Alinity c Direct LDL-14

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SUPERSEDES: Procedure titled _____

INTENDED USE

The Alinity c Direct LDL assay is intended for the direct *in vitro* quantitative determination of low-density lipoprotein (LDL) cholesterol in human serum or plasma on the Alinity c analyzer.

LDL Cholesterol (LDL-C) measurements may be used to determine cardiovascular disease risk, aid in the diagnosis of dyslipidemia and hypercholesterolemia, and monitor LDL-C lowering therapy.

SUMMARY AND EXPLANATION OF THE TEST

Plasma lipoproteins are spherical particles containing varying amounts of cholesterol,

triglycerides, phospholipids, and proteins. The phospholipid, free cholesterol, and protein constitute the outer surface of the lipoprotein particle, while the inner core contains mostly esterified cholesterol and triglycerides. These particles serve to solubilize and transport cholesterol and triglycerides 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* These classes are: chylomicrons, 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 (CHD) risk.*2*, *3*, *4*

The studies all point to LDL-C as the key factor in the pathogenesis of atherosclerosis and CHD,*2*, *3*, *4*, *5*, *6*, *7*, *8* while HDL cholesterol has been observed to have a protective effect. Even within the normal range of total cholesterol concentrations, an increase in LDL-C can occur with an associated increased risk for CHD.*4*

PRINCIPLES OF THE PROCEDURE

The Alinity c Direct LDL assay is an automated clinical chemistry assay.

The Alinity c Direct LDL assay is a homogeneous method for directly measuring LDL levels in serum or plasma, without the need for off-line pretreatment or centrifugation steps.

The method is in a two-reagent format and depends on the properties of a unique detergent. This detergent, R1, solubilizes only the non-LDL particles. The cholesterol released is consumed by cholesterol esterase and cholesterol oxidase in a non-color-forming reaction. A second detergent, R2, solubilizes the remaining LDL particles and a chromogenic coupler allows for color formation. The enzyme reaction with LDL in the presence of the coupler produces color that is proportional to the amount of LDL-C present in the sample.

Methodology: Measured, Liquid 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 Direct LDL Reagent Kit 07P71

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

REF	**07P7120**
Tests per cartridge	290
Number of cartridges per kit	2
Tests per kit	580
R1	68.1 mL
R2	26.0 mL

REF	07P7120

R1 Active ingredients: MES buffer (pH 6.3), Detergent 1 (< 1.0%), Cholesterol esterase (microorganism) (< 1500 U/L), Cholesterol oxidase (microorganism) (< 1500 U/L), Peroxidase (Horseradish) (< 1300 ppg U/L), 4-aminoantipyrine (< 0.01%), Ascorbic acid oxidase (*Cucurbita* sp.) (< 3000 U/L). Contains preservative.

R2 Active ingredients: MES buffer (pH 6.3), Detergent 2 (< 1.0%), N,N-bis(4-sulfobutyl)-m-toluidine, disodium (DSBmT) (< 1.0 mmol/L). Contains preservative.

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 on wet ice.
- 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.
- Protect reagents from direct sunlight.
- 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

- Do not freeze.

	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 potential to compromise reagent performance.

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 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 Alinity ci-series Operations Manual, Section 10**.

INSTRUMENT PROCEDURE

The Alinity c Direct LDL 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	0.02586*13*	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)	Separate serum from red blood cells or gel as soon after collection as possible (within 3 hours).*14*
Plasma	Collection tubes Acceptable anticoagulants are: Lithium heparin (with or without gel barrier) Sodium heparin EDTA	Anticoagulants containing citrate should not be used. Separate plasma from red blood cells or gel as soon after collection as possible (within 3 hours).*14* To ensure accurate results, the plasma specimen tube should be filled with the prescribed minimum volume for an appropriate anticoagulant to specimen ratio.

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	2 to 8°C	5 days
	-80°C	3 months

Avoid more than 1 freeze/thaw cycle.

Refer to Clinical and Laboratory Standards Institute (CLSI) document CLSI GP44-A4 for further instructions on specimen collection, handling, and storage.*15*

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

07P71 Alinity c Direct LDL Reagent Kit

Materials Required but not Provided

- Alinity c Direct LDL assay file
- 09P14 Alinity c Lipid Multiconstituent Calibrator Kit
- Commercially available controls containing LDL-C
- 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: 2 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 material 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 LDL-C value exceeding 800 mg/dL (20.69 mmol/L) are flagged with the code "> 800 mg/dL" ("> 20.69 mmol/L") and may be diluted with the Manual Dilution Procedure.

Specimens with levels of interfering substances (other than triglycerides) higher than the upper limit stated in the Interference section may be diluted with the Manual Dilution Procedure.

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 1 mg/dL (0.03 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 policy. 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

- 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 laboratory, sample results may be suspect. Follow the laboratory 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 Direct LDL 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.**

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 Alinity c Direct LDL assay is **1 to 800** mg/dL (0.03 to 20.69 mmol/L).

LIMITATIONS OF THE PROCEDURE

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

EXPECTED VALUES

The National Cholesterol Education Program (NCEP) Adult Treatment Panel III Report[14] recommends the following patient classification for LDL-C:

Reference Range

LDL-C (mg/dL)	
< 100	Optimal
100 to 129	Near or above optimal
130 to 159	Borderline high
160 to 189	High
≥ 190	Very high

LDL-C values should be interpreted in coordination with patient history and risk factor evaluation. Various population-specific cardiovascular risk factor evaluation tools are available.

SPECIFIC PERFORMANCE CHARACTERISTICS

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

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 Direct LDL Reagent Kit, 1 lot of the Alinity c Lipid Multiconstituent Calibrator Kit, 1 lot of commercially available controls, and 2 instruments. Three controls were assayed in a minimum of 2 replicates at 2 separate times per day on 20 different days.[17]

			Within-Run (Repeatability)		**Within-Laboratory (Total)[a]**	
Sample	**n**	**Mean (mg/dL)**	**SD**	**%CV**	**SD (Range[b])**	**%CV (Range[b])**
Control Level 1	246	60	0.5	0.8	0.9 (0.9 - 0.9)	1.5 (1.4 - 1.5)
Control Level 2	246	78	0.5	0.7	1.2 (1.2 - 1.3)	1.6 (1.5 - 1.6)

Sample	n	Mean (mg/dL)	Within-Run (Repeatability) SD	Within-Run (Repeatability) %CV	Within-Laboratory (Total)[a] SD (Range[b])	Within-Laboratory (Total)[a] %CV (Range[b])
Control Level 3	246	159	0.9	0.6	2.5 (2.3 - 2.7)	1.6 (1.4 - 1.7)

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

[b] Maximum and minimum SD or %CV for each reagent lot and instrument combination.

Sample	n	Mean (mmol/L)	Within-Run (Repeatability) SD	Within-Run (Repeatability) %CV	Within-Laboratory (Total)[a] SD (Range[b])	Within-Laboratory (Total)[a] %CV (Range[b])
Control Level 1	246	1.57	0.013	0.8	0.023 (0.022 - 0.023)	1.5 (1.4 - 1.5)
Control Level 2	246	2.02	0.013	0.7	0.031 (0.030 - 0.031)	1.5 (1.5 - 1.6)
Control Level 3	246	4.12	0.025	0.6	0.065 (0.059 - 0.071)	1.6 (1.4 - 1.7)

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

[b] Maximum and minimum SD or %CV for each reagent lot and instrument combination.

Reproducibility

A study was conducted using 2 lots of Alinity c Direct LDL reagents across 6 Alinity instruments. Three controls and 1 human serum panel were assayed in a minimum of 5 replicates, in 3 runs per instrument for a minimum of 15 required measurements. The performance from a representative lot is shown in the following table.

Sample	n	Mean (mg/dL)	Repeatability SD	Repeatability %CV	Within-Laboratory[a] SD	Within-Laboratory[a] %CV	Reproducibility[b] SD	Reproducibility[b] %CV
Control 1	126	60	0.4	0.7	0.9	1.5	0.9	1.5
Control 2	125	77	0.5	0.6	1.1	1.4	1.1	1.4
Control 3	122	157	0.7	0.5	1.8	1.2	1.8	1.2
Panel	124	14	0.2	1.6	0.3	2.2	0.3	2.5

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

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

Sample	n	Mean (mmol/L)	Repeatability SD	Repeatability %CV	Within-Laboratory[a] SD	Within-Laboratory[a] %CV	Reproducibility[b] SD	Reproducibility[b] %CV
Control 1	126	1.55	0.008	0.5	0.021	1.4	0.021	1.4
Control 2	125	2.00	0.010	0.5	0.027	1.4	0.027	1.4
Control 3	122	4.06	0.015	0.4	0.046	1.1	0.046	1.1
Panel	124	0.36	0.005	1.3	0.005	1.4	0.007	1.9

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

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

Accuracy

The average percent bias of the Direct LDL reagent on a commercially available clinical chemistry analyzer to the Reference Method (ultracentrifugation and cholesterol analysis) was less than or equal to the guidelines established by the National Cholesterol Education Program (NCEP).*14* Fifty-four samples, with LDL values ranging from 68.1 to 214.5 mg/dL, were tested in duplicate using the LDL reagent on a commercially available clinical chemistry analyzer and the Reference Method. Sample means were compared by least squares linear regression analysis. Data from this study are summarized below.

Method	LDL	Reference Method
N	54	54
Mean (mg/dL)	122.5	125.1
Standard Deviation (mg/dL)	30.7	30.9
Regression Analysis	y = 0.95x + 3.02 mg/dL	
Correlation Coefficient	r = 0.96	

Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2. Testing was conducted using 3 lots of Alinity c Direct LDL 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.*18*

	mg/dL	mmol/L
LoB[a]	0	0.00
LoD[b]	1	0.03

	mg/dL	mmol/L
LoQ[c]	**1**	0.03

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

Linearity

A study was performed based on guidance from CLSI EP06-A.*19*

This assay is linear across the measuring interval of **1 to 800 mg/dL** (0.03 to 20.69 mmol/L).

Interference

Potentially Interfering Substances

Samples with triglyceride concentrations > 1293 mg/dL (> 14.61 mmol/L) should not be used for the determination of LDL-C.

Potential interference in the Direct LDL assay from ascorbic acid, bilirubin, gamma globulins, and hemoglobin is less than 10% at the levels indicated below. A study based on guidance from NCCLS publication EP7-P was performed using the Direct LDL assay on a commercially available clinical chemistry analyzer. Varying amounts of potential interferents were added to serum pools with known quantities of cholesterol.*20*

No significant interference was detected in the Direct LDL assay up to and including the concentrations stated below:

	Concentration with No Significant Interference	
Interfering Substance	**Default Units**	**Alternate Units**
Bilirubin (conjugated)	20 mg/dL	237 µmol/L
Bilirubin (unconjugated)	20 mg/dL	342 µmol/L
Hemoglobin	500 mg/dL	5 g/L
Ascorbic Acid	50 mg/dL	2839 µmol/L
Gamma Globulins	5000 mg/dL	50 g/L

The following drugs were tested on the ARCHITECT c System for interference at the concentrations indicated using an acceptance criteria of ± 10% from the target value. Direct LDL is not affected by the presence of the following interferents up to and including the concentrations stated below:

	Concentration with No Significant Interference	
Interfering Substance	**Default Units**	**Alternate Units**

	Concentration with No Significant Interference	
Interfering Substance	**Default Units**	**Alternate Units**
Acetaminophen	200 mg/L	1324.5 µmol/L
Dipyrone	100 mg/L	300.3 µmol/L
N-Acetyl-L-Cysteine	1600 mg/L	9816.0 µmol/L

Interferences from medications or endogenous substances may affect results.[21]

Method Comparison

A study was performed based on guidance from CLSI EP09-A3 using the Passing-Bablok regression method.[22]

	Sample Type	Units	n	Correlation Coefficient	Intercept	Slope	Concentration Range
Alinity c Direct LDL vs ARCHITECT Direct LDL	Serum	mg/dL	173	1.00	-0.01	1.01	3 – 766
		mmol/L	173	1.00	0.00	1.01	0.08 - 19.81

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