TECO DIAGNOSTICS
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CHOLESTEROL
TC MATRIX-240/480

INTENDED USE
For the quantitative determination of cholesterol in serum or plasma on TC Matrix analyzers.

SUMMARY AND EXPLANATION OF THE TEST
Total cholesterol in the blood is elevated in idiopathic hypercholesterolemia, both primary and secondary hyperlipidemias, diabetes mellitus, nephrotic syndrome, hypothyroidism, and biliary obstruction. Pregnancy may also be accompanied by a moderate increase of cholesterol level.

Decreases of cholesterol are seen in patients with severe hepatitis and occasionally in severe anemia or infection.
Human serum contains a mixture of free and esterified cholesterol, both of which are measured to determine the total cholesterol. The cholesterol esterase converts cholesterol ester to free cholesterol, which is then oxidized by the cholesterol oxidase to yield cholest-4-en-3-one and hydrogen peroxide. The hydrogen peroxide reacts with 4-aminoantipyrine and phenol, in the presence of peroxidase, to produce an intense red chromophore.

The TC Matrix System automatically proportions the appropriate sample and reagent volumes into the cuvette. The system monitors the change in absorbance at 700 nanometers. This change in absorbance is directly proportional to the concentration of cholesterol in the sample and is used by the TC Matrix System to calculate and express the cholesterol concentration.

$$\text{Cholesterol ester} + H_2O \xrightarrow{\text{Cholesterol esterase}} \text{cholesterol} + \text{ROOH}$$

$$\text{Cholesterol} + O_2 \xrightarrow{\text{Cholesterol oxidase}} \text{Cholesten-3-one} + H_2O_2$$

$$H_2O_2 + \text{4-aminoantipyrine} + \text{phenol} \xrightarrow{\text{Peroxidase}} H_2O + \text{red quinone dye}$$

REAGENT PREPARATION
No preparation is required.

REAGENT COMPOSITION
4-Aminoantipyrine: 0.28 mmol/L
Phenol: 7.8 mmol/L
Cholesterol esterase:>211 IU/L
Cholesterol Oxidase:>1100 IU/L
Peroxidase: 5000IU/L
Also, non-reactive chemicals for optimal system performance.

REAGENT STORAGE AND STABILITY
Cholesterol Reagent stored unopened at 2ºC to 8ºC is stable until the expiration date shown on the bottle label. Once opened, Cholesterol Reagent is stable for 21 days or until expiration date on label, whichever occurs first.
DO NOT FREEZE.

SPECIMEN COLLECTION AND HANDLING
1. The test can be performed on serum or plasma. For serum, blood is drawn into a tube which does not contain anticoagulant, and it is allowed to clot. The serum should then be separated from the clot within two hours from the time of collection.
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 2ºC to 8ºC. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15ºC to -20ºC. 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
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
Arcal Auto Calibrator
At least two levels of control material.

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

INTERFERENCE
1. Sample or control materials which contain acetic acid, detergents, or surfactants may inhibit the enzymes in the reagent and should not be used.
2. Hemoglobin levels up to 500 mg/dL, Triglyceride levels up to 1500mg/dL and Bilirubin levels up to 30 mg/dL were found to exhibit negligible interference.
3. On this method, refer to the work of Young for a review of drug and comprehensive list of substances which affect cholesterol level.

EXPECTED VALUE
The National Cholesterol Education Program has published reference cholesterol values for cardiovascular risk to be:
Low risk: less than 200 mg/dL
Borderline risk: 201-239 mg/dL
High risk: 240 mg/dL and greater

It is strongly recommended that each laboratory establish its own normal range.

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 Biosafety in Microbiological and Biomedical Laboratories manual, and in accordance with national or local regulations related to the safety precautions of such materials.
3. Each laboratory should perform quality control testing to ensure the results are reliable before testing the specimens.

PROCEDURES

Settings for TC-Matrix 240/480

Test Name:	CHOL	R1:	200
Full Name:	Cholesterol	R2:	0
Pri. Wave:	505 nm	Sample Volume:	2.0
Sec. Wave:	700 nm	Calibration Type:	2 point linear
Assay/ Point:	1 Point end	K Value:	/
Start - End:	1 - 25	Point:	2
Decimal place:	2	Blank Type:	Reagent
Unit:	mg/dL	Point 0 (Blank) Con.:	0.0
Linearity Range:	5.000 - 1000.000	Point 1 (STD) Con.:	Calibrator/ standard
Correlation Factor:	1.0000 - 0.0000		

PERFORMANCE CHARACTERISTICS

Analytical Range: 5- 1000mg/dL

For Cholesterol analysis by Cholesterol Reagent on TC Matrix System, this method has been demonstrated to be linear from 5-1000 mg/dL

Accuracy: Comparison study was performed on TC Matrix System from 40 samples. Beckman Coulter Cholesterol reagent was used to compare with Cholesterol Reagent. The results of this study yielded correlation coefficient of 0.99 with a regression equation of y = 0.99X +5.14.

Precision: Within Run precision for Cholesterol Reagent Set was determined following a modification of NCCLS EP5-A. Two commercial human sera were assayed on TC Matrix System for 25 times.

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	280	131
Standard Deviation (mg/dl)	7.8	3.6
Coefficient of Variation (%)	4.5	4.1

Run-Day precision for Cholesterol Reagent was determined following a modification of NCCLS EP5-A. Two commercial human sera were assayed on TC Matrix Systems five times per day for five days for the total of 25 values.

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	281	132
Standard Deviation (mg/dl)	8.7	4.9
Coefficient of Variation (%)	3.9	3.8

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C507-TC2/TC4: **05/2024**

Manufactured by:

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