAE2**

Precautions & Warnings:

- 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.
- Sodium azide reacts with lead and copper plumbing, to form potentially explosive azide, 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.
- 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.
- The LDL Cholesterol result from this test should not be used as the sole criteria for the diagnosis of lipid disorders, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

References:

1. Naito H.K., et al, Clin Chem 41: 132-133, 1995
2. Seidel D., et al, Internist, 28: 606-614 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 Assessment of Clinical Laboratory Results: First Edition T-H Books, Germany p172

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		Keep away from sunlight

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