Alinity c Ultra HDL-23

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BIENNIAL REVIEW:

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SUPERSEDES: Procedure titled _____

INTENDED USE

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

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], [5], [6], [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 Alinity c 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 chromogenic 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 Alinity ci-series Operations Manual, Section 3.**

REAGENTS

Kit Contents

Alinity c Ultra HDL Reagent Kit 07P75

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

REF	07P7520	07P7530
Tests per cartridge	350	350
Number of cartridges per kit	4	10
Tests per kit	1400	3500

REF	07P7520	07P7530
R1	66.6 mL	66.6 mL
R2	25.1 mL	25.1 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%).

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, 10, 11, 12]

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

For a detailed discussion of safety precautions during system operation, refer to the Alinity ci-series Operations Manual, Section 8.

Reagent Handling

- Reagents are shipped refrigerated.
- Upon receipt, place reagent cartridges in an upright position for 8 hours before use to allow bubbles that may have formed to dissipate.
- If a reagent cartridge is dropped, place in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- 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 Alinity ci-series 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	28 days	
Opened	2 to 8°C	Until expiration date	Store in upright position. Do not reuse original reagent caps or replacement caps due to the risk of contamination and the potential to compromise reagent performance.

- Do not freeze.
- Protect reagents from direct sunlight.

Reagents may be stored on or off the system. If removed from the system, store reagents with new replacement caps in an upright position at 2 to 8°C. For reagents stored off the system, it is recommended that they be stored in their original trays or boxes to ensure they remain upright.

For information on unloading reagents, refer to the Alinity ci-series Operations Manual, Section 5.

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when:

- a calibration error occurs
- 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 Alinity ci-series Operations Manual, Section 10**.

INSTRUMENT PROCEDURE

The Alinity c Ultra HDL assay file must be installed on the Alinity c analyzer prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, **refer to the Alinity ci-series Operations Manual, Section 2.**

For information on printing assay parameters, **refer to the Alinity ci-series Operations Manual, Section 5.**

For a detailed description of system procedures, **refer to the Alinity ci-series Operations Manual.**

Alternate Result Units

Edit assay parameter "Result Units" to select an alternate unit.

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.

Specimen Type	Collection Vessel	Special Conditions
Serum	Serum tubes (with or without gel barrier)	
Plasma	Collection tubes Acceptable anticoagulants are: Lithium heparin (with or without gel barrier) Sodium heparin Spray-dried EDTA	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*

Serum and plasma are acceptable specimens. 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 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. 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.

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]

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

07P75 Alinity c Ultra HDL Reagent Kit

Materials Required but not Provided

- Alinity c Ultra HDL assay file
- 09P1401 or 09P1403 Alinity c Lipid Multiconstituent Calibrator Kit

  NOTE: Some kit sizes may not be available in all countries.
- Commercially available control containing HDL
- Saline (0.85% to 0.90% NaCl) for specimen dilution

For information on materials required for operation of the instrument, refer to the Alinity ci-series Operations Manual, Section 1.

For information on materials required for maintenance procedures, refer to the Alinity ci-series Operations Manual, Section 9.

Assay Procedure

For a detailed description of how to run an assay, **refer to the Alinity ci-series Operations Manual, Section 5.**

- If using primary or aliquot tubes, refer to the Alinity ci-series Operations Manual, Section 4 to ensure sufficient specimen is present.
- 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: 1.7 µL.

    NOTE: This amount does not include the dead volume plus the additional over-aspiration volume. **For total sample volume requirements, refer to the Alinity ci-series Operations Manual, Section 4.**
- Refer to the Alinity c Lipid Multiconstituent Calibrator Kit package insert and commercially available control package insert for preparation and usage.
- For general operating procedures, **refer to the Alinity ci-series Operations Manual, Section 5.**
- For optimal performance, it is important to perform routine maintenance as described in the Alinity ci-series Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Sample Dilution Procedures

Samples with an Ultra HDL value exceeding 180 mg/dL (4.66 mmol/L) are flagged with the code "> 180 mg/dL" (> 4.66 mmol/L) and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

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 Alinity ci-series 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 Specimen or Control tab of the Create Order screen. The system will use this dilution factor to automatically calculate the concentration of the sample 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 less than the lower value of the measuring interval of 5 mg/dL (0.13 mmol/L), do not report the result. Rerun using an appropriate dilution.

For detailed information on ordering dilutions, refer to the Alinity ci-series Operations Manual, Section 5.

Calibration

For instructions on performing a calibration, **refer to the Alinity ci-series Operations Manual, Section 5.**

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 laboratory quality control procedure. 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

- At least two levels of controls (normal and abnormal) are to be run every day testing performed.
- If quality control results do not meet the acceptance criteria defined by the laboratory, sample results may be suspect. Follow the quality control procedures to troubleshoot. Recalibration may be necessary. For troubleshooting information, **refer to the Alinity ci-series Operations Manual, Section 10.**
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Commercial 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.

Quality Control Guidance

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

Verification of Assay Claims

For protocols to verify package insert claims, refer to Verification of Assay Claims in the Alinity ci-series Operations Manual.

RESULTS

Calculation

The Alinity c Ultra HDL assay utilizes the Linear data reduction method to generate a calibration and results.

For information on alternate result units, refer to the INSTRUMENT PROCEDURE, Alternate Result Units section of this package insert.

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 Alinity ci-series Operations Manual, Section 5.

Reportable Interval

	mg/dL	mmol/L
Analytical Measuring Interval (AMI)[a]	5 - 180	0.13 - 4.66

	mg/dL	mmol/L
Reportable Interval[b]	**1 - 180**	0.03 - 4.66

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

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.

SPECIFIC PERFORMANCE CHARACTERISTICS

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

The Alinity c analyzer, and the ARCHITECT c System and AEROSET System utilize the same reagents and sample/reagent ratios.

Unless otherwise specified, all studies were performed on the Alinity c analyzer.

Precision

Within-Laboratory Precision

A study was performed based on guidance from CLSI EP05-A2. Testing was conducted using 1 lot of the Alinity c Ultra HDL Reagent Kit, 1 lot of the Alinity c Lipid Multiconstituent Calibrator Kit, and 1 lot of the commercially available controls and 1 instrument. Three control levels and 1 human serum panel were assayed in a minimum of 2 replicates at 2 separate times per day on 20 different days.[20]

			Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
Sample	**n**	**Mean (mg/dL)**	**SD**	**%CV**	**SD**	**%CV**
Control Level 1	120	42	0.6	1.4	0.9	2.1
Control Level 2	120	52	0.7	1.3	1.1	2.1
Control Level 3	120	83	0.5	0.6	0.9	1.1
Panel	120	21	0.3	1.3	0.4	2.0

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

Sample	n	Mean (mmol/L)	Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
			SD	%CV	SD	%CV
Control Level 1	120	1.08	0.014	1.3	0.022	2.1
Control Level 2	120	1.34	0.017	1.3	0.028	2.1
Control Level 3	120	2.15	0.015	0.7	0.025	1.2
Panel	120	0.54	0.006	1.2	0.009	1.8

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

Reproducibility

A study was conducted using 2 lots of Alinity c Ultra HDL Reagents, 1 lot of Lipid Multiconstituent Calibrator Kit, 1 lot of commercially available controls, and 6 instruments. Three levels of controls were assayed in a minimum of 5 replicates at 3 separate times. The performance from a representative lot is shown in the following table.

Sample	n	Mean (mg/dL)	Repeatability		Within-Laboratory[a]		Reproducibility[b]	
			SD	%CV	SD	%CV	SD	%CV
Control Level 1	123	42	0.8	1.9	0.9	2.1	0.9	2.2
Control Level 2	126	52	0.8	1.5	1.0	1.9	1.1	2.2
Control Level 3	126	83	0.8	0.9	1.0	1.2	1.0	1.2

[a] Within-Laboratory variability contains repeatability (within-run) and between-run variance components.

[b] Reproducibility contains repeatability (within-run), between-run and between-instrument variance components.

Sample	n	Mean (mmol/L)	Repeatability		Within-Laboratory[a]		Reproducibility[b]	
			SD	%CV	SD	%CV	SD	%CV
Control Level 1	123	1.08	0.020	1.8	0.022	2.0	0.023	2.1
Control Level 2	126	1.33	0.019	1.4	0.024	1.8	0.027	2.1
Control Level 3	126	2.15	0.018	0.9	0.023	1.1	0.023	1.1

[a] Within-Laboratory variability contains repeatability (within-run) and between-run variance components.

[b] Reproducibility contains repeatability (within-run), between-run and between-instrument variance components.

Accuracy

This study was performed on the ARCHITECT c System.

Accuracy data for Ultra HDL were collected using the HDL Cholesterol Certification Protocol for Manufacturers.*21* The data were analyzed using CLSI protocol NCCLS EP21-A.*22*

Serum results from the Ultra HDL assay on an ARCHITECT c System were compared with the designated comparison method (DCM) for HDL cholesterol.

	ARCHITECT
Mean %Bias	-1.6
%Total Error	10.9

Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2. Testing was conducted using 3 lots of the Alinity c Ultra HDL Reagent Kit on each of 2 instruments over a minimum of 3 days. The Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) values are summarized below. These representative data support the lower limit of the measuring interval.*23*

	mg/dL	mmol/L
LoB[a]	0	0.00
LoD[b]	1	0.03
LoQ[c, d]	**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.

[d] This value represents the observed LoQ on the ARCHITECT System. The LoQ observed on the Alinity c analyzer supports this LoQ.

Linearity

A study was performed based on guidance from CLSI EP06-A.*24*

This assay is linear across the measuring interval of **5 to 180** mg/dL (0.13 to 4.66 mmol/L).

Interference

This study was performed on the AEROSET System.

Potentially Interfering Endogenous Substances and Potentially Interfering Drugs

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

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

Upper Decision Level

Potentially Interfering Substance	**Interferent Level**		**Target Level (mg/dL)**	**Recovery (% of Target)**
	Default Units	**Alternate Units**		
Ascorbic acid	2.9 mg/dL	165 µmol/L	69	101

Potentially Interfering Substance	Interferent Level		Target Level (mg/dL)	Recovery (% of Target)
	Default Units	Alternate Units		
	3.9 mg/dL	221 µmol/L	69	101
Conjugated bilirubin	32.0 mg/dL	547 µmol/L	68	102
	63.5 mg/dL	1086 µmol/L	68	95
Unconjugated bilirubin	33.9 mg/dL	580 µmol/L	67	102
	67.1 mg/dL	1147 µmol/L	67	102
Hemoglobin	1000 mg/dL	10 g/L	62	99
	2000 mg/dL	20 g/L	62	100
Intralipid	1000 mg/dL	10 g/L	75	99
	2000 mg/dL	20 g/L	75	101

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

Potentially Interfering Substance	Interferent Level		Target Level (mg/dL)	Recovery (% of Target)
	Default Units	Alternate Units		
Acetaminophen	200 mg/L	1324.5 µmol/L	50	101
Dipyrone	100 mg/L	300.3 µmol/L	48	102
N-acetyl-L-cysteine	800 mg/L	4908.0 µmol/L	38	98
	1600 mg/L	9816.0 µmol/L	38	90

Interferences from medication or endogenous substances may affect results.[25]

Method Comparison

A study was performed based on guidance from CLSI EP09-A3 using the Passing-Bablok regression method.[26]

		Units	n	Correlation Coefficient	Intercept	Slope	Concentration Range
Alinity c Ultra HDL vs ARCHITECT Ultra HDL	Serum	mg/dL	130	1.00	2.08	0.97	5 – 179
		mmol/L	130	1.00	0.06	0.97	0.13 - 4.62

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