TECO DIAGNOSTICS
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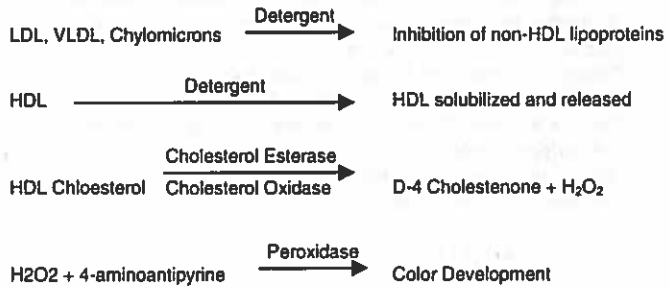
HDL CHOLESTEROL DIRECT METHOD TC MATRIX

INTENDED USE
This reagent is for the use of quantitative determination of High Density Lipoprotein (HDL) Cholesterol in serum on TC Matrix analyzers.

SUMMARY AND EXPLANATION OF THE TEST
Cholesterol is a fatty substance found in blood, bile and brain tissue. It serves as a precursor to bile acids, steroids and vitamin D. The concentration of total cholesterol in serum has been associated with metabolic, infectious and coronary heart diseases. In the plasma, cholesterol is transported by three lipoproteins: high density lipoprotein (HDL-Cholesterol), low density lipoprotein (LDLCholesterol), and very low density lipoprotein (VLDL-Cholesterol).
Castelli and co-workers have indicated that an inverse relationship exists between serum HDL-Cholesterol and the risk of coronary heart disease. The measurement of total and HDL Cholesterol and triglyceride provides valuable information for the prediction of coronary heart disease and for lipoprotein phenotyping.
Serum is reacted with a detergent which is selectively absorbed by non-HDL lipoproteins, ie., LDL, VLDL and Chylomicrons. Thus, only HDL lipoproteins are available to be solubilized and released to react with the cholesterol esterase, cholesterol oxidase and chromogens (to give color). The color that is produced is proportional to the amount of HDL cholesterol present in the sample.



REAGENT CONTENTS:
Each kit contains: Four Direct HDL Cholesterol Reagent1 (4×26 ml)
Four Direct HDL Cholesterol Reagent2 (4×9 ml)

Instruction Insert.

REAGENT PREPARATION
No preparation is required.

REAGENT COMPOSITION
4-aminoantipyrine: 0.8 mmol/L
Good's buffer containgn 4AA (0.9 mmol/L) : 30 mmol/L
Peroxidase (from Horseradish): >2400 IU/L
Cholesterol Oxidase: >20000 IU/L
Cholesterol Esterase: >4000 IU/L
HDAOS: 0.3g/L

STORAGE AND STABILITY
HDL Cholesterol Reagent is stable unit the date of expiration on the kit when stored tightly capped at 2-8°. The reagent should be clear and colorless as packaged. Discard if turbid. Once opened, the Direct HDL Cholesterol Reagent is stable for 30 days.

SPECIMEN COLLECTION AND HANDLING
1. The test can be performed on serum, plasma. For serum, blood is drawn into a tube which does not contain anticoagulant and allow clotting. The serum is them separated from the clot. A maximum limit of two hours from the time of collection is recommended.
2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum and plasma should be stored at 2°C to 8°C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.
3. For plasma, add whole blood directly into a tube containing anticoagulant. Acceptable anticoagulants are listed in the "LIMITATIONS" section

CALIBRATION
1. Calibrator required: TECO LIPID Calibrator.
2. The system must have a valid calibration in memory before controls or patient samples can be run.
3. The TC Matrix system will automatically perform checks on the calibration and produce data at the end of calibration.

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

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT
TECO LIPID Calibrator
At least two levels of control material.

LIMITATIONS
1. The anticoagulants Ammonium Heparin, EDTA, Lithium Heparin, Potassium Oxalate, and Sodium Heparin were found to be compatible with this method.

INTERFERENCES
1. All interference studies were conducted according to the procedures recommended in NCCLS guideline NO. EP7-P for interference testing in clinical chemistry.[12] Hemoglobin levels up to 100 mg/dl, Triglyceride levels up to 1800mg/dl and Bilirubin levels up to 20 mg/dl were found to exhibit negligible interference (<5%) on this method. Samples with levels of interfering substances higher than the upper limits should be diluted with physiological saline before assaying.
2. Refer to the work of Young for a review of drug and comprehensive list of substances effect on serum HDL cholesterol levels.

EXPECTED VALUE
The expected values for serum HDL cholesterol are as follows:

	Conventional Units	S.I. Units
M	29-71 mg/dL	0.75 – 7.85 mmol/L
F	35-85 mg/L	0.91 – 2.21 mmol/L

It is recommended that each laboratory establish its own range of expected values, since differences exist between instruments, laboratories, and local populations.

According to the NCEP, HDL values greater than or equal to 35 mg/dl are considered desirable, and values greater than or equal to 60 mg/dl are considered to offer some protection against coronary heart disease. Values below 35 mg/dl are considered to be a significant independent risk factor for coronary heart disease.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.
3. Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.

PROCEDURES:

TEST NAME:	HDL	R1:	225
TEST NO.		R2:	75
FULL NAME:	HDL Cholesterol	SAMPLE VOLUME:	3
REFERENCE NO.:		R1 BLANK:	/
ANALY.TYPE:	Endpoint	MIX REAG. BLANK:	0.1 - 1.5
PRI. WAVE :	578 nm	CONCENTRATION:	/
SECON. WAVE:	670 nm	LINEARITY LIMIT:	2 - 150
TREND:	Ascending	SUBSTRATE LIMIT:	/
REACT. TIME:	0 - 20	FACTOR:	/
INCUBATE TIME:	20	PROZONE CHECK:	/
UNIT:	mg/dl	Q1: / Q2: /	Q3: / Q4: /
PRECISION:	Integer	PC: /	ABS.: /
Calibration Type: Calibrate+Reag.Blank		Calibration Rule: Two-point linear	

PERFORMANCE CHARACTERISTICS

Assay Range: 2 – 150 mg/dl

For DHDL Cholesterol analyte by DHDL Cholesterol Reagent on TC Matrix System, this method has been demonstrated to be linear from 2-150 mg/dL

Accuracy: Comparison study was performed on TC Matrix System from 40 samples. Beckman Coulter DHDL Cholesterol Reagent was used to compare with DHDL Cholesterol Reagent. The results of this study in yield a correlation coefficient of 0.96 with a regression equation of y=0.96X +0.84.

Precision: Within Day precision for the Direct HDL Cholesterol Reagent was determined following a modification of NCCLS document EP5-T2. Within Day precision studies produced the following results:

N	Sample 1 25	Sample 2 25
Mean HDL Cholesterol	39.4	84.5
Standard Deviation (mg/dl)	1.40	2.99
Correlation of Variation (%)	3.8	2.7

Day to Day precision for the Direct HDL Cholesterol Reagent was also determined following a modification of NCCLS document EP5-T2.[15] Day to Day precision studies produced the following results:

N	Sample 1 25	Sample 2 25
Mean HDL Cholesterol	39.2	84.4
Standard Deviation (mg/dl)	1.85	2.23
Correlation of Variation (%)	4.3	2.8

REFERENCES

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