CHOLESTEROL (2-8°C)

(LYOPHILISED – CHOD PAP)

CATALOGUE NUMBER	KIT SIZE (ML)
MPRLCH1	10x20ml/1x200ml/1x5ml
MPRLCH2	4x50ml/1x200ml/1x5ml
MPRLCH3	2x100ml/1x200ml/1x5ml

Intended Use:
For ***In Vitro*** Diagnostic use only.
This reagent is intended for the quantitative determination of cholesterol in human serum or plasma.

Clinical Significance:
Elevated levels of cholesterol are primarily considered as an indication of increased risk of cardiovascular disease and should be taken into consideration combined with the overall lipid profile.

Test Principle:
Cholesterol is present in serum as cholesterol esters and free cholesterol. The Cholesterol esters present in serum are hydrolysed by cholesterol esterase and the cholesterol is then measured by oxidizing with cholesterol oxidase to form hydrogen peroxide. The hydrogen peroxide in turn reacts with phenol and 4-aminoantipyrine present to form the red quinoneimine dye. The intensity of the dye formed can be measured photometrically, and is directly proportional to the level of cholesterol present in the sample.

Reagent Composition

REAGENT	COMPONENT	CONCENTRATION
Cholesterol Buffer R1	Pipes Buffer	90 mmol/l
	Phenol	26 mmol/l
Enzyme Reagent R2	Choleserol Oxidase	200 U/l
	Cholesterol Esterase	300 U/l
	Peroxidase	1250 U/l
	4-Aminoantipyrine	0.4 mmol/l
Cholesterol Standard	Cholesterol	200 mg/dl

Reagent Preparation and Stability:
R1: Liquid Ready to Use
R2: Lyophilised
R1 and R2 are stable up to the expiry date stated when stored tightly capped at 2-8°C. Once reconstituted the R2 is stable for a period of 28 days when stored without contamination at 2-8°C.
Dispose of reagents carefully in line with local guidelines.
To Reconstitute the R2 –
MPRLCH1 – Add 20ml of the Cholesterol Buffer to the lyophilised material. Ensure that all the lyophilised material has gone into solution by mixing gently without the formation of foam.
MPRLCH2 – Add 50ml of the Cholesterol Buffer to the lyophilised material. Ensure that all the lyophilised material has gone into solution by mixing gently without the formation of foam.
MPRLCH3 – Add 100ml of the Cholesterol Buffer to the lyophilised material. Ensure that all the lyophilised material has gone into solution by mixing gently without the formation of foam.

Sample / Sample Preparation / Sample Stability:
Serum/Heparinised Plasma
Do not use citrate, oxalate or fluoride.
Cholesterol is stable in serum sample for 5 days at 2-8°C and up to 3 months when frozen at -20°C.

Assay Procedure:

WAVELENGTH	505nm (500 – 550nm)
TEMPERATURE	37°C
CUVETTE	1cm Path Length
BLANK	Reagent Blank – one per series

	Blank	Standard	Sample
Sample	-	-	10µl
Standard	-	10µl	-
Reagent	1000µl	1000µl	1000µl
Mix and incubate for 5 minutes at assay temperature. Read the absorbance (Δ Abs) of Sample/Standard against the Reagent Blank.			

Calculation:

$$\text{Concentration (mmol/l)} = \frac{\Delta\text{Abs Sample}}{\Delta\text{Abs Standard}} \times \text{Conc of Standard (5.17mmol/l)}$$

To convert mmol/l to mg/dl multiply the result by 38.66

Performance Characteristics:

Measuring range:
0-900 mg/dl (0.00 – 23.27 mmol/l)
Dilute samples with higher concentrations using Normal saline 1+2 and rerun the assay. Multiply the result by the dilution factor (in the above example of 1+2 dilution, the dilution factor is 3).

Analytical Sensitivity: (Lower detection limit):
1 mg/dl = 0.00152A

Imprecision
Intra-Assay Precision:

Sample	Mean (mg/dl)	SD (mg/dl)	CV %
Pool 1	90.4	1.15	1.27
Pool 2	187	1.01	0.54

Inter-Assay Precision:

Sample	Mean (mg/dl)	SD (mg/dl)	CV %
Pool 1	92.8	1.98	2.14
Pool 2	193	2.39	1.24

Method Comparison:
A comparison of the Prestige Diagnostics Cholesterol Reagent (y) with an alternative commercial assay (x) gave a Correlation Coefficient of 0.9954

Interferences:
Icterus: No significant interference up 10 mg/dl of bilirubin.
Haemolysis: No significant interference up to a concentration of 5 g/l haemoglobin.

Reference Range:

Normal	< 5.2 mmol/l (200 mg/dl)
Borderline Risk	5.2 – 6.2 mmol/l (200-239 mg/dl)
High Risk	>6.2 mmol/l (240 mg/dl)

These values are in line with the recommendations of the European atherosclerosis Society, however we recommend that each laboratory should establish its own mean reference range according to the population.

Automated systems:
Contact Prestige Diagnostics UK Technical Department for applications on a wide range of automated analysers.
For automation we recommend the use of a serum based calibrator.

Quality Control and Calibration Material:
Calibration Serum: **QCCCAL1 / QCCCAL2**
Human Assayed Control Normal: **QCCHAN1 / QCCHAN2 / QCCHAN3**
Human Assayed Control Elevated: **QCCHAE1 / QCCHAE2 / QCCHAE3**

References:

1. Naito HK. Cholesterol. Kaplan A et al Clin Chem The CV. Mosby Co St Louis. Toronto. Princeton, 1984; 1194 and 437.
2. Young DS Effects of drugs on Clinical Laboratory Tests. 4th ed AACC Press 1995.
3. Young DS Effects of disease on Clinical Laboratory Tests. 4th ed AACC Press 2001.
4. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
5. Tietz NW et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		

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Prestige Diagnostics U.K. Ltd 40 Ballymena Business Centre, Galgorm, Co. Antrim, BT42 1FL, United Kingdom. Tel: +44 (0) 28 2564 2100
www.prestigediagnostics.co.uk info@prestigediagnostics.co.uk

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