

HDL CHOLESTEROL DIRECT Multi-Purpose (MPR) **Liquid Reagent**

KIT SPECIFICATIONS:

	51101				
Cat. No.	Quantity Reagent		Storage		
	2x45 ml	HDL CHOLESTEROL- 1			
GL602HD	2x15 ml	HDL CHOLESTEROL- 2			
	1X1ml	HDL-C CALIBRATOR			
	2x90 ml	HDL CHOLESTEROL- 1			
GL612HD	2x30 ml	HDL CHOLESTEROL- 2	2-8°C		
	1X1ml	HDL-C CALIBRATOR			
	4x90 ml	HDL CHOLESTEROL- 1			
GL622HD	4x30 ml	HDL CHOLESTEROL- 2			
	1X1ml	HDL-C CALIBRATOR			

INTENDED USE:

In Vitro Diagnostic reagent pack for the quantitative determination of High Density Lipoprotein Cholesterol (HDL-C) in serum and plasma on automated and semi-automated analysers.

SUMMARY AND EXPLANATION: 1, 2

Blood total cholesterol levels have long been known to be related to coronary heart disease (CHD). In recent years, in addition to total cholesterol, high density lipoprotein cholesterol (HDL-C) has become an important tool used to assess an individual's risk of developing CHD since a strong negative relationship between HDL-C concentration and the incidence of CHD was reported 1. Thus, there has been substantial interest in HDL-C analysis. Selective chemical precipitation techniques are widely used for the determination of HDL-C such as heparin-manganese, dextran-magnesium and phosphotungstate-magnesium. However, these techniques require physical separation via centrifugation, which is not suited to large scale laboratory use.

PRINCIPLE OF THE TEST: 4

The direct HDL Cholesterol assay is a homogeneous method for directly measuring serum HDL-C levels without the need for any pre-treatment and centrifugation steps.

First step, substances with high affinity to LDL, VLDL and chylomicrons block them involving to enzyme

Second step, special surfactant that selectively accelerates reaction with the enzyme reagent with HDL cholesterol and determining them



WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only

Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

Components Colour and Appearance:

Reagent 1: Clear Colourless liquid. Reagent 2: Clear, pale yellow liquid.

Calibrator: Lyophilised pellet

Any significant changes from the above could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor. Safety Precautions:

Product is not hazardous under EU specification. Material Safety Data Sheet is available upon request. Handling precautions:

- Store protected from light.
- Take the necessary precautions required for handling all laboratory reagents.
- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

INSTRUMENTS:

Instrument application procedures are available upon request

COMPONENT COMPOSITION:

	Contents	Conc in test
	TODB	1 mmol/l
	Ascorbate oxidase	3.0 U/ml
	PVS	2 mg/l
Reagent 1	PEGME	0.2%
	MgCl ₂	2 mmol/l
	Buffer (pH 6.5)	10mmol/l
	Cholesterol esterase	4 U/ml
	Cholesterol oxidase	10 U/ml
	Peroxidase	30 U/ml
Reagent 2	4-aminoantipyrine	2.5 mmol/l
	Detergent	0.5%
	Buffer (pH 6.5)	10mmol/l

REAGENT PREPARATION AND STABILITY:

Reagent 1 and 2 are ready for use.

Before use, mix reagent by gently inverting each bottle.

If stored and handled properly, unopened component is stable until expiry date stated on the label.

Calibrator: Carefully remove the stopper ensuring that no lyophilised material is lost. Reconstitute the calibrator using 1ml distilled water and leave to stand for 30 minutes before use. Calibrator concentrations are lot specific. Please check that the lot number on the vial corresponds to the lot number on the calibrator insert.

TYPE OF SPECIMEN: 5

Use serum and heparin plasma as specimen.

It is recommended to follow NCCLS procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification. Serum should be separated from cells within 2 hours after collection. Store the specimen at 2-8°C for 6 days. For prolonged storage, specimens should be stored frozen at -70°C for 1 year

EDTA plasma causes decreased values.

TEST PROCEDURE:

Materials required but not supplied:

Description	Catalog. No.	Description	Catalog. No.	
Lipid Control Level 1	GL9009	Photometer	N/A	
Lipid Control Level 2	GL9019	General Laboratory Equipment	N/A	

Assay procedure:

λ: 600 nm Wavelength: Temperature: 37°C 1 cm light path

	Blank	Calibrator	Sample	
Reagent 1	900 μΙ	900 μΙ	900 µl	
Sample			12 µl	
Calibrator		12 µl		
	Gently mix and Incuba the Optical Density			
Reagent 2	300 µl	300 μΙ	300 µl	
	Gently mix and Incuba e the Optical Density			

Using recommended Calibrator, calibrate the assay:

- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part of the photometer used.
- When Quality Controls are out of range.

Quality Control:

All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program. Controls should be assayed:

- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At intervals established by the QC Laboratory Programme.

CALCULATION:

OD_{Sample} Concentration of HDL-Cholesterol = x Concentration of Calibrator OD_{Calibrator}

(Conversion Factor: Qty in mmol/I = mg/dl x 0.0258).

EXPECTED VALUES: 3

	Male (mmol/l)	Male (mg/dl)	Female(mmol/l)	Female(mg/dl)
<60 years	0.78 – 1.63	30 – 63	0.85 - 2.25	33 – 87
>60 years	0.78 - 1.94	30 – 75	0.85 - 2.49	33 – 96

Each laboratory should establish its own reference range. HDL-C results should always be reviewed with the patient's medical examination and history.

PERFORMANCE CHARACTERISTICS:

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these

Linear up to 2.40 mmol/l

For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 2.

The Lowest Detectable Level was estimated at 0.03 mmol/l

Precision:

Within Run N = 20	Mean (mmol/l)	SD	% CV	Between Run N = 20	Mean (mmol/l)	SD	% CV
Level 1	1.32	0.006	0.52	Level 1	1.31	0.038	2.94
Level 2	2.46	0.032	1.28	Level 2	2.41	0.095	3.93

Interfering substances

Less than 5% interference up to 20 mg/dl Bilirubin. Intralipid: Less than 5% interference up to 500 mg/dl Intralipid. Less than 5% interference up to 500 mg/dl Haemoglobin. Haemolysis: Ascorbic acid: Less than 5% interference up to 50 mg/dl.

Method Comparison:

Using 30 samples, a comparison, between this test (y) and another commercially available test (x), gave the

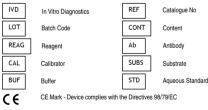
v = 1.119x + 0.0428	r = 0.9869
v = 1 110v · 0 0420	

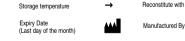
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SYMBOLS:

The following symbols are used in the labelling of Glenbio systems:





Consult Instruction for Use Biological risk



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