TECO DIAGNOSTICS
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DIRECT HDL CHOLESTEROL REAGENT (COLORIMETRIC)

TC MATRIX-240/480

INTENDED USE

The test is used for quantitative determination of HDL cholesterol concentration in human serum and plasma.

SUMMARY AND PRINCIPLE[1, 2, 3, 4, 5]

High-density lipoproteins (HDL) are one of the major classes of plasma lipoproteins. They are composed of a number of heterogeneous particles, including cholesterol and vary with respect to size and content of lipid and apolipoprotein. HDL serves to remove cholesterol from the peripheral cells to the liver, where the cholesterol is converted to bile acids and excreted into the intestine.

An inverse relationship between HDL-cholesterol (HDL-C) levels in serum and the incidence/prevalence of coronary heart disease (CHD) has been demonstrated in a number of epidemiological studies. The importance of HDL-C as a risk factor for CHD is now recognized.

Accurate measurement of HDL-C is of vital importance when assessing patient risk from CHD. In this diagnostic test kit, a method for direct measurement of HDL-C, without sample pretreatment, is presented. Direct measurement gives improved accuracy and reproducibility when compared to precipitation methods.

After adding magnesium ions, dextran sulfate selectively forms water-soluble complexes with LDL, VLDL and chylomicrons which are resistant to PEG-modified enzymes.

The cholesterol amount of HDL-Cholesterol can be tested enzymatically by cholesterol esterase and cholesterol oxidase coupled with PEG to the amino groups. This is around 40% Cholesterol esters are broken down quantitatively into free cholesterol and fatty acids by cholesterol esterase.

HDL-C in human serum is resolved with special detergent and makes color reactions with Cholesterol esterase (CEH), Cholesterol oxidase (CHOD), Peroxidase (POD). Because Non-HDL-Lipoproteins such as chylomicron (CM), low density lipoprotein (LDL), very low density lipoprotein (VLDL) are inhibited by detergents on their surface, the cholesterol in them do not react with the enzyme. Remain HDL Cholesterol is determined by color intensity over trinder reaction.

REAGENTS

Each kit contains:

Reagent 1:

Dextran Sulfate	≤10 g/dL
Magnesium Chloride Hexahydrate	≤5 g/dL
Preservative	
Brij 35	≤10 g/dL

Reagent 2:

Detergent	≤2%
PEG - Cholesterol Esterase	≤5 KU/L
PEG - Cholesterol Oxidase	≤5 KU/L
4-AAP	≤1 g/dL
Peroxidase	≤8000 U/L

REAGENT PREPARATION

Reagents are ready for use

CALIBRATION

Calibration stability is 30 days. Calibration stability depends on the application characteristics and cooling capacity of the autoanalyzer used.

At least two level controls must be run once in every 24 hours. Each laboratory should determine its own quality control scheme and procedures. If quality control results are not within acceptable limits, calibration is required

Note: Refer to the TC Matrix manual for further instructions on calibrating the instrument

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

HDL/LDL Lipids Calibrator
At least two levels of control material

REAGENT STORAGE AND STABILITY[6]

Reagents are stable at 2-8°C until the expiration date stated on the label which is only for closed vials.

Once opened vials are stable for 45 days at 2-8°C in optimum conditions. On board stability is strongly related to auto analyzers' cooling specification and carry-over values.

Reagent stability and storage have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol.

SPECIMEN STORAGE

Fresh Serum or EDTA and heparinized plasma fasting are the recommended specimens. Samples are collected according to the standard procedures.

Separate the serum or plasma as soon as possible after collection (within 3 hours).
Serum is stable for: 12 hours at 20-25°C, 7 days at 2-8°C.

Unit Conversion:

mmol/L x 38.67 = mg/dL
mg/dL x 0.02586 = mmol/L

PROCEDURE

Settings for TC-Matrix 240/480

Test Name:	HDL Chol.	R1:	190
Full Name:	HDL Cholesterol	R2:	57
Pri. Wave:	578 nm	Sample volume:	2
Sec. Wave:	700 nm	Calibration Type:	2 Point Linear
Assay/ Point:	2-Point End	K Value:	/
Start - End:	15 - 30	Point:	2
Decimal place:	1	Blank Type:	Water
Unit:	mg/dL	Point 0 (Blank) Con.:	0.0
Linearity Range:	2.00 - 200.00	Point 1 (CAL) Con.:	Standard/
Correlation Factor:	1.000 - 0.000		Calibrator

REFERENCE INTERVAL (NORMAL VALUES) [7]

Adult Males:	< 35 mg/dL (0.90 mmol/L)	High Risk
	>55mg/dL (1.45mmoI/L)	No Risk
Adult Female:	< 45 mg/dL (1.15 mmol/L)	High Risk
	>65 mg/dL (1.68mmoI/L)	No Risk

National Cholesterol Education Program (NCEP) guidelines:

< 40 mg/dL	Low HDL (Major risk factor for CHD)
≥ 60 mg/dL	High HDL ("Negative" risk factor for CHD)

HDL-cholesterol is affected by a number of factors, e.g., smoking, exercises, hormones, sex and age.
It is recommended that each laboratory establish its own normal range.
Reference interval has been verified by using CLSI EP28- A3c protocol.

INTERFERING SUBSTANCES[12, 13, 14]

No significant interactions were observed for hemoglobin, conjugated bilirubin, lipemia up to the interferent concentration given in the table.

Interfering Substance and Concentration	HDL Target (mg/dL)	N	Observed Recovery %
Hemoglobin 1260 mg/dL	25.8	3	91
Bilirubin 54 mg/dL	46.3	3	103
Lipemia 1062 mg/dL	53.6	3	111

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

Interferences may affect the results due to medication or endogenous substances.
These performance characteristics have been obtained by using an analyzer. Results may vary if a different instrument or a manual procedure is used

PERFORMANCE CHARACTERISTICS

Limit of Detection (LoD): The limit of the test detection is 2.7 mg/dL.
Limit of Quantitation (LoQ) [LoQ values are based on Coefficient of Variation Percentage (CV) ⩽20%]:[8] 3 mg/dL
LoD and LoQ values have been verified by using CLSI EP17-A protocol.

Precision[9]:

Repeatability (Within Run)

Mean Concentration (mg/dL)	SD	CV%	n
71.9	0.57	0.8	40
131.1	0.78	0.6	40

Reproducibility (Run-to-Run)

Mean Concentration (mg/dL)	SD	CV%	n
47.91	0.73	1.53	84
133.25	2.72	2.04	84

±10% CV% differences can be observed between devices.
Precision Studies data have been verified by using CLSI EP05-A3 protocol.

Linearity: The method is linear up to 200 mg/dL
For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilution factor.

Linearity may considerably vary depending on the instrument used.

PRECAUTIONS

IVD: For in Vitro Diagnostic use only.Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines. Contains sodium azide.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

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Manufactured by:

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