| **Gamma-Glutamyl Transferase (GGT)** |
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| **Purpose** | This procedure provides instructions for Gamma-Glutamyl Transferase (GGT) ON ABBOTT INSTRUMENTATION. The Gamma-Glutamyl Transferase (GGT) assay is used for the quantitation of GGT in human serum or plasma. |
| **Policy Statements** | This procedure applies to all personnel responsible for operating the Abbott Alinity c at Children’s Minnesota Laboratory. |
| **Principle** | GGT catalyzes the transfer of the gamma-glutamyl group from the donor substrate (*L*-gamma-glutamyl-3-carboxy-4-nitroanilide) to the glycylglycine acceptor to yield 3-carboxy-4-nitroaniline. The rate of the absorbance increase at 416 nm is directly proportional to the GGT in the sample. The GGT procedure is a modification of themethod described by Theodorsen et al.**Methodology:** L-Gamma-glutamyl-3-carboxy-4-nitroanilide Substrate |
| **Clinical Significance** | GGT was first identified in kidney tissue. Even though renal tissue has the highest level of GGT, the enzyme present in serum appears to originate primarily from the hepatobiliary system, and GGT is elevated in many forms of liver disease. Elevations in GGT levels are seen earlier and are more pronounced than those with other liver enzymes in cases of obstructive jaundice and metastatic neoplasms. It may reach 5 to 30 times normal levels in intra- or post-hepatic biliary obstruction. Only moderate elevations in the enzyme level (2 to 5 times normal) are observed with infectious hepatitis: therefore, GGT measurements are less useful diagnostically than transaminase determinations with this condition. |
| **Analyzer** | **Minneapolis: Abbott Alinity c (Sunquest method code: MACC)****St. Paul: Abbott Alinity c (Sunquest method code: SALIC)** |
| **Sunquest Test Codes** | **GGT** |
| **Specimen** | Sample: Preferred: Lithium Heparin, with or without gelAlternative: Serum with or without gel, NaHep**Minimum sample volume:** 0.6mL blood, 0.2 mL serum/plasma**Stability when separated from cells/gel:** 20 to 25°C 7 days2 to 8°C 7 days-20°C 1 year**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 to a properly labeled sendout tube. Short samples should be pipetted into an Abbott sample cup and nested on a sendout tube; any amount remaining after sampling should be pipetted into the sendout tube and tightly capped.
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 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*** |
| Alinity c Gamma-Glutamyl Transferase Reagent Kit  | 07P7320 | **Store at:** 2 to 8°C**Unopened:** Until expiration date printed on reagent carton**On-board**: 27 Days |

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| **Risk and Safety** |

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| 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. The following warnings and precautions apply to: R1 and R2: contains sodium azide as a preservative, which does not require special handling.Safety data sheets (MSDS/SDS) available on [Children’s Intranet](https://starnet.childrenshc.org/emergency-and-safety/)  |

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| **Calibration** |

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| Assay Range: | 6 to 7500 U/L |
| Reference Material: | Onboard Water |
| Suggested Calibration Levels: | GGT assay utilize the Factor data reduction method to generate a calibration and results. Calibration targets are determined by the Abbott assay configuration |
| Calibration Scheme: | 1 level, Factor data reduction method |
| Calibration Frequency: | 27 days |
| AMR | AMR is verified twice annually using the Maine Standards GC3 Product # 1300ab 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 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 (insert hyperlink) 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”Interferences from medication or endogenous substances may affect results. |
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| **Reference Intervals** | **Both sexes**:**0 to < 15 Days:** 23 - 219 U/L **15 Days to < 1 Year:** 8 - 127 U/L **1 to < 11 Years:** 6 - 16 U/L **11 to < 19 Years:** 7 - 21 U/L **Adult Male:** 12 - 64 U/L **Adult Female:** 9 - 36 U/L |
| **Critical Values** | None specified. |
| **Limitations** | See interferences section. |
| **Dilutions** | Do not dilute. |
| **Result Reporting** | * Results between 6 and 7500 without error messages are released
* Results below 6 without error messages are reported as < 6 U/L
* Results > 7500 should be reported as > 7500 U/L
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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 Gamma-Glutamyl Transferase Instructions for Use, Abbott Diagnostics Division, Abbott Park IL, USA. Revised December 2017
2. Bio-Rad Liquichek Multiqual 1,2,3 Unassayed Control Package Insert, Bio-Rad Laboratories, Irvine, CA USA.
3. [CALIPER Reference Range Studies](https://caliper.research.sickkids.ca/#/), accessed October 27, 2020.
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | Stephen Gripentrog |  | New Procedure for Abbott analyzers |
| 1 | Erin Bartos | October 28, 2020 | Added interferences, correct Alinity Mpls, linearity, cal ver materials, reference intervals, product number, handling of reagents, references. |