Cholesterol2

FOR USE WITH

ARCHITECT

Read Highlighted Changes: Revised January 2023.

REF 04S9220

REF 04S9230

Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

For laboratory professional use only.

NAME

Cholesterol2 (also referred to as Chol2)

INTENDED USE

The Cholesterol2 assay is used for the quantitation of cholesterol in human serum or plasma on the ARCHITECT c Systems.

The Cholesterol2 assay is to be used as an aid in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.

SUMMARY AND EXPLANATION OF THE 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.[1]

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.[2]

PRINCIPLES OF THE PROCEDURE

The Cholesterol2 assay is an automated clinical chemistry assay.

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 oxidatively couples with N,N-Bis(4-sulfobutyl)-3-methylaniline (TODB) and 4-aminoantipyrine to form a chromophore (quinoneimine dye) which is quantitated at 604 nm.

Methodology: Enzymatic

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

REAGENTS

Kit Contents

Cholesterol2 Reagent Kit 04S92

NOTE: Some kit sizes may not be available. Please contact your local distributor.

Volumes (mL) listed in the following table indicate the volume per cartridge.

REF	04S9220	04S9230
Tests per cartridge	250	800
Number of cartridges per kit	4	4
Tests per kit	1000	3200
R1	21.6 mL	62.5 mL

R1 Active ingredients: Cholesterol esterase 0.880 KU/L, Cholesterol oxidase (CONII-FD) 0.330 KU/L, TODB 0.466 g/L, 4-aminoantipyrine 0.134 g/L and Peroxidase (POD) 6.600 KU/L. Preservative: sodium azide.

The Cholesterol2 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).

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use
- Rx ONLY

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials and all consumables contaminated with potentially infectious materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate regional, national, and institutional biosafety practices should be used for materials that contain, are suspected of containing, or are contaminated with infectious agents.[3-6]

The following warnings and precautions apply to: R1	
WARNING	Contains PIPES sodium salt* and sodium azide.
H316*	Causes mild skin irritation.
EUH032	Contact with acids liberates very toxic gas.
Response	
P332+P313*	If skin irritation occurs: Get medical advice / attention.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

* Not applicable where regulation EC 1272/2008 (CLP) or OSHA Hazard Communication 29 CFR 1910.1200 (HCS) 2012 have been implemented.

Follow local chemical disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.

For the most current hazard information, see the product Safety Data Sheet.

Safety Data Sheets are available at www.corelaboratory.abbott or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

Reagent Handling

- Do not pool reagents within a kit or between kits.
- Do not reuse containers, caps or plugs due to the risk of contamination and the potential to compromise reagent performance.
- Upon receipt, place reagent cartridges in an upright position for 4 hours before use to allow bubbles that may have formed to dissipate.
- If a reagent cartridge is dropped, place in an upright position for 4 hours before use to allow bubbles that may have formed to dissipate.

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- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.

For a detailed discussion of reagent handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Reagent Storage

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2 to 8°C	Until expiration date	Store in upright position.
Onboard	System Temperature	30 days	
Opened	2 to 8°C	Until expiration date	Store in upright position.

Reagents may be stored on or off the ARCHITECT c System. If reagents are removed from the system, store at 2 to 8°C (with replacement caps) in their original boxes.

For information on unloading reagents, refer to the ARCHITECT System Operations Manual, Section 5.

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when a calibration error occurs or a control value is out of the specified range. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary.

For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The Cholesterol2 assay file must be installed on the ARCHITECT c System prior to performing the assay.

Installation of all the required SmartWash updates on the ARCHITECT c Systems Assay Disk Version 17.00 (or higher) and the ARCHITECT c Systems Special Chemistry Assay Disk Version 7.00 (or higher) must be completed prior to performing the assay. See below for impacted assays:

				VERSION	
Assay Name	Short Name	REF	Assay Number	Conventional Units / Alternate Units	SI Units / Alternate Units
Lipase	Lip	7D80	1029	12	12
Magnesium	MAG	3P68	1070	6	4
Magnesium Urine	MAGU	3P68	1099	8	4
Total Bile Acids	TBAL	3R04	2888	3	3

For detailed information on assay file installation and viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.

For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.

For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.

Alternate Result Units

Conversion formula:

(Concentration in Default result unit) x (Conversion factor) = (Concentration in Alternate result unit)

Default Result Unit	Conversion Factor	Alternate Result Unit
mg/dL	0.0259	mmol/L

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

The specimen types listed below were verified for use with this assay.

Other specimen types and collection tube types have not been verified with this assay.

Specimen Types	Collection Tubes
Serum	Serum
	Serum separator
Plasma	Lithium heparin
	Lithium heparin separator
	Sodium heparin

- Liquid anticoagulants may have a dilution effect resulting in lower concentration values for individual specimens. Only plasma tubes containing dried additive have been validated for use with this assay.

The instrument does not provide the capability to verify specimen types. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.

Specimen Conditions

- Do not use:
  - heat-inactivated specimens
  - pooled specimens
  - grossly hemolyzed specimens
  - specimens with obvious microbial contamination
  - specimens with fungal growth
- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.
- Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

To ensure consistency in results, recentrifuge specimens prior to testing if

- they contain fibrin, red blood cells, or other particulate matter.

NOTE: If fibrin, red blood cells, or other particulate matter are observed, mix by low-speed vortex or by inverting 10 times prior to recentrifugation.

Prepare frozen specimens as follows:

- Frozen specimens must be completely thawed before mixing.
- Mix thawed specimens thoroughly by low-speed vortex or by inverting 10 times.
- Visually inspect the specimens. If layering or stratification is observed, mix until specimens are visibly homogeneous.
- If specimens are not mixed thoroughly, inconsistent results may be obtained.
- Recentrifuge specimens.

Recentrifugation of Specimens

- Transfer specimens to a centrifuge tube and centrifuge.
- Transfer clarified specimen to a sample cup or secondary tube for testing. For centrifuged specimens with a lipid layer, transfer only the clarified specimen and not the lipemic material.

Specimen Storage

Specimen Type	Temperature	Maximum Storage Time
Serum/Plasma	Room temperature (20 to 25°C)	7 days[7]
	2 to 8°C	7 days[7]
	-20°C	3 months[8]

Avoid more than 10 freeze/thaw cycles.[8]

It is the responsibility of the individual laboratory to determine specific specimen stability criteria for their laboratory per their laboratory workflow.

For additional information on sample handling and processing, refer to CLSI GP44-A4.[9] The storage information provided here is based on references or data maintained by the manufacturer.

Each laboratory may establish a range around -20°C from either the freezer manufacturer's specifications or your laboratory standard operating procedure(s) for specimen storage.

Stored specimens must be inspected for particulates. If present, mix with a low-speed vortex or by inversion and centrifuge the specimen to remove particulates prior to testing.

Specimen Shipping

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

Do not exceed the storage limitations listed above.

PROCEDURE

Materials Provided

04S92 Cholesterol2 Reagent Kit

Materials Required but not Provided

- Cholesterol2 assay file found on www.corelaboratory.abbott
- 04V1501 Consolidated Chemistry Calibrator
- Controls containing cholesterol
- Saline (0.85% to 0.90% NaCl) for specimen dilution

For information on materials required for operation of the instrument, refer to the ARCHITECT System Operations Manual, Section 1.

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

Assay Procedure

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

- If using primary or aliquot tubes, refer to the ARCHITECT System Operations Manual, Section 5 to ensure sufficient specimen is present.
- Minimum sample cup volume is calculated by the system and printed on the Order List report. To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.
- Minimum sample volume requirements:
  - Sample volume for single test: 1.6 µL.

    NOTE: This amount does not include the dead volume plus the additional over-aspiration volume. For total sample volume requirements, refer to the ARCHITECT System Operations Manual, Section 5.
- Refer to the Consolidated Chemistry Calibrator package insert REF 04V1501 and/or commercially available control material package insert for preparation and usage.
- For general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
- For optimal performance, it is important to perform routine maintenance as described in the ARCHITECT System Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Sample Dilution Procedures

The standard dilution factor, applied automatically by the system software to all serum/plasma results for the Cholesterol2 assay, is 1:1.49.

Samples with a cholesterol value exceeding 748 mg/dL (19.37 mmol/L) are flagged with the code "> 748 mg/dL" ("> 19.37 mmol/L") and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

Automated Dilution Protocol

The automated dilution factor for the Cholesterol2 assay is 1:5.97. The system performs a dilution of the sample with saline (0.85% to 0.90% NaCl), relative to the standard dilution, and automatically calculates the concentration by multiplying the result by the dilution factor.

For details on configuring automated dilutions, refer to the ARCHITECT System Operations Manual, Section 2.

Dilution Name	Dilution Factor
Standard	1:1.49
1:4	1:5.97

Manual Dilution Procedure

The manual dilution factor of 1:4 was evaluated for the Cholesterol2 assay.

Dilute the sample 1:4 with saline (0.85% to 0.90% NaCl).

The operator must enter the sample dilution in the Patient or Control order screen. The system will use this sample dilution to automatically calculate the concentration of the sample and report the result.

If the operator does not enter the sample dilution, the result must be manually multiplied by the appropriate sample dilution before reporting the result.

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

Calibration

For instructions on performing a calibration, refer to the ARCHITECT System Operations Manual, Section 6.

Calibration is stable for approximately 30 days (720 hours), with a blank adjustment after 15 days (360 hours). Calibration is required with each change in reagent lot. Verify calibration with at least 2 levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary.

This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

Quality Control Procedures

As appropriate, refer to your laboratory standard operating procedure(s) and/or quality assurance plan for additional quality control requirements and potential corrective actions.

- At least two levels of controls (low and high) 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, sample results may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Controls should be used according to the guidelines and recommendations of the control manufacturer. Concentration ranges provided in the control package insert should be used only for guidance.

For any control material in use, the laboratory should ensure that the matrix of the control material is suitable for use in the assay per the assay package insert.

Additional controls may be tested in accordance with local, state, and/or federal regulations or accreditation requirements and your laboratory's quality control policy.

Quality Control Guidance

Refer to "Basic QC Practices" by James O Westgard, Ph.D. for guidance on laboratory quality control practices.[10]

RESULTS

Calculation

The Cholesterol2 assay utilizes the Linear data reduction method to generate a calibration and results.

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the ARCHITECT System Operations Manual, Section 5.

Reportable Interval

Based on representative data for the limit of quantitation (LoQ) and the limit of detection (LoD), the ranges over which results can be reported are provided below according to the definitions from CLSI EP34, 1st ed.[11]

	mg/dL	mmol/L
Analytical Measuring Interval (AMI)[a]	5 - 748	0.13 - 19.37
Extended Measuring Interval (EMI)[b]	748 - 2992	19.37 - 77.49
Reportable Interval[c]	2 - 2992	0.05 - 77.49

[a] AMI: The AMI extends from the LoQ to the upper limit of quantitation (ULoQ). This is determined by the range of values in mg/dL (mmol/L) that demonstrated acceptable performance for linearity, imprecision, and bias.

[b] EMI: The EMI extends from the ULoQ to the ULoQ × sample dilution.

[c] The reportable interval extends from the LoD to the upper limit of the EMI.

NOTE: The default Low Linearity value of the assay file corresponds to the lower limit of the analytical measuring interval. Samples with cholesterol values below 5 mg/dL (0.13 mmol/L) are reported as "<5 mg/dL" ("<0.13 mmol/L").

LIMITATIONS OF THE PROCEDURE

- Results should be used in conjunction with other data; e.g., symptoms, results of other tests, and clinical impressions.
- Specimens with conjugated bilirubin levels greater than 7 mg/dL or unconjugated bilirubin greater than 11 mg/dL may cause falsely depressed results with the Cholesterol2 assay. Refer to the SPECIFIC PERFORMANCE CHARACTERISTICS, Analytical Specificity, Interference section of this package insert. To estimate sample icterus levels, refer to the Sample Interference Indices instructions for use to assess hemolysis (H), icterus (I) and lipemia (L) (HIL) indices.
- Substances that demonstrated interference with the Cholesterol2 assay are listed in the SPECIFIC PERFORMANCE CHARACTERISTICS, Analytical Specificity, Interference section of this package insert.
- Potential interference has not been evaluated for substances other than those described in the SPECIFIC PERFORMANCE CHARACTERISTICS, Interference section of this package insert.
- SmartWashes for assays impacted by Cholesterol2 must be configured to avoid interference due to reagent carryover. See the INSTRUMENT PROCEDURE section of this package insert for the required assay file updates.

EXPECTED VALUES

The National Cholesterol Education Program (NCEP) recommended cut points for children and adults are summarized in the following table.[12]

Serum/Plasma		Range (mg/dL)	Range (mmol/L)
Child	Desirable	< 170	< 4.40
	Borderline	170 - 199	4.40 - 5.15
	High	≥ 200	≥ 5.18
Adult	Desirable	< 200	< 5.18
	Borderline	200 - 239	5.18 - 6.19
	High	≥ 240	≥ 6.22

SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

Precision

Within-Laboratory Precision

A study was performed based on guidance from CLSI EP05-A3.[13] Testing was conducted using 3 lots of the Cholesterol2 reagent, 3 lots of the Consolidated Chemistry Calibrator, 1 lot of commercially available controls and 3 instruments. Two controls and 3 human serum panels were tested in duplicate, twice per day on 20 days on 3 reagent lot/calibrator lot/instrument combinations, where a unique reagent lot and a unique calibrator lot is paired with 1 instrument. The performance from a representative combination is shown in the following table.

			Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	n	Mean (mg/dL)	SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	80	251	1.9	0.7	2.6 (2.6 - 3.1)	1.0 (1.0 - 1.2)
Control Level 2	80	106	1.0	1.0	1.3 (1.3 - 1.7)	1.2 (1.2 - 1.6)
Panel A	80	21	0.6	3.0	0.8 (0.7 - 0.8)	4.0 (3.2 - 4.1)
Panel B	80	237	2.8	1.2	4.5 (3.7 - 4.9)	1.9 (1.5 - 2.0)
Panel C	80	718	6.4	0.9	6.6 (4.6 - 6.9)	0.9 (0.7 - 1.0)

[a] Includes within-run, between-run, and between-day variability.

[b] Minimum and maximum SD or %CV across all reagent lot and instrument combinations.

			Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	n	Mean (mmol/L)	SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	80	6.50	0.048	0.7	0.067 (0.067 - 0.081)	1.0 (1.0 - 1.2)
Control Level 2	80	2.74	0.028	1.0	0.033 (0.033 - 0.045)	1.2 (1.2 - 1.6)
Panel A	80	0.53	0.015	2.9	0.020 (0.015 - 0.021)	3.8 (2.9 - 3.9)
Panel B	80	6.15	0.073	1.2	0.115 (0.095 - 0.127)	1.9 (1.5 - 2.1)
Panel C	80	18.60	0.167	0.9	0.172 (0.119 - 0.178)	0.9 (0.7 - 1.0)

[a] Includes within-run, between-run, and between-day variability.

[b] Minimum and maximum SD or %CV across all reagent lot and instrument combinations.

Reproducibility

Serum/Plasma

A study was performed based on guidance from Clinical and Laboratory Standards Institute (CLSI) document EP05-A3.[13] Testing was conducted using 1 lot of Cholesterol2 reagent, 1 lot of the Consolidated Chemistry Calibrator, 1 lot of each commercially available controls, and 3 instruments. Each instrument was operated by a different technician, and each technician prepared an individual sample set. Five controls were tested in a minimum of 3 replicates (from separate sample cups) at 2 separate times per day (separated by a minimum of 2 hours), on at least 5 different days.

			Repeatability		Within-Laboratory[a]		Reproducibility[b]	
Sample	n	Mean (mg/dL)	SD	%CV	SD	%CV	SD	%CV
Control Level 1	90	241	2.1	0.9	2.4	1.0	3.4	1.4
Control Level 2	90	106	1.0	1.0	1.6	1.5	2.0	1.9
Control Level A	90	92	0.9	1.0	1.1	1.1	1.8	2.0
Control Level B	90	161	1.5	0.9	1.6	1.0	2.4	1.5
Control Level C	90	221	1.7	0.8	2.1	0.9	3.4	1.5

[a] Includes repeatability (within-run), between-run, and between-day variability.

[b] Includes repeatability (within-run), between-run, between-day, and between-instrument variability.

			Repeatability		Within-Laboratory[a]		Reproducibility[b]	
Sample	n	Mean (mmol/L)	SD	%CV	SD	%CV	SD	%CV
Control Level 1	90	6.24	0.054	0.9	0.062	1.0	0.090	1.4
Control Level 2	90	2.75	0.023	0.8	0.039	1.4	0.051	1.9
Control Level A	90	2.38	0.023	1.0	0.027	1.1	0.046	1.9
Control Level B	90	4.16	0.038	0.9	0.042	1.0	0.061	1.5
Control Level C	90	5.74	0.044	0.8	0.052	0.9	0.086	1.5

[a] Includes repeatability (within-run), between-run, and between-day variability.

[b] Includes repeatability (within-run), between-run, between-day, and between-instrument variability.

Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.[14] Testing was conducted using 3 lots of the Cholesterol2 reagent kit on each of 2 instruments over a minimum of 3 days. The maximum observed limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) values are summarized below.

	mg/dL	mmol/L
LoB[a]	1	0.03
LoD[b]	2	0.05
LoQ[c]	5	0.13

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c] The LoQ is defined as the lowest concentration at which a maximum allowable precision of 20% CV was met and was determined from n ≥ 60 replicates of low-analyte level samples.

Linearity

A study was performed based on guidance from CLSI EP06-A.[15] This assay is linear across the analytical measuring interval of 5 to 748 mg/dL (0.13 to 19.37 mmol/L).

Analytical Specificity

Interference

A study was performed based on guidance from CLSI EP07, 3rd ed.[16] Each substance was tested at 2 levels of the analyte (approximately 150 mg/dL and 220 mg/dL). No significant interference (interference within ± 10%) was observed at the following concentrations.

Potentially Interfering Endogenous Substances

	Interferent Level	
Potentially Interfering Substance	Default Units	Alternate Units
Conjugated Bilirubin	7 mg/dL	83.0 µmol/L
Unconjugated Bilirubin	11 mg/dL	188 µmol/L
Hemoglobin	1000 mg/dL	10.0 g/L
Total Protein	15 g/dL	150 g/L

Interference beyond ± 10% [based on 95% Confidence Interval (CI)] was observed at the concentrations shown below for the following substances.

Potentially Interfering Substance	Interferent Default Units	Interferent Alternate Units	Cholesterol Default Units	Cholesterol Alternate Units	% Interference
Conjugated Bilirubin	40 mg/dL	474 µmol/L	150 mg/dL	3.89 mmol/L	-39% (-40%, -39%)
Conjugated Bilirubin	40 mg/dL	474 µmol/L	220 mg/dL	5.70 mmol/L	-31% (-31%, -30%)
Unconjugated Bilirubin	16 mg/dL	274 µmol/L	150 mg/dL	3.89 mmol/L	-11% (-11%, -10%)

Potentially Interfering Exogenous Substances

	Interferent Level	
Potentially Interfering Substance	Default Units	Alternate Units
Acetaminophen	160 mg/L	1059 µmol/L
Acetylcysteine	150 mg/L	920 µmol/L
Acetylsalicylic Acid	30 mg/L	167 µmol/L
Aminoantipyrine	40 mg/L	197 µmol/L
Ampicillin-Na	80 mg/L	215 µmol/L
Ascorbic Acid	55 mg/L	312 µmol/L
Biotin	4250 ng/mL	17.4 µmol/L
Ca-dobesilate	60 mg/L	143 µmol/L
Cefotaxime	53 mg/dL	1166 µmol/L
Cefoxitin	6600 mg/L	15 444 µmol/L
Cyclosporine	2 mg/L	1.66 µmol/L
Desacetylcefotaxime	6 mg/dL	145 µmol/L
Dipyrone	100 mg/L	300 µmol/L
Dobutamine	0.2 mg/dL	6.64 µmol/L
Doxycycline	20 mg/L	45.0 µmol/L
Ibuprofen	220 mg/L	1067 µmol/L
Intralipid	1050 mg/dL	10.5 g/L
Levodopa	8 mg/L	40.6 µmol/L
Methotrexate	140 mg/dL	3080 µmol/L
Metronidazole	130 mg/L	759 µmol/L
Methylaminoantipyrine	40 mg/L	184 µmol/L
Methyldopa	20 mg/L	94.6 µmol/L
N-Acetyl-p-benzoquinone (NAPQI)	20 mg/L	134 µmol/L
Phenylbutazone	330 mg/L	1069 µmol/L
Phenytoin	6 mg/dL	238 µmol/L
Rifampicin	50 mg/L	61.0 µmol/L
Sodium Heparin	4 U/mL	N/A*
Sulpiride	15 mg/L	43.9 µmol/L
Theophylline (1.3-dimethylxanthine)	60 mg/L	333 µmol/L

* N/A = Not applicable

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Interference beyond ± 10% [based on 95% Confidence Interval (CI)] was observed at the concentrations shown below for the following substances.

Potentially Interfering Substance	Interferent		Cholesterol		% Interference
	Default Units	Alternate Units	Default Units	Alternate Units	
Ascorbic Acid	60 mg/L	341 µmol/L	150 mg/dL	3.89 mmol/L	-10% (-11%, -10%)
Intralipid	2000 mg/dL	20.0 g/L	150 mg/dL	3.89 mmol/L	-27% (-27%, -28%)
Intralipid	2000 mg/dL	20.0 g/L	220 mg/dL	5.70 mmol/L	-22% (-21%, -23%)
Methyldopa	30 mg/L	142 µmol/L	150 mg/dL	3.89 mmol/L	-14% (-14%, -13%)

Interferences from medication or endogenous substances may affect results.[17]

Method Comparison

A study was performed based on guidance from CLSI EP09-A3[18] using the Passing-Bablok regression method.

Cholesterol2 vs. Cholesterol on the ARCHITECT c8000 System

	n	Units	Correlation Coefficient	Intercept	Slope	Concentration Range
Serum	138	mg/dL	1.00	0.41	0.98	7 - 684
		(mmol/L)		(0.01)		(0.18 - 17.72)

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Key to Symbols

ISO 15223 Symbols	
	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
REF	List Number
SN	Serial number

Other Symbols	
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
DISTRIBUTED IN THE USA BY	Distributed in the USA by
FOR USE WITH	Identifies products to be used together
INFORMATION FOR USA ONLY	Information needed for United States of America only
PRODUCT OF IRELAND	Product of Ireland
R1	Reagent 1
Rx ONLY	For use by or on the order of a physician only (applicable to USA classification only).

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Note for number formatting:

- A space is used as thousands separator (example: 10 000 specimens).
- A period is used to separate the integer part from the fractional part of a number written in decimal form (example: 3.12%).

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

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For customers in the European Union: if, in the course of using this device, you have reason to believe that a serious incident has occurred, report it to the manufacturer and to your national authority.

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