

AEROSET®

c8000™

# CHOLESTEROL

This package insert contains information to run the Cholesterol assay on the AEROSET System and the ARCHITECT® c8000 System.











**NOTE: Changes to AEROSET System Information Highlighted**  
*(Supplemental and format changes are not highlighted)*


**NOTE: This package insert must be read carefully prior to product use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.**

## Customer Support

**United States:** 1-800-527-1869  
**Canada:** 1-800-387-8378 (English speaking customers)  
1-800-465-2675 (French speaking customers)  
**International:** Call your local Abbott representative

### Symbols in Product Labeling

	Authorized Representative		Consult instructions for use
	For in vitro diagnostic use		Legal Manufacturer
	Batch code/Lot number		Temperature limitation
	Reagent 1		Use by/Expiration date
	Catalog number/List number		
	Serial number		

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**NAME**CHOLESTEROL

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**INTENDED USE**

The Cholesterol assay is used for the quantitation of cholesterol in human serum or plasma.

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**SUMMARY AND EXPLANATION OF TEST**

Measurement of serum cholesterol levels can serve as an indicator of liver function, biliary function, intestinal absorption, propensity toward coronary artery disease, and thyroid function. Cholesterol levels are important in the diagnosis and classification of hyperlipoproteinemias. Stress, age, gender, hormonal balance, and pregnancy affect normal cholesterol levels.<sup>1</sup>

The Adult Treatment Panel of the National Cholesterol Education Program (NCEP) recommends that all adults 20 years of age and over should have a fasting lipoprotein profile (total cholesterol, LDL cholesterol, HDL cholesterol, and triglyceride) once every five years to screen for coronary heart disease risk.<sup>2</sup>

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**PRINCIPLES OF PROCEDURE**

The use of enzymes to assay cholesterol has been studied by many investigators.<sup>3, 4</sup> This reagent is based on the formulation of Allain, et al.<sup>5</sup> and the modification of Roeschlau<sup>6</sup> with further improvements to render the reagent stable in solution.

Cholesterol esters are enzymatically hydrolyzed by cholesterol esterase to cholesterol and free fatty acids. Free cholesterol, including that originally present, is then oxidized by cholesterol oxidase to cholest-4-ene-3-one and hydrogen peroxide. The hydrogen peroxide combines with Hydroxybenzoic Acid (HBA) and 4-aminoantipyrine to form a chromophore (quinoneimine dye) which is quantitated at 500 nm.

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**REAGENTS****Reagent Kit**

Cholesterol, List No. 7D62, is supplied as a liquid, ready-to-use, single reagent kit which contains:

- Reagent 1 (R1) 10 x 84 mL

Estimated tests per kit are 3,032. Calculation based on minimum reagent fill volume per kit.

**Reactive Ingredients**

Ingredient	Concentration
Cholesterol Oxidase (Microbial)	> 200 U/L
Cholesterol Esterase (Microbial)	> 500 U/L
Peroxidase (Horseradish)	> 300 U/L
4-Aminoantipyrine	0.25 mmol/L
HBA	10 mmol/L

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The Abbott Clinical Chemistry Cholesterol reagent is certified to be traceable to the National Reference System for Cholesterol, against the Abell-Kendall reference method in a CDC-Certified Cholesterol Reference Method Laboratory Network (CRMLN).

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**REAGENT HANDLING AND STORAGE****Reagent Handling**

Remove air bubbles, if present in the reagent cartridge, with a new applicator stick. Alternatively, allow the reagent to sit at the appropriate storage temperature to allow the bubbles to dissipate. To minimize volume depletion, do not use a transfer pipette to remove the bubbles.

**CAUTION:** Reagent bubbles may interfere with proper detection of reagent level in the cartridge, causing insufficient reagent aspiration which could impact results.

**Reagent Storage**

The unopened reagents are stable until the expiration date when stored at 2 to 8°C.

Reagent stability is 30 days if the reagent is uncapped and onboard.

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**WARNINGS AND PRECAUTIONS****Precautions for Users**

1. For in vitro diagnostic use.
2. Do not use components beyond the expiration date.
3. Do not mix materials from different kit lot numbers.
4. Contains nonsterile bovine serum albumin.

Information for European customers: For reagents not classified as dangerous per European Directive 1999/45/EC, safety data sheet available for professional user on request.

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## SPECIMEN COLLECTION AND HANDLING

### Suitable Specimens

Serum and plasma are acceptable specimens. The National Cholesterol Education Program (NCEP) recommends using fasting specimens.<sup>2</sup>

**Serum:** Use serum with or without gel barrier collected by standard venipuncture techniques in glass or plastic tubes. Ensure complete clot formation has taken place prior to centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may exhibit increased clotting time. If the specimen is centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results. Separate from red blood cells as soon after collection as possible.

**Plasma:** Use plasma without gel barrier (acceptable anticoagulants: lithium heparin, ammonium heparin, and sodium heparin) collected by standard venipuncture techniques in glass or plastic tubes. Ensure centrifugation is adequate to remove platelets. Separate from red blood cells as soon after collection as possible.

For total sample volume requirements, refer to the instrument-specific ASSAY PARAMETERS section of this package insert and *Section 5* of the instrument-specific operations manual.

**CAUTION:** This product requires the handling of human specimens. It is recommended that all human sourced materials are considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens.<sup>7</sup> Biosafety Level 2<sup>8</sup> or other appropriate biosafety practices<sup>9, 10</sup> should be used for materials that contain or are suspected of containing infectious agents.

### Specimen Storage

#### Serum and plasma:

Temperature	Maximum Storage	Reference
20 to 25°C	7 days	11
2 to 8°C	7 days	11, 12
-20°C	3 months	11

Guder et al.<sup>11</sup> suggest storage of frozen specimens at -20°C for no longer than the time intervals cited above. However, limitations of laboratory equipment make it necessary in practice for clinical laboratories to establish a range around -20°C for specimen storage. This temperature range may be established from either the freezer manufacturer's specifications or the laboratory Standard Operating Procedure(s) for specimen storage.

**NOTE:** Stored specimens must be adequately mixed prior to testing.

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## PROCEDURE

### Materials Provided

Cholesterol Reagent Kit, List No. 7D62

### Materials Required but not Provided

- AEROSSET System or ARCHITECT c8000 System
- Multiconstituent Calibrator, List No. 1E65
  - CAL 1: 3 x 5 mL
  - CAL 2: 3 x 5 mL
- Control Material
- Saline (0.85 to 0.90%), if desired for specimen dilution

### Assay Procedure

For a detailed description of how to run an assay, refer to *Section 5* of the instrument-specific operations manual.

### Specimen Dilution Procedures

Use saline to dilute samples outside of the linearity of the assay. The AEROSSET System and the ARCHITECT c8000 System have Automatic Dilution features; refer to *Section 2* of the instrument-specific operations manual for additional information.

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## CALIBRATION

Calibration is stable for approximately 30 days (720 hours) and calibration is required with each lot number change. Verify calibration curve with at least two levels of controls according to the established Quality Control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary.

For a detailed description of how to calibrate an assay, refer to *Section 6* of the instrument-specific operations manual.

For information on calibrator standardization, refer to the Multiconstituent Calibrator package insert.

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## QUALITY CONTROL

The following process is the recommendation of Abbott Laboratories for quality control during the Cholesterol procedure. As appropriate, refer to your laboratory Standard Operating Procedure(s) and/or Quality Assurance Plan for additional quality control requirements and potential corrective actions.

- Two levels of controls (normal and abnormal) are to be run every 24 hours.
- If more frequent control monitoring is required, follow the established Quality Control procedures for your laboratory.
- If quality control results do not fall within an acceptable range defined by your laboratory, patient values may be suspect. Follow the established Quality Control procedures for your laboratory.
- If quality control results fall outside acceptance criteria, recalibration may be necessary.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

## RESULTS

Refer to the instrument-specific operations manual for information on results calculations.

- **AEROSET System Operations Manual—Appendix A**
- **ARCHITECT System Operations Manual—Appendix C**

## LIMITATIONS OF THE PROCEDURE

Refer to the SPECIMEN COLLECTION AND HANDLING and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert.

## EXPECTED VALUES

### Reference Range

#### Serum/Plasma

	Range (mg/dL)	Range (mmol/L)
Child <sup>13</sup>		
Desirable	< 170	< 4.40
Borderline	170 to 199	4.40 to 5.15
High	≥ 200	≥ 5.18
Adult <sup>2</sup>		
Desirable	< 200	< 5.18
Borderline	200 to 239	5.18 to 6.19
High	≥ 240	≥ 6.22

To convert results from mg/dL to mmol/L, multiply mg/dL by 0.0259.

The National Cholesterol Education Program (NCEP) Adult Treatment Panel III Report<sup>2</sup> recommends the adult classification shown above. Laboratories should follow recommendations for lipid ranges effective in their locale if they differ from those of the NCEP.

## SPECIFIC PERFORMANCE CHARACTERISTICS

# AEROSET

# c8000

### Linearity

Cholesterol is linear up to 705 mg/dL (18.26 mmol/L).

Linearity was verified using NCCLS protocol EP6-P.<sup>14</sup>

### Limit of Detection (LOD)

The LOD is the mean concentration of an analyte-free sample + 2 SD, where SD = the pooled, within-run standard deviation of the analyte-free sample. The LOD for Cholesterol is 0.8 mg/dL (0.021 mmol/L).

### Limit of Quantitation (LOQ)

The LOQ is the analyte concentration at which the CV = 20%. The limit of quantitation for Cholesterol is 6.2 mg/dL (0.161 mmol/L).

### Interfering Substances<sup>15</sup>

Interference studies were conducted on the AEROSET System using NCCLS protocol EP7-P.<sup>16</sup> Interference effects were assessed by Dose Response and Paired Difference methods, at the medical decision level of the analyte concentration or activity.

Interfering Substance	Interferent Concentration	N	Target (mg/dL)	Observed (% of Target)
Bilirubin	7.5 mg/dL (128 μmol/L)	4	252.3	91.7
Bilirubin	15 mg/dL (257 μmol/L)	4	252.3	86.8
Hemoglobin	750 mg/dL (7.5 g/L)	4	241.1	109.5
Hemoglobin	1,000 mg/dL (10.0 g/L)	4	241.1	111.9
Intralipid	1,000 mg/dL (10.0 g/L)	4	236.1	102.5
Intralipid	2,000 mg/dL (20.0 g/L)	4	236.1	101.9
Ascorbate	1.5 mg/dL (85 μmol/L)	4	282.2	98.7
Ascorbate	3 mg/dL (170 μmol/L)	4	282.2	97.6

Bilirubin levels were prepared by the addition of a bilirubin stock to human serum pools. Hemoglobin levels were prepared by addition of hemolysate to human serum pools. Intralipid levels were prepared by addition of Intralipid to human serum pools. Ascorbate levels were prepared by addition of ascorbic acid to human serum pools.

## SPECIFIC PERFORMANCE CHARACTERISTICS (Continued)

# AEROSET

### Precision

The results from precision studies for serum using NCCLS protocol EP5-T2<sup>17</sup> are found below.

Control	N	Mean (mg/dL)	Within Run		Between Run		Between Day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Level 1	80	268.5	1.84	0.7	0.77	0.3	0.98	0.4	2.23	0.8
Level 2	80	129.9	1.25	1.0	0.71	0.5	1.55	1.2	2.11	1.6

### Method Comparison

Correlation studies were performed using NCCLS protocol EP9-A.<sup>18</sup> Serum results from the Cholesterol assay on the AEROSET System were compared with the Boehringer Mannheim Cholesterol assay (enzymatic methodology) on the Hitachi 717 Analyzer. Serum results observed on the AEROSET System ranged from 70.6 to 416.8 mg/dL.

	Serum
Y - Intercept	0.933
Correlation Coefficient	0.993
Slope	1.016
Number of Samples	79

**SPECIFIC PERFORMANCE CHARACTERISTICS (Continued)**



**Precision**

The results from precision studies for serum using NCCLS protocol EP5-A<sup>19</sup> are found below.

Control	N	Mean (mg/dL)	Within Run		Between Run		Between Day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
<b>Level 1</b>										
Instrument 1	80	263.2	1.45	0.6	0.65	0.3	2.23	0.9	2.74	1.0
Instrument 2	80	261.4	1.98	0.8	1.01	0.4	3.36	1.3	4.03	1.5
Instrument 3	80	264.2	0.88	0.3	2.48	0.9	2.30	0.9	3.49	1.3
<b>Level 2</b>										
Instrument 1	80	127.7	0.59	0.5	0.96	0.8	1.46	1.1	1.84	1.4
Instrument 2	80	127.5	0.78	0.6	0.89	0.7	1.23	1.0	1.70	1.3
Instrument 3	80	129.2	0.78	0.6	1.03	0.8	1.64	1.3	2.09	1.6

**Method Comparison**

Correlation studies were performed based on NCCLS protocol EP9-A.<sup>18</sup> Serum results from the Cholesterol assay on the ARCHITECT c8000 System were compared with the Cholesterol assay on the AEROSET System. Serum results observed on the AEROSET System ranged from 39.5 to 687.6 mg/dL.

	Instrument 1	Instrument 2	Instrument 3
Y - Intercept	-0.997	-0.840	-0.266
Correlation Coefficient	0.994	0.993	0.994
Slope	0.994	0.979	0.984
Number of Samples	101	101	101

# AEROSSET SYSTEM ASSAY PARAMETERS

## AEROSSET

### Cholesterol Serum/Plasma—Conventional Units

Assay Configuration: Outline Page						
Assay Name	Assay #		Line			
Chol	18		B-Line			
Quantitative Ranges						
Min Text	Min	Panic-L	L-Reference-H	Panic-H	Max	Max Text
*	0.0*	0.0	0 199	0.0	0.0*	*
		L-Linear Range-H	705			
Reference Ranges*						
Age	Male	Female				
0 Year	0.0 – 0.0	0.0 – 0.0				
0 Year	0.0 – 0.0	0.0 – 0.0				
0 Year	0.0 – 0.0	0.0 – 0.0				
0 Year	0.0 – 0.0	0.0 – 0.0				
Qualitative Ranges						
N/A						

### Cholesterol Serum/Plasma—SI Units

Assay Configuration: Outline Page						
Assay Name	Assay #		Line			
Chol	18		B-Line			
Quantitative Ranges						
Min Text	Min	Panic-L	L-Reference-H	Panic-H	Max	Max Text
*	0.0*	0.0	0.00 5.17	0.0	0.0*	*
		L-Linear Range-H	18.26			
Reference Ranges*						
Age	Male	Female				
0 Year	0.0 – 0.0	0.0 – 0.0				
0 Year	0.0 – 0.0	0.0 – 0.0				
0 Year	0.0 – 0.0	0.0 – 0.0				
0 Year	0.0 – 0.0	0.0 – 0.0				
Qualitative Ranges						
N/A						

Assay Configuration: Base Page						
Reaction Mode	Wavelength-Prim/Sec		Read Time-Main/Flex		AbsMax/Var	
END UP	500 / 660		31 – 33 / 0 – 0		0.0	
Sample Blank Test	Blank Read Time		Abs Window		Abs Limits	
____ ( ____ )	0 – 0		0 – 0		0.0 – 0.0	
Standard	S.Vol	DS.Vol	D.Vol	W.Vol	Rgt Name/Pos	
Dil 1	2.4	0.0	0	0	Diluent DILUENT D-18*	
Dil 2	2.4	0.0	0	0	Type#*** 0	
Reagent 1	Rgt Name/Pos	R.Vol	W.Vol	Type#***		
CHOL061 – ____*	240	0	0			
Reaction Check	Read Time-A/B		Range		Minimum	
____	1 – 1 / 1 – 1		0.0 – 0.0		0.0	
Factor/Intercept	Decimal Places		Units			
1.0 / 0.0	0		mg/dL			

Assay Configuration: Base Page						
Reaction Mode	Wavelength-Prim/Sec		Read Time-Main/Flex		AbsMax/Var	
END UP	500 / 660		31 – 33 / 0 – 0		0.0	
Sample Blank Test	Blank Read Time		Abs Window		Abs Limits	
____ ( ____ )	0 – 0		0 – 0		0.0 – 0.0	
Standard	S.Vol	DS.Vol	D.Vol	W.Vol	Rgt Name/Pos	
Dil 1	2.4	0.0	0	0	Diluent DILUENT D-18*	
Dil 2	2.4	0.0	0	0	Type#*** 0	
Reagent 1	Rgt Name/Pos	R.Vol	W.Vol	Type#***		
CHOL061 – ____*	240	0	0			
Reaction Check	Read Time-A/B		Range		Minimum	
____	1 – 1 / 1 – 1		0.0 – 0.0		0.0	
Factor/Intercept	Decimal Places		Units			
1.0 / 0.0	2		mmol/L			

Assay Configuration: Calibration Page						
Calib Mode	Interval (H)					
Linear	720					
Blank/Calib Replicates	Extrapolation%		Span	Span Abs Range		
3 / 3	0		BLK – 1	0.0 – 0.0		
BLK	Sample	S.Vol	DS.Vol	D.Vol	W.Vol	BLK Abs Range
Water	2.4	0.0	0	0	0	0.0 – 0.0
C1	MCC 1	2.4	0.0	0	0	Cal Deviation
C2	MCC 2	2.4	0.0	0	0	0.0
						FAC Limit (%)***
						10

Assay Configuration: Calibration Page						
Calib Mode	Interval (H)					
Linear	720					
Blank/Calib Replicates	Extrapolation%		Span	Span Abs Range		
3 / 3	0		BLK – 1	0.0 – 0.0		
BLK	Sample	S.Vol	DS.Vol	D.Vol	W.Vol	BLK Abs Range
Water	2.4	0.0	0	0	0	0.0 – 0.0
C1	MCC 1	2.4	0.0	0	0	Cal Deviation
C2	MCC 2	2.4	0.0	0	0	0.0
						FAC Limit (%)***
						10

Assay Configuration: SmartWash Page			
Rgt Probe			
Reagent	Wash	Vol	
ALBP061	Water	300	
Cuvette			
Assay Name	Wash	Vol	
—	—	—	
Sample Probe			
Wash			
—			

Assay Configuration: SmartWash Page			
Rgt Probe			
Reagent	Wash	Vol	
ALBP061	Water	300	
Cuvette			
Assay Name	Wash	Vol	
—	—	—	
Sample Probe			
Wash			
—			

Refer to **Assay Configuration** in *Section 2* of the **AEROSSET System Operations Manual** for information regarding assay parameters.

\* User defined or instrument defined.

\*\* The linear low value (L-Linear Range) is LOQ rounded up to the number of decimal places defined in the decimal places parameter field.

\*\*\*This field is not available with AEROSSET Software v1.00ER005 or 1.00ER005.2.

# ARCHITECT c8000 SYSTEM ASSAY PARAMETERS

## c8000

### Cholesterol Serum/Plasma—Conventional and SI Units

Configure assay parameters – General				
<input checked="" type="radio"/> General	<input type="radio"/> Calibration	<input type="radio"/> SmartWash	<input type="radio"/> Results	<input type="radio"/> Interpretation
Assay: <b>Chol</b>	Type: <b>Photometric</b>	Version: 1		
Number: <b>1018</b>				
<input checked="" type="radio"/> Reaction definition	<input type="radio"/> Reagent / Sample	<input type="radio"/> Validity checks		
Reaction mode: <b>End up</b>				
Primary		Secondary	Read times	
Wavelength: <b>500 / 660</b>		Main: <b>31 - 33</b>		
Last required read: <b>33</b>				
Absorbance range: ___ - ___		Color correction: ___ - ___		
Sample blank type: <b>None</b>				

Configure assay parameters – Reagent / Sample				
<input type="radio"/> Reaction definition	<input checked="" type="radio"/> Reagent / Sample	<input type="radio"/> Validity checks		
Reagent: <b>CHOL0</b>				
Diluent: <b>Saline</b>		Reagent volume: <b>240</b>		R1
Diluent dispense mode: <b>Type 0</b>		Water volume: ___		
		Dispense mode: <b>Type 0</b>		
Dilution name	Sample	Diluted sample	Diluent	Water
<b>STANDARD:</b>	<b>2.4</b>	___	___	___ = <b>1:1.00</b>
<b>1:4</b>	<b>25.0</b>	<b>2.4</b>	<b>75</b>	___ = <b>1:4.00</b>
___	___	___	___	___ = ___
				Default dilution
				<input checked="" type="radio"/>
				<input type="radio"/>
				<input type="radio"/>

Configure assay parameters – Validity checks				
<input type="radio"/> Reaction definition	<input type="radio"/> Reagent / Sample	<input checked="" type="radio"/> Validity checks		
Reaction check: <b>None</b>				
Maximum absorbance variation: ___				

Configure assay parameters – Calibration				
<input type="radio"/> General	<input checked="" type="radio"/> Calibration	<input type="radio"/> SmartWash	<input type="radio"/> Results	<input type="radio"/> Interpretation
Assay: <b>Chol</b>		Calibration method: <b>Linear</b>		
<input checked="" type="radio"/> Calibrators	<input type="radio"/> Volumes	<input type="radio"/> Intervals	<input type="radio"/> Validity checks	
Calibrator set: <b>MCC</b>		Calibrator level: <b>Water</b>		Concentration: <b>0<sup>††</sup></b>
Replicates: <b>3</b> [Range 1 – 3]		Blank: <b>MCC1</b>	⚡	
		Cal 2: <b>MCC2</b>	⚡	

Configure assay parameters – Volumes				
<input type="radio"/> Calibrators	<input checked="" type="radio"/> Volumes	<input type="radio"/> Intervals	<input type="radio"/> Validity checks	
Calibrator: <b>MCC</b>				
Calibrator level		Sample	Diluted sample	Diluent
Blank: <b>Water</b>		<b>2.4</b>	___	___
Cal 1: <b>MCC1</b>		<b>2.4</b>	___	___
Cal 2: <b>MCC2</b>		<b>2.4</b>	___	___

Configure assay parameters – Intervals				
<input type="radio"/> Calibrators	<input type="radio"/> Volumes	<input checked="" type="radio"/> Intervals	<input type="radio"/> Validity checks	
Calibration intervals:				
Full interval: <b>720</b> (hours)				
Calibration type:				
Adjust type: <b>None</b>				

Configure assay parameters – Validity checks				
<input type="radio"/> Calibrators	<input type="radio"/> Volumes	<input type="radio"/> Intervals	<input checked="" type="radio"/> Validity checks	
Blank absorbance range: ___ - ___				
Span: <b>Blank - Water</b>				
Span absorbance range: ___ - ___				
Expected cal factor: <b>0.00</b>				
Expected cal factor tolerance %: <b>0</b>				

Configure assay parameters – SmartWash				
<input type="radio"/> General	<input type="radio"/> Calibration	<input checked="" type="radio"/> SmartWash	<input type="radio"/> Results	<input type="radio"/> Interpretation
Assay: <b>Chol</b>				
COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates
<b>R1</b>	<b>ALBP0</b>	<b>Water</b>	<b>300</b>	<b>1</b>
<b>Cuvette</b>	<b>Trig</b>	<b>Detergent B</b>	<b>345</b>	

### Cholesterol Serum/Plasma—Conventional Units

Configure assay parameters – Results – Conventional units				
<input type="radio"/> General	<input type="radio"/> Calibration	<input type="radio"/> SmartWash	<input checked="" type="radio"/> Results	<input type="radio"/> Interpretation
Assay: <b>Chol</b>		Result units: <b>mg/dL</b>		
Assay defaults:				
Low-Linearity: <b>7<sup>†</sup></b>				
High-Linearity: <b>705</b>				
Gender and age specific ranges:				
GENDER	AGE (UNITS)	NORMAL	EXTREME	
<b>Either</b>	<b>0 – 130 (Y)</b>	<b>0 – 199</b>		

Configure result units – Conventional units	
Assay: <b>Chol</b>	Version: 1
Result units: <b>mg/dL</b>	Decimal places: <b>0</b> [Range 0 – 4]
Correlation factor: <b>1.000</b>	Intercept: <b>0.000</b>

### Cholesterol Serum/Plasma—SI Units

Configure assay parameters – Results – SI units				
<input type="radio"/> General	<input type="radio"/> Calibration	<input type="radio"/> SmartWash	<input checked="" type="radio"/> Results	<input type="radio"/> Interpretation
Assay: <b>Chol</b>		Result units: <b>mmol/L</b>		
Assay defaults:				
Low-Linearity: <b>0.17<sup>†</sup></b>				
High-Linearity: <b>18.26</b>				
Gender and age specific ranges:				
GENDER	AGE (UNITS)	NORMAL	EXTREME	
<b>Either</b>	<b>0 – 130 (Y)</b>	<b>0.00 – 5.17</b>		

Configure result units – SI units	
Assay: <b>Chol</b>	Version: 1
Result units: <b>mmol/L</b>	Decimal places: <b>2</b> [Range 0 – 4]
Correlation factor: <b>1.000</b>	Intercept: <b>0.000</b>

† The linear low value (Low-Linearity) is LOQ rounded up to the number of decimal places defined in the decimal places parameter field.

‡ Refer to concentration specified on calibrator labeling or value sheet.

†† Displays the number of decimal places defined in the decimal places parameter field.

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