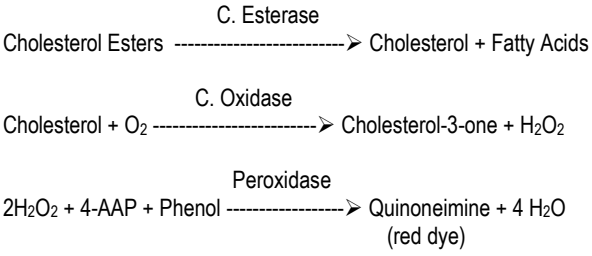
Cholesterol (Liquid) Reagent Set

Intended Use
For the quantitative determination of Total Cholesterol in serum using the Mindray BS-200 analyzer.

Method History
A Cholesterol method developed in the late 1800's by Lieberman[1] and Burchard[2] is still in use today despite its corrosive nature and its susceptibility to many interfering substances.
Work on an enzymatic procedure was begun by Flegg[3] and Richmond[4] in the early 70's. Allain[5] and Roeschlau[6] began using cholesterol esterase and oxidase, in a single reagent to determine total cholesterol in serum.
Trinder's[7] color system of peroxidase/phenol/4-aminoantipyrine has been used successfully for some time now. With appropriate calibrator value assignment, this method has been shown to provide excellent accuracy in relation to the reference methodology.

Principle


The intensity of the red color produced is directly proportional to the total cholesterol in the sample when read at 500nm.

Reagents
4-Aminoantipyrine 0.25mM, Cholesterol Esterase >150u/L, Cholesterol Oxidase >150u/L, Peroxidase >1500u/L, Phenol >15mM, Phosphate Buffer, pH 6.8, non-reactive stabilizers and preservatives.

Reagent Preparation
The reagent is ready to use.

Reagent Storage
1. Store reagent at 2-8°C.
2. The reagent is stable until the expiration date when stored at 2-8°C.

Reagent Deterioration
Do not use if:
1. The reagent is turbid.
2. The reagent does not meet stated performance parameters.

Precautions
1. This reagent is for *in vitro* diagnostic use only.
2. Not to be used internally in humans or animals. Normal precautions for handling laboratory reagents should be followed.
3. Additional safety information concerning storage and handling of this product is in the Material Safety Data Sheet for this product.

Specimen Collection and Storage
Nonhemolyzed serum is recommended. Cholesterol in serum is reported stable for seven days at room temperature (18-25°C) and six months when frozen and properly protected against evaporation.[8,9]

Interferences
A number of drugs and substances affect concentrations of cholesterol. See Young, et al.[10]

Materials Provided
Cholesterol Reagent

Materials Required but not Provided
1. Mindray BS-200 Analyzer
2. BS-200 Operation manual
3. Chemistry Calibrator, catalog number C7506-50
4. Chemistry Control, catalog number C7592-100

Mindray BS-200 Test Parameters

Test :	CHOL	R1 :	300
No.:	012	R2 :	0
Full Name:	Cholesterol	Sample Volume:	3
Standard No.:		R1 Blank:	
Reac.Type:	Endpoint	Mixed Rgt. Blank:	
Pri. Wave:	510nm	Linearity Range:	0 - 500
Sec. Wave:	670nm	Linearity Limit:	
Direction:	Increase	Substrate Limit:	
Reac. Time:	0 / 20	Factor:	
		Compensate: Slope 1.0	Intercept: 0
Incuba.Time:		□ Prozone check	
Unit:	mg/dl	q1: q2: q3: q4:	
Precision:	Integer	PC: Abs:	

Calibration Parameters

Rule:	Two-point linear	Calibrator 1:	Deionized Water
Sensitivity:		Calibrator 2:	Chem Cal
Replicates:	2	Calibrator 3:	
Interval (day):		Calibrator 4:	
Difference Limit:		Calibrator 5:	
SD:		Calibrator 6:	
Blank Response:			
Error Limit:			
Coefficient:	0		

Limitations
Samples with values exceeding 500 mg/dl should be diluted 1:1 with saline and re-run. The final answer should be multiplied by two.

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Calibration
Use an NIST-traceable serum calibrator. The procedure should be calibrated according to the instrument manufacturer's instructions. If control results are found to be out of range, the procedure should be re-calibrated.

Calculation (Example)
Abs. = Absorbance

$$\frac{\text{Abs. (Patient)}}{\text{Abs. (Standard)}} \times \text{Concentration of Std. (mg/dl)} = \text{Cholesterol (mg/dl)}$$

Example: Abs. (Patient) = 0.40, Abs. (Standard) = 0.32, Concentration of Standard = 200 mg/dl

$$\frac{0.40}{0.32} \times 200 = 250 \text{ mg/dl}$$

Quality Control
Serum controls with known normal and elevated values should be run routinely to monitor the validity of the reaction. These controls should be run at least with every working shift in which Cholesterol assays are performed. It is recommended that each laboratory establish its own frequency of control determination. Quality control requirements should be performed in conformance with local, state, and/or Federal regulations or accreditation requirements.

Expected Values[11]
Recommended Range:

Desirable Cholesterol:	<200mg/dl
Borderline-High Cholesterol:	200-239mg/dl
High Cholesterol:	>240mg/dl

Performance
1. Linearity: 500 mg/dl
2. Comparison: A study was performed between the Mindray BS-200 and a similar analyzer using this method, resulting in a correlation coefficient of y = 1.068x - 2.5 with a correlation coefficient of 0.968.
3. Precision: Precision studies were performed using the Mindray BS-200 analyzer following a modification of the guidelines which are contained in NCCLS document EP5-T2.[12]

Within Run			Day to Day		
Mean	**S.D.**	**C.V.%**	**Mean**	**S.D.**	**C.V.%**
140.4	3.1	2.2	123.1	3.0	2.4
269.1	4.0	1.5	251.4	6.9	2.7

4. Specificity: Cholesterol oxidase is not totally specific for cholesterol. Other analogs of cholesterol (dihydrocholesterol, 7-dehydrocholesterol, 20-hydroxycholesterol, etc.) are also oxidized. These analogs do not normally occur in any appreciable amounts in serum.

References

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2. Burchard, H., Chem. Fentr. 61:25 (1890).
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5. Allain, C.C., et al, Clin. Chem. 20:470 (1974).
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7. Trinder, P., Ann. Clin. Biochem. 6:24 (1969).
8. Perlstein, M.T., et al, J. Microchem. 22:403 (1977).
9. Witte, D.L., et al, Clin. Chem. 20:1282 (1974).
10. Young, D.S. et al, Clin. Chem. 21:1D (1975).
11. National Institute of Health Publication No. 88-2926 "Detection, Evaluation, and Treatment of High Cholesterol in Adults", November (1987).
12. NCCLS document "Evaluation of Precision Performance of Clinical Chemistry Devices", 2nd Ed. (1992).

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Use by (YYYY-MM) | LOT Lot and batch code | REF Catalog number | Manufacturer | IVD *In vitro* diagnostic medical device
Temperature limitation | Consult instructions for use | CE mark | EC REP Authorized representative in the European Community