| **Triglyceride** |
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| **Purpose** | This procedure provides instructions TRIGLYCERIDE ON ABBOTT INSTRUMENTATION. The Alinity c Triglyceride assay is used for the quantitation of triglyceride in human serum or plasma and body fluids 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** | Triglycerides are enzymatically hydrolyzed by lipase to free fatty acids and glycerol. The glycerol is phosphorylated by adenosine triphosphate (ATP) with glycerol kinase (GK) to produce glycerol-3-phosphate and adenosine diphosphate (ADP). Glycerol-3- phosphate is oxidized to dihydroxyacetone phosphate (DAP) by glycerol phosphate oxidase (GPO) producing hydrogen peroxide (H2O2). In a color reaction catalyzed by peroxidase, the H2O2 reacts with 4-aminoantipyrine (4-AAP) and 4-chlorophenol (4-CP) to produce a red colored dye. The absorbance of this dye is proportional to the concentration of triglyceride present in the sample. This analytical methodology is based on the reaction sequence described by Fossati et al.and by McGowan et al. In this reagent, 4-chlorophenol is used rather than 2-hydroxy-3,5- dichlorobenzenesulfonate, used in the Fossati and McGowan studies.**Methodology:** Glycerol Phosphate Oxidase*For additional information on system and assay technology, refer to the Alinity ci-series Operations Manual, Section 3.* |
| **Clinical Significance** | Triglycerides are a family of lipids absorbed from the diet and produced endogenously from carbohydrates and fatty acids. Measurement of triglyceride is important in the diagnosis and management of hyperlipidemia. These diseases can be genetic or secondary to other disorders including nephrosis, diabetes mellitus, and endocrine disturbances. The National Cholesterol Education Program (NCEP) cites evidence that triglycerides are an independent risk factor for atherosclerosis. Individuals with hypertension, obesity, and/or diabetes are at greater risk than are those without these conditions.The Adult Treatment Panel of the 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: MALIC)****St. Paul: Abbott Alinity c (Sunquest method code: SALIC)**Backup: Opposite campus |
| **Sunquest Test Codes** | **TRIG** Triglyceride**FTRG** Triglyceride in Body Fluid |
| **Specimen** | Sample: Plasma or Serum (with or without gel barrier)**Preferred:** Lithium Heparin**Alternative:** SST, Sodium HeparinSee [CH 4.021 Body Fluid Chemistry](https://starnet.childrenshc.org/References/labsop/chem/collect/ch-4.021-body-fluid-chemistry-testing.pdf) Testing procedure for body fluid specimen requirements and information. **Minimum sample volume:** 0.6 mL blood, 0.2 mL serum/plasma**Stability when separated from cells/gel:** **20 to 25°C:** 2 days**2 to 8°C:** 7 days**-20°C:** > 1 year**Body fluids** should not be frozen. Store up to 7 days at 2 to 8°C. **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 48 hours before use to allow bubbles that may have formed to dissipate. If a reagent cartridge is dropped, place in an upright position for 8 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 Triglyceride Reagent Kit | 07P7720 | **Store at:** 2 to 8°C**Unopened:** Until expiration Date**On-board**: 42 days |
| Abbott Alinity c Multiconstituent Calibrator | 08P6001 | **Store at:** 2 to 8°C**Unopened:** Until expiration Date**Opened expiration:** 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 and R2:* Contains sodium azide. Contact with acids liberates very toxic gas.Safety data sheets (MSDS/SDS) available on [Children’s Intranet](https://starnet.childrenshc.org/emergency-and-safety/) |
| **Calibration** |

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| Assay Range: | Serum or plasma: 11 to 1420 mg/dLBody Fluid: 11 to 900 mg/dL |
| Reference Material: | Multiconstituent Calibrator |
| Suggested Calibration Levels: | 2 levels |
| Calibration Scheme: | Linear data reduction method |
| Calibration Frequency: | 41 days |
| AMR | AMR is verified twice annually using the Maine Standards GC1 Product # 1100ab by running all applicable levels in triplicate. AMR is verified twice annually on Body Fluid Triglycerides using the Maine Standards Body Fluid product # 205bf. 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) 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** | **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”N-Acetyl-L-Cysteine at therapeutically achieved concentrations (800mmg/dL) may lead to falsely low results.Interferences from medication or endogenous substances may affect results |
| **Reference Intervals** | Serum or Plasma:Normal:0-9 years <100 9-18 years: <130 Adult: <200Body fluid reference intervals have not been established.  |
| **Critical Values** | None Specified |
| **Limitations** | N-Acetyl-L-Cysteine at therapeutically achieved concentrations (800mmg/dL) may lead to falsely low results.Interferences from medication or endogenous substances may affect results |
| **Dilutions** |

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| Max Auto Dilution: | Serum or plasma: 1:4Do not dilute body fluids. |
| Maximum Manual Dilution: | None |
| Diluent: | Onboard Saline |
| Automated 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 a diluted sample result is less than the lower value of the measuring interval of 11, do not report the result. Rerun and/or investigate for other possible causes of error. |

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| **Result Reporting** | Serum or Plasma:* Results between 11 and 1420 without error messages are released
* Results bel­ow 11 without error messages are reported as < 11 mg/dL.
* Results > 1420 should be diluted using the onboard automated 1:4. Release results without error messages following this dilution.
* Results > 5680 following automated dilution are reported as > 5680 mg/dL.

Body Fluid:* Results between 11 and 900 without error messages are released
* Results below 11 without error messages are reported as < 11 mg/dL.
* Results greater than 900 without error messages are reported as >900 mg/dL. Do not dilute.
* For error “1061 – Unable to calculate result. Endpoint absorbance reads unstable.” Contact technical specialist for guidance.­
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| **Specimen Storage** | Serum or Plasma: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.Body Fluid: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 refrigerator. |
| **References** | 1. 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.
2. Abbott Alinity c Triglyceride Reagent Kit Instructions for Use, Abbott Diagnostics Division, Abbott Park, IL USA. December 2017
3. Abbott Alinity c Multiconstituent Calibrator Package Insert, Abbott Diagnostics Division, Abbott Park, IL USA. December 2017
4. Bio-Rad Liquichek Unassayed Multiqual 1,2,3, Package Insert, Bio-Rad Laboratories, Irvine CA USA.
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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 reference interval, references, dilution, interferences, product numbers,QC material, cal ver material, correct mpls alinity system, added trig body fluid |
|  | Matt Johnson | 3/15/2023 | Reviewed, no changes. MCJ 3/15/2023 |
|  | 2 | Matt Johnson | 5/15/2023 | Added comment for error 1061, result section.  |