| **AST (Aspartate Aminotransferase)** |
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| **Purpose** | This procedure provides instructions for AST (ASPARTATE AMINOTRANSFERASE) ON ABBOTT INSTRUMENTATION. The AST method is an *in vitro* diagnostic test for the quantitative measurement of AST in human serum and plasma on the Abbott Architect c4000 or Abbott Alinity c automated chemistry analyzers. |
| **Policy Statements** | This procedure applies to all personnel responsible for operating the Abbott Architect c4000 or Abbott Alinity c at Children’s Minnesota Laboratory.  |
| **Principle** | AST present in the sample catalyzes the transfer of the amino group from L-aspartate to α-ketoglutarate, forming oxaloacetate and L-glutamate. Oxaloacetate in the presence of NADH and malate dehydrogenase (MDH) is reduced to L-malate. In this reaction, NADH is oxidized to NAD. The reaction is monitored by measuring the rate of decrease in absorbance at 340 nm due to the oxidation of NADH to NAD.Methodology: Enzymatic (NADH (without P-5'-P)) |
| **Clinical Significance** | Aspartate Aminotransferase (AST), also referred to as glutamate oxaloacetate transaminase (GOT), is one of a group of enzymes which catalyzes the interconversion of amino acids and α-keto acids by transfer of amino groups. Both AST and alanine aminotransferase (ALT) are normally found in most body fluids, but not in urine except in instances of kidney lesions. The greatest concentrations of AST are found in heart, liver, muscle, and kidney tissues. Damage to these tissues can greatly elevate serum AST levels. AST is mostly used in the evaluation of liver disease. Elevated levels are found with acute myocardial infarction, severe angina, hepatitis, liver necrosis, cancer of the liver, alcoholism, musculoskeletal disease, recent convulsions, heat stroke, severe burns, acute pancreatitis, strenuous exercise, toxic shock syndrome, cerebral infarction, trauma, and intramuscular injection, among others. Following myocardial infarction, AST in serum begins to increase within 6 to 8 hours of onset of pain, reaching a peak within 18 to 24 hours and falling to normal by the fourth or fifth day. Serum values may increase to 10 to 15 times normal levels and the increase is roughly proportional to the degree of tissue damage.Depressed levels are seen in uremia, vitamin B deficiency, and with the administration of some drugs. |
| **Analyzer** | **Minneapolis: Abbott Alinity c (Sunquest method code: MALIC) or Abbott Alinity ci (Sunquest method code: MACC)****St. Paul: Abbott Architect c4000 (Sunquest method code: ARCH4), Abbott Alinity c (Sunquest method code: SALIC)** |
| **Sunquest Test Codes** | AST: AST in serum and plasma. |
| **Specimen** | Sample: Plasma (lithium heparin with or without gel) preferred. Sodium heparin plasma and serum (with or without gel) are also acceptable. Refer to specimen collection procedures.**Minimum sample volume:** 200 µL preferred, 150 µL minimum**Stability when separated from cells/gel:** RT / 4 days, 2-8 °C / 7 Days , < -20°C / 84 Days**Rejection criteria:** Unlabeled tube, sample type other than serum or heparinized plasma. See Interferences section regarding hemolyzed samples.**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** | **Alinity c and Architect c4000:****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 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 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.

**Alinity c:**Reagents may be stored on or off the system. If removed from the system, store reagents with new replacement caps in an upright position at 2 to 8°C. For reagents stored off the system, it is recommended that they be stored in their original trays or boxes to ensure they remain upright.**Alinity c:**

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| ***Product Description*** | ***Product Code*** | ***Stability*** |
| Abbott Alinity c AST ReagentCHC# 32621 | 08P17-20 | **Store at:** 2 – 8 °C**Unopened:** Manufacturer’s printed expiration date**On-board: 30 days****Opened, off the analyzer (with clean caps):** Manufacturer’s printed expiration date. (Reagents may be stored on or off the system. The system tracks time onboard.) |

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|  | **Architect c4000:**

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| ***Product Description*** | ***Product Code*** | ***Stability*** |
| Abbott Architect AST ReagentCHC# 32540 | 07D81-21 | **Store at:** 2 – 8 °C**Unopened:** Manufacturer’s printed expiration date.**On-board: 30 Days** |

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| **Risk and Safety** |

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| **CAUTION:** For in vitro diagnostic use. This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens. Appropriate Personal Protective Equipment (PPE) must be worn according to Children’s Minnesota Laboratory policies. Current SDSs are kept on the [Children’s StarNet](https://msdsmanagement.msdsonline.com/a07dc954-23d8-42a9-b591-ef5763cdfd33/ebinder/?nas=True) pageR2 reagent: May cause minor skin irritation.Dispose of used reagent in normal trash. Unused (full) reagents should be disposed of in Regulated Medical Waste (red trash). |

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| **Calibration** | **Alinity c and Architect c4000:**

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| Assay Range: | 5 – 4000 U/L |
| Reference Material: | Onboard water |
| Suggested Calibration Levels: | Assay configuration calibration factor: 8141 |
| Calibration Scheme: | Factor data reduction method |
| Calibration Frequency: | 30 Days |
| AMR | AMR is verified twice annually using the Maine Standards CHEM Product # 104ab 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. Any questionable results are investigated and corrective actions documented.  |

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| **Quality Control** | **Alinity c and Architect c4000:** Bio-Rad Liquichek™ Unassayed Multiqual Chemistry Control (Human) Levels 1 & 3**Frequency:** Two levels each day of use**Stability:** Once thawed, opened, and stored tightly capped at 2 to 8°C, this 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 product **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** | **Alinity c and Architect c4000:** **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”**CAUTION**: Hemolysis in serum or plasma can increase test results. Samples that contain visible hemolysis should not be used, whenever possible.Interference studies were conducted using NCCLS EP7-P. Interference effects were assessed by Dose Response and Paired Difference methods, at the medical decision level of the analyte. Interference is less than 10% for AST concentration levels at medical decision points for the analyte at:* Hemoglobin: up to 60 mg/dL
* Bilirubin: up to 60 mg/dL
* Lipemia (Intralipid®): up to 625 mg/dL

Lipemia causes interference. Clarify samples that are moderately lipemic by ultracentrifugation. Attach appropriate comment (-LINT) to the result. Interferences from medication or endogenous substances may affect results.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.  |
|  | **Alinity c and Architect c4000:**  |
| **Reference Intervals** |

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| Age | AST |
| 0 – 14 Days | 32 - 162 U/L |
| 15 days – 364 days | 20 - 67 U/L |
| 1 year to 6 years | 21 - 44 U/L |
| 7 – 11 years | 18 – 36 U/L |
| 12 – 18 years female | 13 - 26 U/L |
| 12 – 18 years male | 14 – 35 U/L |
| Adult | 5 - 34 U/L |
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| **Critical Values** | None specified. |
| **Limitations** | The instrument reporting system contains flags and comments to provide the user with information regarding instrument processing errors, instrument status information and potential errors in AST results. Refer to the [Abbott Architect](https://starnet.childrenshc.org/References/labsop/chem/operator/abbott-architect-operations-manual.pdf) or [Alinity](https://starnet.childrenshc.org/References/labsop/chem/operator/alinity-ci-series-operations-manual.pdf) Operator’s Guides for the meaning of report flags and comments, and instructions for addressing them. Do not report results until a report containing flags and/or comments is resolved.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.Refer to Interferences section for handling of lipemic and hemolyzed samples.  |
| **Dilutions** |

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| **Alinity c and Architect c4000:**  |
| Automated Dilution: | none |
| Maximum Manual Dilution: | 1:5 |
| Manual Diluent: | Saline |
| Manual Dilution: | Follow Abbott [Architect Operator’s Manual](https://starnet.childrenshc.org/References/labsop/chem/operator/abbott-architect-operations-manual.pdf) or [Alinity Operator’s Manual](https://starnet.childrenshc.org/References/labsop/chem/operator/alinity-ci-series-operations-manual.pdf) instructions for programming manual dilutions. The operator must enter the dilution factor when ordering the manual dilution. The system will use this dilution factor to 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 3 U/L, do not report the result. Rerun using an appropriate (lower) dilution or investigate for other possible causes. |

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| **Result Reporting** | **Alinity c** and **Architect c4000:** * Results between 3 – 4000 U/L without error messages are released
* Results below 3 U/L g/dL: report as < 3 U/L instead of the numerical value.
* Results >4000 g/dL without error messages should have a 1:5 manual dilution performed. Results >20000 U/L after automated dilution are reported as >20000 U/L. Do not manually dilute.

Hemolysis in serum or plasma can increase test results. Samples that contain visible hemolysis should not be used, whenever possible. Otherwise, append the –HP comment. Lipemia causes interference. Clarify samples that are moderately lipemic by ultracentrifugation. Attach appropriate comment (-LINT) to the result.  |
| **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. Jacobs & DeMott Laboratory Test Handbook, Lexi-Comp, Inc., Hudson, OH, 5th Edition, 2001
2. Architect AST Package Insert, Abbott Laboratories Diagnostics Division, Abbott Park, IL 60064, March 2017.
3. Alinity AST Package Insert, Abbott Laboratories Diagnostics Division, Abbott Park, IL 60064, February 2018.
4. CALIPER pediatric reference range database. (2019). Retrieved October 3, 2019, from https://caliper.research.sickkids.ca/#/
5. Bio-Rad Liquichek Unassayed Chemistry Control Product Insert, Bio-Rad Laboratories, Irvine, CA 92618
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | Erin Bartos | 10/15/2019 | New Procedure for Abbott analyzers |
| 2  | Erin Bartos, Elauteria Earnhardt | October 28, 2020 | Added St Paul Alinity c as an analyzer; added Mpls Alinity ci, changed QC, added HIL, changed AMR |
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