HDL CHOLESTEROL (2-8°C)

(DIRECT)

CATALOGUE NUMBER	KIT SIZE (mL)
MPRHDL5	1X60ml / 1x20ml / 1 x 3ml

Intended Use:

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

This reagent is intended for the quantitative determination of HDL Cholesterol in human serum and plasma.

Clinical Significance:

High Density Lipoproteins (HDL) are responsible for the reverse transport of cholesterol from the peripheral cells to the liver. HDL is one of the major classes of plasma lipoproteins. Cholesterol is transformed to bile acids in liver which are excreted into the intestine via the biliary tract.

Monitoring of HDL- cholesterol in serum is of clinical importance since an inverse correlation exists between serum HDL- cholesterol concentrations and the risk of atherosclerotic disease. Elevated HDL- cholesterol concentrations are protective against coronary heart disease, while reduced HDL-cholesterol concentrations, particularly in conjunction with elevated triglycerides, increase the cardiovascular risk.

Test Principle:

The direct HDL Cholesterol assay is a homogeneous method for directly measuring serum HDL-C levels without the need for any sample pre-treatment step. A complex blue dye is formed, the rate of formation of which is directly proportional to the HDL cholesterol level in the sample.

Reagent Composition

REAGENT	COMPONENT	CONCENTRATION
Reagent R1	Buffer pH 7.0	100 mmol/l
	HDAOS	1 mmol/l
	Dextran sodium sulphate	10 mg/l
	Ascorbate Oxidase	3.0 U/ml
	Magnesium Sulphate	20 mmol/l
Reagent R2	Buffer pH 7.0	100 mmol/l
	Cholesterol Esterase	6 U/ml
	Cholesterol Oxidase	20 U/ml
	4 Aminoantipyrine	2.5 mmol/l
	Peroxidase	20 U/ml
HDL / LDL Calibrator	HDL / LDL Cholesterol	Lot dependent – Concentration 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 / Sample Preparation / Sample Stability:

Use Serum or Heparinised Plasma. Stable up to 7 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

	Standard	Sample
Sample	-	3 µl
Standard	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 = Abs 2 – Abs 1

Calculation:

HDL Concentration = $\frac{\Delta Abs\ Sample}{\Delta Abs\ Calibrator}$ x Concentration of Calibrator

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

Performance Characteristics:

Measuring range:

0.16 to 5.18 mmol/l (6 - 200 mg/dl)

Dilute samples with higher concentrations (or with Triglyceride concentration greater than 2000 mg/dl) 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	0.78	0.012	1.50
Level 2	1.96	0.020	1.04

Inter-Assay Precision:

Sample	Mean (mmol/l)	SD (mmol/l)	CV %
Level 1	0.76	0.020	2.68
Level 2	1.90	0.061	3.22

Method Comparison:

Prestige Diagnostics HDL cholesterol (y) was compared with another commercially available reagent (x) and gave the following results:

y = 1.1119 x + 0.0428, r = 0.9869

Interferences:

The following analytes were tested up to the levels indicated and found not to interfere:

Ascorbic Acid: 40 mg/dl

Bilirubin: 20 mg/dl

Haemoglobin: 400 mg/dl

Triglycerides: 2000 mg/dl

Reference Range:

	Male	Female
Low Risk	>1.42 mmol/l (55 mg/dl)	>1.68 mmol/l (65 mg/dl)
Standard Risk Level	0.90 – 1.42 mmol/l (35-55 mg/dl)	1.16 – 1.68 mmol/l (45 – 65 mg/dl)
High Risk	<0.90 mmol/l (35 mg/dl)	<1.16 mmol/l (45 mg/dl)

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

Automated systems:

Contact Prestige Diagnostics 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 azides, 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. Use local regulations for handling and disposing of materials during and after testing.
- Clinical diagnosis should not be formed on a single result, all results must be considered with other clinical information available to the physician.

References:

1. National Institutes of Health Consensus Development Conference Statement: Triglyceride, HDL and Coronary Heart Disease. Washington D.C. Feb 26-28, 1992
2. Izawa S., Okada M., Matsui H., and Horita Y J Medicine and Pharmaceutical Sci., 1385 – 1388, 37 (1997)
3. Shih WJ, Bachorik PS, Haga JA, Myers GL, Stein EA: Clinical Chemistry, 2000; 46:3:351-364.
4. 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 Publication, Vol 285, No 19 P2486 – 2497; 2001.

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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