| **Cholesterol, Total** |
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| **Purpose** | This procedure provides instructions for performing TOTAL CHOLESTEROL ON ABBOTT INSTRUMENTATION. The Alinity c Cholesterol assay is used for the quantitation of 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 use of enzymes to assay cholesterol has been studied by many investigators. This reagent is based on the formulation of Allain, et al. and the modification of Roeschlau with further improvements to render the reagent stable in solution. 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 combines with hydroxybenzoic acid (HBA) and 4-aminoantipyrine to form a chromophore (quinoneimine dye) which is quantitated at 500 nm.**Methodology**: Enzymatic For additional information on system and assay technology, refer to the Alinity ci-series Operations Manual, Section 3. |
| **Clinical Significance** | 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.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. |
| **Analyzer** | **Minneapolis: Abbott Alinity c (Sunquest method code: MACC)****St. Paul: Abbott Alinity c (Sunquest method code: SALIC)** |
| **Sunquest Test Codes** | **CHOL** |
| **Specimen** | Sample: Plasma or Serum **Preferred:** Lithium Heparin (with or without gel) **Alternative:** SST (with or without gel), Sodium Heparin**Minimum sample volume:** 0.6 mL blood, 0.2 mL serum/plasma**Stability when separated from cells/gel:** **20 to 25°C:** 7 days **2 to 8°C:** 7 days**-20°C:** 3 months **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 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 hours 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 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*** |
| Alinity c Cholesterol Reagent Kit | 07P7620 | **Store at:** 2 to 8°C**Unopened:** Until manufacturer’s printed expiration date**On-board:** 30 days |
| Alinity c Multiconstituent Calibrator Kit | 08P6001 | **Store at:** 2 to 8°C**Unopened:** Until manufacturer’s printed expiration date**On-board:** 7 days |

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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 OSHA Standard 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. *The following warnings and precautions apply to R1:* Contains sodium azide as a preservative. Contact with acids liberates very toxic gas.No special disposal is required.Safety data sheets (MSDS/SDS) available on [Children’s Intranet](https://starnet.childrenshc.org/emergency-and-safety/) |
| **Calibration** |

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| Assay Range: | 10 to 625 mg/dL |
| Reference Material: | Multiconstituent Calibrator Kit |
| Suggested Calibration Levels: | 2 Levels |
| Calibration Scheme: | Linear data reduction method  |
| Calibration Frequency: | 30 days  |
| AMR | AMR is verified twice annually using the Maine Standards GC1 Product # 1100ab 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 Multiqual 1,2,3 Unassayed Control Levels 1 & 3**Frequency:** Two levels each day of use **Stability:** Once thawed, opened, and stored tightly capped at 2 to 8°C, **Multiqual** **Unassayed Chemistry Control** 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) hour
* 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** | **Alinity c** **Hemolysis, Icterus & Lipemia (HIL) Index Values:**

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| **H** | **I** | **L** |
| **4** | **3** | **-** |

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”It may be possible to dilute the sample with the automated 1:4 dilution to negate the effect of hemolysis or lipemia. If the result is less than 40 mg/dL with the 1:4 automated dilution, do not report the diluted value. Append the applicable comment(s) above to the original result (if there are no other flags than H or I.)  |
| **Reference Intervals** | Normal: 42 to 199 mg/dL Abnormal: >= 200 mg/dL |
| **Critical Values** | None specified. |
| **Limitations** | * N-Acetyl-L-Cysteine at therapeutically achieved concentrations may lead to falsely low results.
* Do not use ultra-centrifuged samples for total cholesterol analysis.
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| **Dilutions** |

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| Max Auto Dilution: | 1:4 |
| Maximum Manual Dilution: | Do not manually dilute. |
| Diluent: | Onboard saline |
| Manual Dilution: | Follow Abbott [Alinity Operator’s Manual](https://starnet.childrenshc.org/References/labsop/chem/operator/alinity-ci-series-operations-manual.pdf) instructions for programming automated dilutions. The system will automatically calculate the concentration of the sample and report the result. If the diluted result is less than the linearity of the test, investigate for causes of error and do not report the result until resolved. |

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| **Result Reporting** | * Results between 10 and 625 without error messages are released
* Results below 10 without error messages are reported as < 10 mg/dL.
* Results > 625 should be diluted using the onboard automated 1:4 dilution. Release results without error messages following this dilution.
* Results > 2500 following automated dilution are reported as > 2500 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 Cholesterol Instructions for Use, Abbott Diagnostics Division, Abbott Park, IL, USA. December 2017.
2. Abbott Alinity c Lipid Multiconstituent Calibrator Package Insert, Abbott Diagnostics Division, Abbott Park, IL, USA
3. Bio-Rad Liquichek Multiqual 1,2,3, Unassayed Chemistry Control Package Insert, BioRad Laboratories.
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 17,2020 | New Procedure for Abbott analyzers |
| 1 | Erin Bartos | 10/28/2020 | Added AMR, interferences, Cal Ver materials, product numbers, references, dilution, correct instruments, reference range, changed title |