

## LiquiMAX CHOLESTEROL-SLR

(5 Minutes End Point)  
(CHOD/PAP TRINDER'S METHOD)

### ORDERING INFORMATION

Ref./Cat. No.	Pack Size	Presentation
AVCHO - 50	2 x 25 ml	Single Liquid Reagent
AVCHO - 100	4 x 25 ml	
AVCHO - 250	5 x 50 ml	
AVCHO - 500	10 x 50 ml	

### INTENDED USE

LiquiMAX CHOLESTEROL is an in-vitro diagnostic kit for the quantitative determination of cholesterol in human serum and plasma.

### PRODUCT FEATURES :

1. Single Liquid Reagent.
2. 5 minutes End Point Assay .
3. Linearity: Total Cholesterol 1000 mg/dl.
4. With Lipid Clearing Factor (LCF).
5. Can be used on any colorimeter, spectrophotometer, discrete semi automated and automated analyzers

### CLINICAL SIGNIFICANCE

Cholesterol is a steroid with a secondary hydroxyl group in the C3 position. It is synthesized in many types of tissue, but particularly in the liver and intestinal wall. Approximately three quarters of cholesterol is newly synthesized and a quarter originates from dietary intake. Cholesterol assays are used for screening for atherosclerotic risk and in the diagnosis and treatment of disorders involving elevated cholesterol levels as well as lipid and lipoprotein metabolic disorders. Cholesterol analysis was first reported by Liebermann in 1885 followed by Burchard in 1889. In the Liebermann-Burchard reaction, cholesterol forms a blue-green dye from polymeric unsaturated carbohydrates in an acetic acid/acetic anhydride/concentrated sulfuric acid medium. The Abell and Kendall method is specific for cholesterol, but is technically complex and requires the use of corrosive reagents. In 1974, Roeschlau and Allain described the first fully enzymatic method. This method is based on the determination of  $\Delta^4$  cholestenone after enzymatic cleavage of the cholesterol ester by cholesterol esterase conversion of cholesterol by cholesterol oxidase, and subsequent measurement by the Trinder reaction of the hydrogen peroxide formed. Optimization of ester cleavage (>99.5%) allows standardization using primary and secondary standards and a direct comparison with the CDC and NIST reference methods. The LiquiMAX CHOLESTEROL-SLR (5 Minutes End Point) assay meets the 1992 National Institutes of Health (NIH) goal of less than or equal to 3% for both precision and bias.

### PRINCIPLE:



### STORAGE & STABILITY:

LiquiMAX CHOLESTEROL-SLR (5 Minutes End Point) is available as Single Liquid Reagent and is ready to use. Reagent and Standard should be stored at 2-8°C and are stable till the expiry date mentioned on the labels.

### KIT COMPONENTS

1. Cholesterol Reagent
2. Cholesterol Standard : Concentration as stated on the label

### COMPOSITION

Cholesterol Oxidase	- 3 KU/L
Cholesterol Esterase	- 1.2 KU/L
Peroxidase	- 2 KU/L
4-Aminoantipyrene	- 0.5 m mol/L
Phenol	- 20 m mol/L
Phosphate Buffer	- 50 m mol/L. pH-7.0
Activators & Stabilizers.	

### REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

1. When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

### MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

### REAGENT DETERIORATION

Discard any turbid reagent if blank reagent absorbance exceeds 0.25 at 505 nm against distilled water.

### WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

### SPECIMEN COLLECTION & STORAGE

Serum / Heparinised or EDTA Plasma.

### SYSTEM PARAMETERS:

Reaction Mode	: End Point
Units	: mg/dl
Wave Length	: 505 nm (490-550)
Blanking with	: Reagent
Flow Cell Temp.	: 37°C
Low Normal	: 130
High Normal	: 250
Sample Volume	: 10 µl
Reagent Volume	: 1000 µl
Linearity	: 1000
Standard Conc.	: 200

### TEST PROCEDURE:

Pipette into 3 test tubes labeled Blank (B), Standard(S) and Test (T) as shown below:

Reagent	B	S	T
(1) Cholesterol Reagent	1000 µl	1000 µl	1000 µl
(2) Cholesterol Standard (Conc. 200 mg/dl)	--	10 µl	--
Specimen	--	--	10 µl

Mix well and incubate for 5 minutes at 37°C or 10 minutes at R.T. Read the absorbance of Standard (S), Test (T) against Blank (B) at 505 nm (490-550 nm).

## CALCULATIONS

$$\text{a) Total Cholesterol (in mg/dl)} = \frac{\text{Abs. of Test}}{\text{Abs. of Standard}} \times 200$$

## EXPECTED VALUES

Total Cholesterol: 130 - 250 mg/dl

It is recommended that laboratories establish their own normal range.

## QUALITY CONTROL & CALIBRATION:

To ensure adequate quality control, the use of commercial reference control serum is recommended with each assay batch. Use of Quality Control material checks both, the instrument and the reagent functions.

## PERFORMANCE CHARACTERISTICS

### 1. Linearity

Linearity : 3-1000 mg/dl

### 2. Sensitivity/ Limit of Detection (LOD)

Detection limit : 3 mg/dl

The lower detection limit represents the lowest measurable cholesterol concentration that can be distinguished from zero.

### 3. Interferences

No significant interference was observed from Bilirubin up to 20 mg/dl, Hemoglobin up to 450 mg/dl and Triglycerides up to 1250 mg/dl.

### 4. Precision

Reproducibility was determined using controls. The following results were obtained:

#### Intra-Assay

Sample	Mean (mg/dl)	SD (mg/dl)	% CV
Control 1	103	1.35	1.32
Control 2	158	0.98	0.62
Control 3	180	0.99	0.55

#### Inter-Assay

Sample	Mean (mg/dl)	SD (mg/dl)	% CV
Control 1	124	1.71	1.38
Control 2	162	3.13	1.93
Control 3	186	1.97	1.06

### 5. Method Comparison:

A comparison of the LiquiMAX CHOLESTEROL-SLR (5 Minutes End Point) (y) with a commercial obtainable assay (x) gave following result:

$$y = 1.006x + 0.258 ; r = 0.999$$

## LIMITATIONS

3-1000 mg/dl

Determine samples having higher activities via the rerun function. On instruments without rerun function, manually dilute the samples with 0.9% NaCl-solution or distilled/deionized water (e.g. 1 + 2). Multiply the result by the appropriate dilution factor (e.g. factor 3).

## WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.














## NOTES:

- The Enzyme Reagent on storage at 2-8°C develops a slight pink color. However, this does not affect the performance of the test.
- As with all the diagnostic procedures, the physician should evaluate data obtained by the use of this kit in light of other clinical information.

## REFERENCES:

- Allain, C.C. Clin. Chem 20, 470 (1974)
- Abell L. et al. Standard Methods in Clinical Chemistry 1958; 26:2.
- Allain C.C. et al. Clin Chem 1974;20:470
- Bablok W. et al. A General Regression Procedure for Method Transformation. J Clin Chem Clin Biochem 1988;26:783-790
- Burchard H. Beiträge zur Kenntnis der Cholesterine. Dissertation Rostock 1889.

## Symbols Used on Pack

 REF	Catalogue Number		Warning/Caution
 LOT	Batch No.		In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		



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