



en

CHOLESTEROL

REF 7D62

304796/R02

## ARCHITECT

# CHOLESTEROL

This package insert contains information to run the Cholesterol assay on the ARCHITECT c Systems.

**Read Highlighted Changes Revised October 2012**

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

**Customer Service:** Contact your local representative or find country-specific contact information on [www.abbottdiagnostics.com](http://www.abbottdiagnostics.com).

### Key to Symbols Used

<b>CONTAINS: AZIDE</b>	Contains sodium azide. Contact with acids liberates very toxic gas.	<b>R1</b>	Reagent 1
<b>EC REP</b>	Authorized Representative in the European Community	<b>REF</b>	Catalog number/List number
<b>FOR USE WITH</b>	Identifies products to be used together	<b>SN</b>	Serial number
<b>GTIN</b>	Global Trade Item Number		Consult instructions for use
<b>INFORMATION FOR USA ONLY</b>	Information needed for United States of America only		Manufacturer
<b>IVD</b>	<i>In Vitro</i> Diagnostic Medical Device		Sufficient for
<b>LOT</b>	Batch code/Lot number		Temperature limitation
<b>PRODUCT OF USA</b>	Product of USA		Use by/Expiration date

## NAME

CHOLESTEROL

## INTENDED USE

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

## 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>

## 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.

**Methodology:** Enzymatic

## REAGENTS

### Reagent Kit

[REF] 7D62-21 Cholesterol is supplied as a liquid, ready-to-use, single reagent kit which contains:

[R1] 10 x 84 mL

Estimated tests per kit: 3,032

Calculation is based on the minimum reagent fill volume per kit.

Reactive Ingredients	Concentration
Cholesterol oxidase (microbial)	> 200 U/L
Cholesterol esterase (microbial)	> 500 U/L
Peroxidase (horseradish)	> 300 U/L
4-aminoantipyrine	< 0.5 mmol/L
HBA	10 mmol/L

Inactive Ingredients: [R1] contains sodium azide (0.01%) as a preservative and bovine serum albumin (BSA) (0.02%).

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).

## 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

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.

### Indications of Deterioration

Instability or deterioration should be suspected if there are precipitates, visible signs of leakage, extreme turbidity, microbial growth, if calibration does not meet the appropriate package insert and/or ARCHITECT System Operations Manual criteria, or if controls do not meet the appropriate criteria.

## WARNINGS AND PRECAUTIONS

### Precautions for Users

- [IVD]
- For *In Vitro* Diagnostic Use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Contains nonsterile bovine serum albumin.
- **CAUTION:** This product requires the handling of human specimens. It is recommended that all human sourced materials be 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.
- The following warning and precaution apply to [R1]:
  - Contains sodium azide.
  - EUH032 Contact with acids liberates very toxic gas.
- This material and its container must be disposed of in a safe way.  
**NOTE:** Refer to *Section 8* of the ARCHITECT System Operations Manual for proper handling and disposal of reagents containing sodium azide.
- Safety Data Sheets are available at [www.abbottdiagnostics.com](http://www.abbottdiagnostics.com) or contact your local representative.

## 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 collected by standard venipuncture techniques into glass or plastic tubes with or without gel barriers. Ensure complete clot formation has taken place prior to centrifugation. Centrifuge according to tube manufacturer's instructions to ensure proper separation of serum from blood cells.  
  
Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may take longer to complete their clotting processes. Fibrin clots may subsequently form in these sera and the clots could cause erroneous test results.
- **Plasma:** Use plasma collected by standard venipuncture techniques into glass or plastic tubes. Acceptable anticoagulants are lithium heparin (with or without gel barrier) and sodium heparin. Ensure centrifugation is adequate to remove platelets. Centrifuge according to tube manufacturer's instructions to ensure proper separation of plasma from blood cells.

For total sample volume requirements, refer to the ASSAY PARAMETERS section of this package insert and *Section 5* of the ARCHITECT System Operations Manual.

### Specimen Storage

#### Serum and Plasma

Temperature	Maximum Storage	Bibliographic 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 interval 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 your laboratory standard operating procedure(s) for specimen storage.

**NOTE:** Stored specimens must be inspected for particulates. If present, mix and centrifuge the specimen to remove particulates prior to testing.

## PROCEDURE

### Materials Provided

[REF] 7D62 Cholesterol Reagent Kit

### Materials Required but not Provided

- [REF] 1E65 Multiconstituent Calibrator
- Control Material
- Saline (0.85% to 0.90% NaCl) for specimens that require dilution

### Assay Procedure

For a detailed description of how to run an assay, refer to *Section 5* of the **ARCHITECT System Operations Manual**.

### Specimen Dilution Procedures

The ARCHITECT *c*Systems have an automatic dilution feature; refer to *Section 2* of the **ARCHITECT System Operations Manual** for additional information.

**Serum and Plasma:** Specimens with cholesterol values exceeding 705 mg/dL (18.26 mmol/L) are flagged and may be diluted by following either the Automated Dilution Protocol or the Manual Dilution Procedure.

### Automated Dilution Protocol

If using the Automated Dilution Protocol, the system performs a 1:4 dilution of the specimen and automatically corrects the concentration by multiplying the result by the appropriate dilution factor.

### Manual Dilution Procedure

Manual dilutions should be performed as follows:

- Use saline (0.85% to 0.90% NaCl) to dilute the sample.
- The operator must enter the dilution factor in the patient or control order screen. The system uses this dilution factor to automatically correct the concentration by multiplying the result by the entered factor.
- If the operator does not enter the dilution factor, the result must be multiplied by the appropriate dilution factor before reporting the result.

**NOTE:** If a diluted sample result is flagged indicating it is less than the linear low limit, do not report the result. Rerun using an appropriate dilution.

For detailed information on ordering dilutions, refer to *Section 5* of the **ARCHITECT System Operations Manual**.

## CALIBRATION

Calibration is stable for approximately 30 days (720 hours) and is required with each change in reagent lot number. 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 **ARCHITECT System Operations Manual**.

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

## QUALITY CONTROL

The following is the recommendation of Abbott Laboratories for quality control. 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 meet the acceptance criteria defined by your laboratory, patient values may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

## RESULTS

Refer to *Appendix C* of the **ARCHITECT System Operations Manual** for information on results calculations.

Representative performance data are given in the EXPECTED VALUES and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert. Results obtained in individual laboratories may vary.

## 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

### Linearity

Cholesterol is linear up to 705 mg/dL (18.26 mmol/L). Linearity was verified using Clinical and Laboratory Standards Institute (CLSI) protocol NCCLS EP6-P.<sup>14</sup>

### Limit of Detection (LOD)

The LOD for Cholesterol is 5.0 mg/dL (0.13 mmol/L). 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. A study performed on an ARCHITECT *c*System produced an LOD for the Cholesterol assay of 0.80 mg/dL (0.021 mmol/L).

### Limit of Quantitation (LOQ)

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

### Interfering Substances

Interference studies were conducted using CLSI protocol NCCLS EP7-P.<sup>15</sup> Interference effects were assessed by Dose Response and Paired Difference methods, at the medical decision level of the analyte.

Interfering Substance	Interferent Concentration	N	Target (mg/dL)	Observed (% of Target)
Bilirubin	7.5 mg/dL (128 µmol/L)	4	252.3	91.7
	15 mg/dL (257 µmol/L)	4	252.3	86.8
Hemoglobin	750 mg/dL (7.5 g/L)	4	241.1	109.5
	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
	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
	3 mg/dL (170 µmol/L)	4	282.2	97.6

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

Interferences from medications or endogenous substances may affect results.<sup>16</sup>

## SPECIFIC PERFORMANCE CHARACTERISTICS

### (Continued)

#### Precision

The imprecision of the Cholesterol assay is  $\leq 3\%$  Total CV. Representative data from studies using CLSI protocol NCCLS EP5-A<sup>17</sup> are summarized below.

Control		Level 1	Level 2
N		80	80
Mean (mg/dL)		261.4	129.2
Within Run	SD	1.98	0.78
	%CV	0.8	0.6
Between Run	SD	1.01	1.03
	%CV	0.4	0.8
Between Day	SD	3.36	1.64
	%CV	1.3	1.3
Total	SD	4.03	2.09
	%CV	1.5	1.6

#### Method Comparison

Correlation studies were performed using CLSI protocol NCCLS EP9-A.<sup>18</sup>

Serum results from the Cholesterol assay on the AEROSSET System were compared with those from a commercially available enzymatic methodology.

Serum results from the Cholesterol assay on an ARCHITECT cSystem were compared with the Cholesterol assay on the AEROSSET System.

	AEROSSET vs. Comparative Method	ARCHITECT vs. AEROSSET
N	79	101
Y - Intercept	0.933	-0.840
Correlation Coefficient	0.993	0.993
Slope	1.016	0.979
Range (mg/dL)*	70.6 to 416.8	39.5 to 687.6

\*AEROSSET Range

## BIBLIOGRAPHY

1. Burtis CA, Ashwood ER, editors. *Tietz Fundamentals of Clinical Chemistry*, 5th ed. Philadelphia, PA: WB Saunders; 2001:480–5.
2. Executive summary of the third report of the National Cholesterol Education Program (NCEP) Expert Panel on detection, evaluation, and treatment of high blood cholesterol in adults (Adult Treatment Panel III). *JAMA* 2001;285:2486–97.
3. Flegg HM. An investigation of the determination of serum cholesterol by an enzymatic method. *Ann Clin Biochem* 1973;10:79–84.
4. Richmond W. Preparation and properties of a cholesterol oxidase from *Nocardia* sp. and its application to the enzymatic assay of total cholesterol in serum. *Clin Chem* 1973;19(12):1350–6.
5. Allain CC, Poon LS, Chan CS, et al. Enzymatic determination of total serum cholesterol. *Clin Chem* 1974;20(4):470–5.
6. Roeschlau P, Bernt E, Gruber WA. Enzymatic determination of total cholesterol in serum. *Z Klin Chem Klin Biochem* 1974;12:226.
7. US Department of Labor, Occupational Safety and Health Administration. 29 CFR Part 1910.1030. *Bloodborne Pathogens*.
8. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*, 5th ed. Washington, DC: US Government Printing Office, December 2009.
9. World Health Organization. *Laboratory Biosafety Manual*, 3rd ed. Geneva: World Health Organization, 2004.
10. Sewell DL, Bove KE, Callihan DR, et al. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Third Edition (M29-A3)*. Wayne, PA: Clinical and Laboratory Standards Institute, 2005.
11. Guder WG, Narayanan S, Wissner H, et al. List of analytes—preanalytical variables. Annex In: *Samples: From the Patient to the Laboratory*. Darmstadt, Germany: GiT Verlag; 1996:Annex 12–3.
12. US Pharmacopeial Convention, Inc. General notices. In: *US Pharmacopeia National Formulary*, 1995 ed (USP 23/NF 18). Rockville, MD: The US Pharmacopeial Convention, Inc; 1994:11.
13. American Academy of Pediatrics, Committee on Nutrition. Cholesterol in childhood. *Pediatrics* 1998;101(1);141–7.
14. Passey RB, Bee DE, Caffo A, et al. *Evaluation of the Linearity of Quantitative Analytical Methods; Proposed Guideline (EP6-P)*. Villanova, PA: The National Committee for Clinical Laboratory Standards, 1986.
15. Powers DM, Boyd JC, Glick MR, et al. *Interference Testing in Clinical Chemistry; Proposed Guideline (EP7-P)*. Villanova, PA: The National Committee for Clinical Laboratory Standards, 1986.
16. Young DS. *Effects of Drugs on Clinical Laboratory Tests*, 4th ed. Washington, DC: AACC Press; 1995:3-143–3-163.
17. Kennedy JW, Carey RN, Coolen RB, et al. *Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline (EP5-A)*. Wayne, PA: The National Committee for Clinical Laboratory Standards, 1999.
18. Kennedy JW, Carey RN, Coolen RB, et al. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline (EP9-A)*. Wayne, PA: The National Committee for Clinical Laboratory Standards, 1995.

## TRADEMARKS

The ARCHITECT cSystem family of instruments consists of c4000, c8000, and c16000 instruments.

AEROSSET, ARCHITECT, c4000, c8000, c16000, cSystem, and SmartWash are trademarks of Abbott Laboratories in various jurisdictions.

All trademarks are property of their respective owner(s).



304796/R02



Abbott Laboratories  
Abbott Park, IL 60064 USA

October 2012  
©2009, 2012 Abbott Laboratories



ABBOTT  
Max-Planck-Ring 2  
65205 Wiesbaden  
Germany  
+49-6122-580

ARCHITECT c SYSTEMS ASSAY PARAMETERS

# ARCHITECT

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

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

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

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

Configure assay parameters — Calibration			
<input type="radio"/> General <input checked="" type="radio"/> <b>Calibration</b> <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"/> <b>Calibrators</b> <input type="radio"/> Volumes <input type="radio"/> Intervals <input type="radio"/> Validity checks			
Calibrator set: <b>MCC</b>		Blank: <b>Water</b>	
Replicates: <b>3</b> [Range 1 – 3]		Calibrator level: <b>0††</b>	
		Cal 1: <b>MCC1</b>	
		Cal 2: <b>MCC2</b>	

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

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

Configure assay parameters — Calibration			
<input type="radio"/> Calibrators <input type="radio"/> Volumes <input type="radio"/> Intervals <input checked="" type="radio"/> <b>Validity checks</b>			
Blank absorbance range: ___ – ___			
Span: <b>Blank</b> – <b>Blank</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"/> <b>SmartWash</b> <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>10% Detergent B</b>	<b>345</b>	
**Not required for ARCHITECT Software version 7.00 and above.				

**Cholesterol Serum/Plasma—Conventional Units**

Configure assay parameters — Results			
<input type="radio"/> General <input type="radio"/> Calibration <input type="radio"/> SmartWash <input checked="" type="radio"/> <b>Results</b> <input type="radio"/> Interpretation			
Assay: <b>Chol</b>		Assay number: <b>1018</b>	
Dilution default range:		Result units: <b>mg/dL</b>	
Low-Linearity: <b>7††</b>			
High-Linearity: <b>705</b>			
Gender and age specific ranges:			
GENDER	AGE (UNITS)	NORMAL	EXTREME
<b>Either</b>	<b>0 – 130</b>	<b>0 – 199</b>	

Configure result units	
Assay:	<b>Chol</b>
Version:	†
Result units:	<b>mg/dL</b>
Decimal places:	<b>0</b> [Range 0 – 4]
Correlation factor:	<b>1.0000</b>
Intercept:	<b>0.0000</b>

**Cholesterol Serum/Plasma—SI Units**

Configure assay parameters — Results			
<input type="radio"/> General <input type="radio"/> Calibration <input type="radio"/> SmartWash <input checked="" type="radio"/> <b>Results</b> <input type="radio"/> Interpretation			
Assay: <b>Chol</b>		Assay number: <b>1018</b>	
Dilution default range:		Result units: <b>mmol/L</b>	
Low-Linearity: <b>0.17††</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	
Assay:	<b>Chol</b>
Version:	†
Result units:	<b>mmol/L</b>
Decimal places:	<b>2</b> [Range 0 – 4]
Correlation factor:	<b>1.0000</b>
Intercept:	<b>0.0000</b>

† Due to differences in instrument systems and unit configurations, version numbers may vary.  
 \* Parameter is available in ARCHITECT Software version 7.00 and above.  
 †† Displays the number of decimal places defined in the decimal places parameter field.  
 ‡ Refer to the concentration specified on calibrator labeling or value sheet. In ARCHITECT Software version 5.00 and above, these values are defined on the Configure calibrator set screen.  
 ‡‡ The linear low value (Low-Linearity) is LOQ rounded up to the number of decimal places defined in the decimal places parameter field.





