| **Amylase** |
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| **Purpose** | This procedure provides instructions for Amylase ON ABBOTT INSTRUMENTATION. The Amylase assay is used for the quantitation of amylase in human serum and plasma. |
| **Policy Statements** | This procedure applies to all personnel responsible for operating the Alinity c at Children’s Minnesota Laboratory. |
| **Principle** | **Methodology: Enzymatic (**CNPG3 Substrate)α-Amylase hydrolyzes the 2-chloro-4-nitrophenyl-α-*D*-maltotrioside (CNPG3) to release 2-chloro-4-nitrophenol (CPNP) and form 2‑chloro‑4‑nitrophenyl‑α‑*D*‑maltoside (CNPG2), maltotriose, and glucose. The rate of formation of the 2-chloro-4-nitrophenol can be detected spectrophotometrically at 404 nm to give a direct measurement of α‑amylase activity in the sample. |
| **Clinical Significance** | Normal individuals have low but measurable serum and α‑amylase activity which is produced in the pancreas and parotid glands. Measurement of α-amylase activity is of value in diagnosing pancreatitis and other pancreatic disorders which result in elevation of serum and α-amylase activity. Numerous methods have been used for clinical analysis. |
| **Analyzer** | **Minneapolis: Abbott Alinity c (Sunquest method code: MACC)****St. Paul: Abbott Alinity c(Sunquest method code: SALIC)** |
| **Sunquest Test Codes** | **AMYL** |
| **Specimen** | Sample: Preferred: Lithium HeparinAlternative: SST, Sodium Heparin **Minimum sample volume:** 0.6ml blood, 0.2 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, gently invert cartridges 5 times, then place reagent cartridges in an upright position for 1 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 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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|  | **Alinity c:**

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| ***Product Description*** | ***Product Code*** | ***Stability*** |
| Alinity c AMYLASE Reagent Kit | 07P5820 | **Store at:** 2 to 8°C**Unopened:** Until manufacturer’s expiration date**On-board**: 19 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.The following warnings and precautions apply to: R1 contains sodium azide and potassium thiocyanate. No special disposal indicated.

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| Safety data sheets (MSDS/SDS) available on [Children’s Intranet](https://starnet.childrenshc.org/emergency-and-safety/)  |

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| **Calibration** | **Alinity c:**

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| Assay Range: | 6 to 6000 U/L |
| Reference Material: | Onboard Water  |
| Suggested Calibration Levels: | Assay configuration calibration factor: 3431 |
| Calibration Scheme: | 1 level, Factor data reduction method |
| Calibration Frequency: | 19 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 Chemistry 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 (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”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. |
| **Reference Intervals** | **Amylase, in U/L****0 to < 15 Days**: 3 to 10 U/L**15 Days to < 13 Weeks**: 2 to 22 U/L **13 Weeks to < 1 Year**: 3 to 50 U/L**1 year to < 19 Years**: 25 to 101 U/L **19 years to 69 years**: 25 to 125 U/L**70 years+**: 20 to 160 U/L |
| **Critical Values** | None Specified. |
| **Limitations** | Note Bilirubin and Hemoglobin interferences. See interferences section. |
| **Dilutions** |

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| **Alinity c:**  |
| Max Auto Dilution: | 1:2 |
| Maximum Manual Dilution: | Do not manually dilute |
| Diluent: | 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 a diluted sample result is less than the lower value of the measuring interval of 6, do not report the result. Rerun and/or investigate for other possible causes of error. |

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| **Result Reporting** | **Alinity c:*** Results between 6 and 6000 without error messages are released
* Results below 6 without error messages are reported as < 6 U/L.
* Results > 6000 should be diluted using the onboard automated 1:2 dilution. Release results without error messages following this dilution.
* Results > 12000 following automated dilution are reported as > 12000.
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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 Amylase Reagent Kit Instructions for Use, Abbott Diagnostics Division, Abbott Park IL, USA. March 2018
2. Bio-Rad Multiqual 1,2,3 Unassayed Control Package Insert, BioRad Laboratories, USA.
3. [CALIPER reference range study](https://caliper.research.sickkids.ca/#/), Accessed 10/27/2020.
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | Erin Bartos, Stephen Gripentrog | 10/28/2020 | New Procedure for Abbott analyzers |
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