

## Intended Use

For the quantitative determination of Total Cholesterol in serum using the Yumizen C560 analyzer. For *in vitro* diagnostic use only. **Rx Only.**

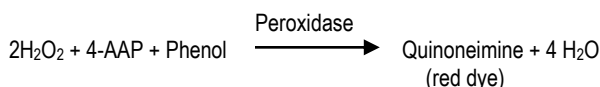
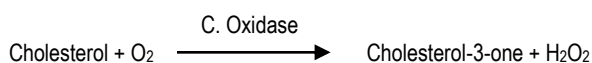
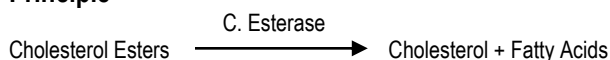
## Method History

A Cholesterol method developed in the late 1800's by Lieberman<sup>1</sup> and Burchard<sup>2</sup> 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<sup>3</sup> and Richmond<sup>4</sup> in the early 70's. Allain<sup>5</sup> and Roeschlau<sup>6</sup> began using cholesterol esterase and oxidase, in a single reagent to determine total cholesterol in serum.

Trinder's<sup>7</sup> 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.
3. Manufacturer studies have shown reagent is stable for 30 days once placed in the refrigerated reagent carousel (2-10°C), however reagent stability may vary based on individual laboratory conditions.

## Reagent Deterioration

Do not use if:

1. The reagent is turbid.
2. The reagent does not meet stated performance parameters.

## Precautions and Hazards

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.

### Hazards:

**Hazard Classifications:** Reproductive Toxicity (Category 2)

**Hazard Statements:** H361: Suspected of damaging fertility or the unborn child

**Precautionary Statements:** **Prevention:** P202 Do not handle until all safety precautions have been read and understood.

P281 Use personal protective equipment as required. **Response:** P308 + P313 IF exposed or concerned: Get medical advice/attention. **Storage:** P404 Store in a closed container. **Disposal:** P501: Dispose of contents to an approved waste disposal plant. **Refer to the Safety Data Sheet for this product (SDS-C7510) available by calling 1-734-487-8300.**

## 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.<sup>8,9</sup>

## Interferences

A number of drugs and substances affect concentrations of cholesterol. See Young, et al.<sup>10</sup>

## Materials Provided

Cholesterol Reagent



**Signal Word: Warning**

# Pointe Cholesterol Reagent Set

## Materials Required but not Provided

1. Yumizen C560 Analyzer
2. Yumizen C560 Operation manual
3. Chemistry Calibrator, catalog number C7506-50
4. Chemistry Control, catalog number C7592-100

## 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.

## 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 test may need to be re-calibrated. Under typical operating conditions manufacturer calibration stability studies have shown the calibration curve will be stable for at least 14 days.

## 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<sup>11</sup>

Recommended Range:

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

## Performance

1. Assay Range: 0-500 mg/dl
2. Comparison: A study was performed between the Yumizen C560 and a similar analyzer using this method, resulting in the following:

Method	Cholesterol
N	84
Mean Cholesterol (mg/dL)	210.8
Range (mg/dL)	57-398
Standard Deviation	73.9
Regression Analysis	$y = 0.974x - 2.1$
Correlation Coefficient	0.9968

3. Precision: Precision studies were performed using the Yumizen C560 analyzer following a modification of the guidelines which are contained in NCCLS document EP5-T2.<sup>12</sup>

Sample	Within Day			Total		
	LOW	MID	HIGH	LOW	MID	HIGH
N	20	20	20	40	40	40
Mean	137.4	287.3	504.3	137.3	290.0	510.9
Standard Deviation	1.5	1.0	2.0	3.1	7.6	10.6
Coefficient of Variation (%)	1.1%	0.3%	0.4%	2.3%	2.6%	2.1%

4. Sensitivity: 2SD limit of detection (95% Conf) = 0 mg/dL
5. 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

1. Lieberman, C., Ber. 18:1803 (1885).
2. Burchard, H., Chem. Fentr. 61:25 (1890).
3. Flegg, H.M., Ann. Clin. Biochem. 10:79 (1973).
4. Richmond, W., Scand. J. Clin. Lab. Invest. 29:Suppl. 26, abstr. 3:25 (1972).
5. Allain, C.C., et al, Clin. Chem. 20:470 (1974).
6. Roeschlau, P., et al, Z. Klin. Chem. Klin. Biochem 12:226 (1974).
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", 2<sup>nd</sup> Ed. (1992).

### CHEMISTRY PARAMETERS

Chem:	CHOL	No.:	210	Sample Type:	Serum
Chemistry:	Cholesterol	Print Name:	CHOL	Reaction Direction:	Positive
Reaction Type:	End Point	Sec Wave:	660	Decimal	0
Pri Wave:	505	Reaction Time:	50	52	
Unit:	mg/dL	Reagent Vol.	Diluent		
Blank Time:	10	12			
	Sample Vol.	Aspirated	Diluent		
Standard:	1.5 ul	--- ul	--- ul	R1:	150 ul --- ul
Decreased:	--- ul	--- ul	--- ul	R2:	--- ul -- ul
Increased:	--- ul	--- ul	--- ul	R3:	--- ul -- ul
	<input type="checkbox"/> Sample Blank	<input checked="" type="checkbox"/> Auto Rerun		R4:	--- ul --- ul

**Slope/Offset Adjustment**  
Slope: 1      Offset: 0

Linearity Range (Standard)	0	500	Linearity Limit:
Linearity Range (Decreased)	---	---	Substrate Depletion:
Linearity Range (Increased)	---	---	Mixed Blank Abs:
R1 Blank Abs:	---	---	Uncapping Time
Blank Response:	---	---	Reagent Alarm Limit:
Twin Chemistry:			<input type="checkbox"/> Enzyme Linear Extension
<input type="checkbox"/> Prozone Check		<input type="radio"/> Rate Check	<input type="radio"/> Antigen Addition
Q1:	Q2:	Q3:	Q4:
PC:	ABS:		

# Pointe Cholesterol Reagent Set

## CALIBRATION PARAMETERS

<b>Calibrator Definition</b>						
Calibrator:	*	Lot No.:	*			
Exp Date:	*					
<b>Carousel</b>		<b>Pos</b>				
Sample Carousel 1	*					
Sample Carousel 2						
Sample Carousel 3						
<b>Reagent/Calibration</b>						
<u>Calibrator</u>	<u>Pos</u>	<u>Lot No</u>	<u>Exp Date</u>	<u>Chem</u>	<u>Conc</u>	<u>Unit</u>
Water	W	*	*	CHOL	0	mg/dL
Chemistry Calibrator	*	*	*	CHOL	*	mg/dL
<b>Calibration Setup</b>						
Chem:	CHOL					
<u>Calibration Settings</u>						
Math Model:	Two-Point Linear					
Factor:		Replicates:	2			
<u>Acceptance Limits</u>						
Cal Time:	336	Hour				
Slope Diff:	---	SD:	---			
Sensitivity :	---	Repeatability:	---			
Deter Coeff:	---					
<u>Auto Calib.</u>						
<input type="checkbox"/> Bottle Changed	<input type="checkbox"/> Lot Changed	<input type="checkbox"/> Cal Time				

It is recommended that two levels of control material be assayed daily.

\* Indicates user defined parameter.

**REF** 14-C7510-480



Manufactured by  
HORIBA Instruments Incorporated-Pointe Brand  
5449 Research Drive Canton, MI 48188



2°C - 8°C



### Certified to Perform Reagents

The Pointe reagents are certified to be manufactured according to specified parameters. Any Pointe reagent product not meeting specifications through its listed expiration date will be remedied immediately without charge.

Manufactured by HORIBA Instruments Incorporated – Pointe Brand  
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### Symbol Key

Use by (YYYY-MM-DD)	<b>LOT</b> Lot and batch code	<b>REF</b> Catalog number
Manufacturer	Temperature limitation	Consult instructions for use
<b>IVD</b> <i>In vitro</i> diagnostic medical device <b>Rx Only</b> : Prescription Use Only		