| **LDL Cholesterol, Direct** |
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| **Purpose** | This procedure provides instructions LDL CHOLESTEROL ON ABBOTT INSTRUMENTATION. The Alinity c Direct LDL assay is used for the direct, quantitative determination of low-density lipoprotein (LDL) cholesterol in human serum or plasma on the Alinity c analyzer. |
| **Policy Statements** | This procedure applies to all personnel responsible for operating the Abbott Alinity c at Children’s Minnesota Laboratory. |
| **Principle** | The Alinity c Direct LDL assay is a homogeneous method for directly measuring LDL levels in serum or plasma, without the need for offline 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 cholesterol present in the sample.**Methodology**: Measured, Liquid Selective DetergentFor additional information on system and assay technology, refer to the Alinity ci-series Operations Manual, Section 3.  |
| **Clinical Significance** | 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.The studies all point to LDL cholesterol as the key factor in the pathogenesis of atherosclerosis and CHD while HDL cholesterol has been observed to have a protective effect. Even within the normal range of total cholesterol concentrations, an increase in LDL cholesterol can occur with an associated increased risk for CHD. |
| **Analyzer** | **Minneapolis: Abbott Alinity ci (Sunquest method code: MACC)****St. Paul: Abbott Alinity c (Sunquest method code: SALIC)**Backup: Opposite campus |
| **Sunquest Test Codes** | **LDLC** |
| **Specimen** | Sample: Serum or Plasma (with or without gel barrier)**Preferred:** Lithium Heparin**Alternative:** SST, Sodium Heparin, EDTA**Minimum sample volume:** 0.6 mL blood, 0.2 mL serum/plasma**Stability when separated from cells/gel:** **2 to 8°C:** 5 days**-20°C:** 3 months\* *\*Avoid more than 1 freeze/thaw cycle.***Rejection criteria:** Unlabeled tube, sample type other than serum or acceptable plasma**Preparation:** 1. Whole blood specimens should be centrifuged following complete clot formation, according to Specimen Processing procedures prior to analysis.
2. Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection.
3. Specimens should be free of particulate matter.
4. Transfer serum or plasma directly to a properly labeled pilot tube.
5. Architect and Alinity systems utilize a specimen level detect mechanism, so special racks specific to tube-type are not required.
6. Minimum labeling includes sample accession ID, and/ or patient name, medical record number, collection date and time.
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| **Reagents** | **Reagent Handling** Upon receipt, place reagent cartridges in an upright position for 8 hour 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. Use a pipette to remove all bubbles prior to loading on the Alinity or Architect system.* Do not use reagents 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.
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| ***Product Description*** | ***Product Code*** | ***Stability*** |
| Abbott Alinity c Direct LDL Reagent Kit  | 07P7120 | **Store at:** 2 to 8°C**Unopened:** Until manufacturer’s printed expiration date**On-board**: 28 days |
| Abbott Lipid Multiconstituent Calibrator | 09P1403 | **Store at:** 2 to 8°C**Unopened:** Until manufacturer’s printed expiration date**Opened expiration:** 7days |

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| **Risk and Safety** | This product requires the handling of human specimens. It is recommended that all human-sourced materials be considered potentially infectious and handled in accordance with the OSHAStandard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.**WARNING** Contains methylisothiazolones.May cause an allergic skin reaction. The following warnings and precautions apply to: Lyophilized Calibrator: Contains methylisothiazolone and gentamicin sulfate.Safety data sheets (MSDS/SDS) available on [Children’s Intranet](https://starnet.childrenshc.org/emergency-and-safety/) |
| **Calibration** |

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| Assay Range: | 5 to 800 mg/dL |
| Reference Material: | Abbott Alinity Lipid Multiconstituent Calibrator |
| Suggested Calibration Levels: | 1 level |
| Calibration Scheme: | Linear data reduction method |
| Calibration Frequency: | 28 days |
| AMR | AMR is verified twice annually using the Maine Standards LP Product # 501ab by running all applicable levels in triplicate. Assay results are submitted to Maine Standards for compilation and comparison to peers. Results are reviewed and approved by the Technical Specialist. Questionable results are investigated and corrective actions documented. |

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| **Quality Control** | **QC Material**: Bio-Rad Liquichek Unassayed Multiqual 1,2,3 Levels 1 and 3**Frequency:** Two levels each day of use **Stability:** Once thawed, opened, and stored tightly capped at 2 to 8°C, product will be labeled with an expiration date equal to the shortest stability of the included analytes, which is **7 days.** **Preparation**: This product should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit, or reagent being used. * To thaw the product, allow it to stand at room temperature (18° to 25°C) until completely thawed but no longer than one (1)
* After thawing, the products **MUST** be gently swirled and inverted several times to ensure homogeneity.
* For optimal analyte stability in the thawed state, promptly return to 2 to 8°C storage after each use and minimize the time at room temperature to no more than 20 minutes daily.
* **Before each use**, gently swirl the contents until homogeneous with no visible signs of precipitate.

**Acceptable ranges:** * Non-Bio-Rad controls will utilize manufacturer ranges and 2 SD Westgard rules.
* New lots of Bio-Rad controls should be run for 20 days in parallel with the current lot whenever possible prior to switching to the new lot.
* Refer to the Westgard Rules in Chemistry procedure for current Westgard rules in place for each analyte.
* **Acceptable ranges are current in Unity Real Time only.** Quality Control results must be rejected in Sunquest when the results cross the interface.
* In the event of a QC failure, refer to the [Unity Real Time QC Review, General User](https://starnet.childrenshc.org/References/labsop/chem/quality/ch-2.17-unity-real-time-qc-review-general-user.pdf) and navigate to the QC Troubleshooting section.
* Do not load or release patients until QC is acceptable in Unity Real Time.
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| **Interferences** | **Hemolysis, Icterus & Lipemia (HIL) Index Values:**

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At HIL levels at or above the specified cutoff value, append the appropriate comment AFTER visually confirming presence of interferent: -HP for “Hemolysis present, may affect results.” -BIN for “Bilirubin Interference”-LINT for “Lipid Interference”Samples with triglyceride concentrations > 1293 mg/dL (> 14.61 mmol/L) should not be used for the determination of LDL cholesterol. Ultracentrifugation should not be used on any testing for cholesterol, including LDL. Also tested with no significant interference: Bilirubin up to 20 mg/dL, Hemoglobin 500 mg/dL |
| **Reference Intervals** | All ages: abnormal high >= 130 |
| **Critical Values** | None specified |
| **Limitations** | Interferences from medications or endogenous substances may affect results. |
| **Dilutions** | Do not dilute |
| **Result Reporting** | * Results between 5 and 800 without error messages are released
* Results below 5 without error messages are reported as < 5 mg/dL.
* Results > 800 following automated dilution are reported as > 800 mg/dL
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| **Specimen Storage** | Promptly stopper tested specimen and store upright in a specimen rack. Every 8 hours remove specimens to refrigerator/freezer storage. Samples are retained 7 days in specimen storage freezer. |
| **References** | 1. Abbott Alinity c Direct LDL Instructions for Use, Abbott Diagnostics, Abbott Park IL, USA. Revised December 2017
2. Abbott Alinity Lipid Multiconstituent Calibrator, Abbott Diagnostics Division, Abbott Park, IL USA.
3. Bio-Rad Liquichek Unassayed Multiqual 1,2,3 Control Package Insert, Bio-Rad Laboratories, Irvine, CA USA
4. 2018 Guideline on the Management of Blood Cholesterol, GUIDELINES MADE SIMPLE A Selection of Tables and Figures. American College of Cardiology, acc.org/GMSCholesterol. Updated June 2019.
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | Elauteria Earnhardt | April 23, 2020 | New Procedure for Abbott analyzers |
| 1 | Erin Bartos | October 28, 2020 | Added correct Mpls Alinity ci, AMR, reference range, interferences, references, etc for new Abbott instruments |