Ultra HDL

FOR USE WITH
ARCHITECT

Read Highlighted Changes: Revised August 2021.

REF 3K33-22

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

Ultra HDL (also referred to as UHDL)

INTENDED USE

The Ultra HDL (UHDL) assay is used for the quantitation of high-density lipoprotein (HDL) cholesterol in human serum or plasma.

SUMMARY AND EXPLANATION OF THE TEST

Plasma lipoproteins are spherical particles containing varying amounts of cholesterol, triglycerides, phospholipids, and proteins. Phospholipids, free cholesterol, and proteins constitute the outer surface of the lipoprotein particle, while the inner core contains mostly esterified cholesterol and triglyceride. These particles serve to solubilize and transport cholesterol and triglyceride in the bloodstream.

The relative proportions of protein and lipid determine the density of these lipoproteins and provide a basis on which to begin their classification.[1] The classes are: chylomicron, very-low-density lipoprotein (VLDL), low-density lipoprotein (LDL), and high-density lipoprotein (HDL). Numerous clinical studies have shown that the different lipoprotein classes have very distinct and varied effects on coronary heart disease risk.[2]

The principle role of HDL cholesterol in lipid metabolism is the uptake and transport of cholesterol from peripheral tissues to the liver through a process known as reverse cholesterol transport (a proposed cardioprotective mechanism).[3] Low HDL cholesterol levels are strongly associated with an increased risk of coronary heart disease.[4-7]

Hence, the determination of serum HDL cholesterol is a useful tool in identifying high-risk patients. The Adult Treatment Panel of the National Cholesterol Education Program (NCEP) recommends that in all adults 20 years of age and over, a fasting lipoprotein profile (total cholesterol, LDL cholesterol, HDL cholesterol, and triglyceride) should be obtained once every five years to screen for coronary heart disease risk.[8]

PRINCIPLES OF THE PROCEDURE

The Ultra HDL assay is an automated clinical chemistry assay.

The Ultra HDL assay is a homogeneous method for directly measuring HDL cholesterol concentrations in serum or plasma without the need for off-line pretreatment or centrifugation steps.

The method uses a two-reagent format and depends on the properties of a unique detergent. This method is based on accelerating the reaction of cholesterol oxidase (CO) with non-HDL unesterified cholesterol and dissolving HDL cholesterol selectively using a specific detergent. In the first reagent, non-HDL unesterified cholesterol is subject to an enzyme reaction and the peroxide generated is consumed by a peroxidase reaction with DSBmT yielding a colorless product. The second reagent consists of a detergent (capable of solubilizing HDL cholesterol), cholesterol esterase (CE), and chromagenic coupler to develop color for the quantitative determination of HDL cholesterol.

Methodology: Accelerator Selective Detergent

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

REAGENTS

Kit Contents

Ultra HDL Reagent Kit 3K33

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

REF	3K33-22
Tests per cartridge set	360
Number of cartridge sets per kit	4
Tests per kit	1440*
R1	84 mL
R2	32 mL

R1 Active ingredients: Cholesterol oxidase (E. coli) (< 1000 U/L), Peroxidase (Horseradish) (< 1300 ppg U/L), N, N-bis (4-sulfobutyl)-m-toluidine-disodium (DSBmT) (< 1.0 mmol/L), Accelerator (< 1.0 mmol/L), Ascorbic oxidase (Cucurbita sp.) (< 3000 U/L). Preservative: ProClin 300 (< 0.06%).

R2 Active ingredients: Cholesterol esterase (Pseudomonas sp.) (< 1500 U/L), 4-aminoantipyrine (< 0.1%), Detergent (< 3%). Preservative: ProClin 300 (< 0.06%).

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

The Ultra HDL reagent is certified as traceable to the HDL cholesterol designated comparison method, covering the NCEP medical decision points, by the 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.[9-12]

The following warnings and precautions apply to: R1 and R2	
	
WARNING	Contains methylisothiazolones.
H317	May cause an allergic skin reaction.

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Prevention	
P261	Avoid breathing mist / vapors / spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

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 use components beyond the expiration date.
- Do not pool reagents within a kit or between kits.
- Do not use components from one lot with components from another lot.
- Do not reuse containers, caps or plugs due to the risk of contamination and the potential to compromise reagent performance.
- 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.
- 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.

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

Reagent Storage

- Do not freeze.
- Protect from light.

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2 to 8°C	Until expiration date	Store in upright position.
Onboard	System Temperature	28 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 Ultra HDL assay file must be installed on the ARCHITECT cSystem prior to performing the assay.

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 National Cholesterol Education Program (NCEP) recommends using fasting specimens for a lipoprotein profile. If the specimen is nonfasting, only the values for total cholesterol and HDL cholesterol are usable.[13]

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

Specimen Types	Collection Tubes
Serum	Glass or plastic tubes with or without gel barrier
Plasma	Glass or plastic tubes Acceptable anticoagulants are: Lithium heparin (with or without gel barrier) Sodium heparin Spray-dried EDTA*

* NOTE: Lower HDL cholesterol results obtained from EDTA plasma have been attributed to an osmotic dilution effect. The NCEP has suggested multiplying EDTA plasma results by a factor of 1.03 to correct the EDTA result to a serum equivalent value.[13]

Other specimen types, collection tube types, and anticoagulants have not been verified 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

- 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.

  For accurate results, plasma specimens should be free of platelets and other particulate matter. Ensure centrifugation is adequate to remove platelets.
- 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.
- 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.

Specimen Storage

Specimen Type	Temperature	Maximum Storage Time
Serum/Plasma	20 to 25°C	2 days[14]
	2 to 8°C	7 days[14, 15]
	-20°C	3 months[14]

Avoid multiple freeze/thaw cycles.

Guder et al. suggest storage of frozen specimens at -20°C for no longer than the time intervals cited above.[14]

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

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

REF 3K33-22 Ultra HDL Reagent Kit

Materials Required but not Provided

- REF 5P56-02 Lipid Multiconstituent Calibrator
  NOTE: If REF 5P56-02 Lipid Multiconstituent Calibrator is not available, use REF 1E68-03 HDL Calibrator.
- Control Material
- 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: 2.0 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 Lipid Multiconstituent Calibrator REF 5P56-02 and/or HDL Calibrator REF 1E68-03 package inserts 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.

Specimen Dilution Procedures

The ARCHITECT cSystems have an automatic dilution feature; for additional information, refer to the ARCHITECT System Operations Manual, Section 2.

Serum and Plasma: Specimens with HDL cholesterol values exceeding 180 mg/dL (4.66 mmol/L) are flagged and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

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

Automated Dilution Protocol

If using an automated dilution protocol, the system performs a dilution of the sample 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.

Manual Dilution Procedure

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

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

If the operator does not enter the dilution factor, the result must be manually multiplied by the appropriate dilution factor before reporting the result. 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 the ARCHITECT System Operations Manual, Section 5.

Calibration

Calibration is stable for approximately 28 days (672 hours), but 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.

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

For information on calibrator standardization, refer to the REF 5P56-02 Lipid Multiconstituent Calibrator or REF 1E68-03 HDL Calibrator package insert, as appropriate.

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.

- 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.

Quality Control Guidance

Refer to "Basic QC Practices" by James O Westgard, Ph.D. for guidance on laboratory quality control practices.[16]

RESULTS

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

Calculation

For additional information on results calculations, refer to the ARCHITECT System Operations Manual, Appendix C.

Interpretation of Results

As with all analyte determinations, the HDL cholesterol value should be used in conjunction with information available from clinical evaluation and other diagnostic procedures.

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.

Measuring Interval

Measuring interval is defined as the range of values in mg/dL (mmol/L) which meets the limits of acceptable performance for linearity, imprecision, and bias.

The measuring interval of the Ultra HDL assay is 5 to 180 mg/dL (0.13 to 4.66 mmol/L).

LIMITATIONS OF THE PROCEDURE

Using three homogenous HDL assays, Camps, et al. have reported artificially low HDL results in patients with liver cirrhosis.[17] Published studies are not available that define the severity of liver disease necessary to affect lipoprotein and HDL metabolism, or establish other possible patterns of interference with HDL results. When an HDL result is diagnostically critical with concomitant clinically relevant liver disease, use a recognized precipitation or ultracentrifugation HDL-reference method for confirmation. Artificially decreased or increased HDL values in the presence of dyslipidemias have been reported.[18, 19]

N-acetyl-L-cysteine at elevated concentrations may lead to falsely low results.

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

EXPECTED VALUES

Serum/Plasma[13]

	Range (mg/dL)	Range (mmol/L)
Major risk factor for heart disease	< 40	< 1.04
Negative risk factor for heart disease	≥ 60	≥ 1.55

The National Cholesterol Education Program (NCEP) Adult Treatment Panel III Report recommends the classification shown above.

Laboratories should follow recommendations for lipid ranges effective in their locale if they differ from those of the NCEP.

It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

SPECIFIC PERFORMANCE CHARACTERISTICS

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

Linearity

Ultra HDL is linear up to 180 mg/dL (4.66 mmol/L), with recovery within 10% of the predicted value with 95% confidence.

Linearity was verified using a modified Clinical and Laboratory Standards Institute (CLSI) protocol NCCLS EP6-A.[20] An internal verification study produced linear results up to 221 mg/dL (5.72 mmol/L).

Limit of Detection and Quantitation

The limit of quantitation (LOQ) for Ultra HDL is 5.0 mg/dL (0.13 mmol/L), and the limit of detection (LOD) is 2.5 mg/dL (0.06 mmol/L).

The LOD testing for Ultra HDL was performed using a study design based on CLSI protocol NCCLS EP17-A.[21] An internal verification study produced an LOD for Ultra HDL of 0.3 mg/dL (0.01 mmol/L). The proportions of false positives (α) and false negatives (β) were less than 5% and the limit of blank (LOB) was 0.2 mg/dL (0.01 mmol/L).

The LOQ is the analyte concentration at which the CV = 20%. An internal verification study produced a CV of 8.7% at an HDL cholesterol concentration of 4.5 mg/dL (0.12 mmol/L).

Interference

Interference studies were conducted using an acceptance criteria of 5% of the target value. Interference effects were assessed by Dose Response method, at the medical decision levels of the analyte.

Lower Decision Level

Interfering Substance	Interferent Concentration	N	Target (mg/dL)	Observed (% of Target)
Ascorbic acid	2.9 mg/dL (165 µmol/L)	3	35	99
	3.9 mg/dL (221 µmol/L)	3	35	99
Conjugated bilirubin	32.6 mg/dL (557 µmol/L)	3	34	104
	63.3 mg/dL (1082 µmol/L)	3	34	77
Unconjugated bilirubin	32.4 mg/dL (554 µmol/L)	3	33	105
	65.5 mg/dL (1120 µmol/L)	3	33	107
Hemoglobin	1000 mg/dL (10 g/L)	3	31	102
	2000 mg/dL (20 g/L)	3	31	104
Intralipid	1000 mg/dL (10 g/L)	3	32	102
	2000 mg/dL (20 g/L)	3	32	115

Upper Decision Level

Interfering Substance	Interferent Concentration	N	Target (mg/dL)	Observed (% of Target)
Ascorbic acid	2.9 mg/dL (165 µmol/L)	3	69	101
	3.9 mg/dL (221 µmol/L)	3	69	101
Conjugated bilirubin	32.0 mg/dL (547 µmol/L)	3	68	102
	63.5 mg/dL (1086 µmol/L)	3	68	95
Unconjugated bilirubin	33.9 mg/dL (580 µmol/L)	3	67	102
	67.1 mg/dL (1147 µmol/L)	3	67	102
Hemoglobin	1000 mg/dL (10 g/L)	3	62	99
	2000 mg/dL (20 g/L)	3	62	100
Intralipid	1000 mg/dL (10 g/L)	3	75	99
	2000 mg/dL (20 g/L)	3	75	101

Ascorbic acid solutions at the above concentrations were prepared by addition of L-ascorbic acid to human serum pools. Conjugated bilirubin solutions at the above concentrations were prepared by addition of a ditaurobilirubin stock to human serum pools. Unconjugated bilirubin solutions at the above concentrations were prepared by addition of a NIST SRM 916a 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.

Interferences from medication or endogenous substances may affect results.[22]

The following drugs were tested for interference at the concentrations indicated using an acceptance criteria of ± 5% from the target value.

Interfering Substance	Interferent Concentration	N	Target (mg/dL)	Observed (% of Target)
Acetaminophen	200 mg/L (1324.5 µmol/L)	3	50	101
Dipyrone	100 mg/L (300.3 µmol/L)	3	48	102
N-Acetyl-L-Cysteine	800 mg/L (4908.0 µmol/L)	3	38	98
	1600 mg/L (9816.0 µmol/L)	3	38	90

Precision

A study was performed based on guidance from CLSI protocol NCCLS EP5-A.[23] Testing was conducted using 1 lot of the Ultra HDL reagent, 1 lot of Ultra HDL Calibrator, 1 lot of commercially available controls, and 1 instrument. Two controls were tested in a minimum of 2 replicates at 2 separate times per day on 20 different days.

		Mean	Within-Run		Within-Laboratory[a]	
Sample	N	(mg/dL)	SD	%CV	SD	%CV
Control 1	80	23.67	0.46	1.94	0.79	3.33
Control 2	80	84.06	0.83	0.99	1.15	1.37

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

Reproducibility

A study was performed based on guidance from CLSI EP05-A3.[24] A study was performed to estimate within-laboratory precision and reproducibility. Testing was conducted using 1 lot of Ultra HDL reagent, a minimum of 1 lot of Lipid Multiconstituent Calibrator, 1 lot of commercially available controls, and 3 instruments. Three levels of controls and 1 human serum panel were tested in a minimum of 3 replicates at 2 separate times per day on 5 different days. The performance from a representative lot is shown in the following table.

		Mean	Repeatability		Within-Laboratory[a]		Reproducibility[b]	
Sample	N	(mg/dL)	SD	%CV	SD	%CV	SD	%CV
Control 1	90	30	0.4	1.3	0.6	2.0	1.2	3.8
Control 2	90	47	0.5	1.0	0.6	1.3	1.1	2.3
Control 3	90	67	0.6	0.9	0.9	1.3	1.1	1.7
Panel	90	42	0.5	1.2	0.7	1.7	0.7	1.7

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

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

		Mean	Repeatability		Within-Laboratory[a]		Reproducibility[b]	
Sample	N	(mmol/L)	SD	%CV	SD	%CV	SD	%CV
Control 1	90	0.79	0.010	1.2	0.015	1.9	0.031	3.9
Control 2	90	1.22	0.012	1.0	0.016	1.3	0.029	2.4
Control 3	90	1.75	0.015	0.9	0.025	1.4	0.031	1.8
Panel	90	1.09	0.010	0.9	0.015	1.4	0.016	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.

Accuracy

Accuracy data for Ultra HDL were collected using the HDL Cholesterol Certification Protocol for Manufacturers.[25] The data were analyzed using CLSI protocol NCCLS EP21-A.[26]

Serum results from the Ultra HDL assay on an ARCHITECT cSystem and the AEROSET system were compared with the designated comparison method (DCM) for HDL cholesterol.

	ARCHITECT	AEROSET
Mean %Bias	-1.6	-1.8
%Total Error	10.9	10.2

Method Comparison

Correlation studies were performed using CLSI protocol NCCLS EP9-A2.[27]

Serum results from the Ultra HDL assay on the AEROSET System were compared with those from a commercially available accelerator selective detergent methodology.

Serum results from the Ultra HDL assay on an ARCHITECT cSystem were compared with those from the Ultra HDL assay on the AEROSET System.

	AEROSET vs. Comparative Method	ARCHITECT vs. AEROSET
N	111	110
Y - Intercept	0.46	0.61
Correlation Coefficient	0.999	0.999
Slope	0.97	1.00
%Bias at 35 mg/dL	-2	1
%Bias at 60 mg/dL	-2	1
Range (mg/dL)	12 - 188	12 - 179

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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	
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
MANUFACTURED FOR	Manufactured for
PRODUCT OF CANADA	Product of Canada
R1	Reagent 1
R2	Reagent 2
Rx ONLY	For use by or on the order of a physician only (applicable to USA classification only).

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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Customer Service: Contact your local representative or find country-specific contact information on www.corelaboratory.abbott

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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Abbott