| **Sodium** | | | | |
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| **Purpose** | This procedure provides instructions for SODIUM ON ABBOTT INSTRUMENTATION. The sodium method is an *in vitro* diagnostic test for the quantitative measurement of sodium in human serum and plasma on the Abbott Architect c4000 or Abbott Alinity c automated chemistry analyzers, and in urine on the Minneapolis Alinity ci and Saint Paul Alinity c. | | | |
| **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** | The Abbott Architect c4000 and Alinity c analyzers utilize Integrated Chip Technology (ICT). The ICT contains ion-selective electrodes (ISE) for sodium, potassium, and chloride and utilizes membranes selective to each of these ions. An electrical potential (voltage) is developed across the membranes between the reference and measuring electrodes in accordance with the Nernst equation. The voltage is compared to previously determined calibrator voltages and converted into ion concentration.  Methodology: Ion-selective electrode diluted (Indirect) | | | |
| **Clinical Significance** | Sodium is the major cation of extracellular fluid; it plays an essential role in the normal distribution of water and in the maintenance of osmotic pressure in extracellular fluid compartments. Decreased levels of sodium may be caused by an excessive use of diuretics, prolonged vomiting, a decrease in the intake of sodium in the diet, and metabolic acidosis. Increased levels of sodium may be found in Cushing’s syndrome, severe dehydration, or in high levels of salt intake without an adequate supply of water. | | | |
| **Analyzer** | **Minneapolis: Abbott Alinity c (Sunquest method code: MALIC) and 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** | NA: Sodium in serum and plasmaUNAR: Sodium in urine (MACC and SALIC only) | | | |
| **Specimen** | Sample:  Plasma (lithium heparin with or without gel) preferred. Serum (with or without gel) also acceptable. Refer to specimen collection procedures.  Urine: Sterile container. Centrifuge to remove particulate matter.  **Minimum sample volume:** 200 µL preferred, 150 µL minimum  **Stability when separated from cells/gel:** RT / 14 days, 2-8 °C / 14 days, < -20°C / 12 months  **Rejection criteria:** Unlabeled tube, sample type other than serum or plasma or urine  **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. | | | |
| **Reagents** | **Alinity c and Architect c4000:**  **Reagent Handling**  Upon receipt, 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 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 15 - 30 °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:**   |  |  |  | | --- | --- | --- | | ***Product Description*** | ***Product Code*** | ***Stability*** | | Abbott Alinity c ICT Sample Diluent (ICTD5) Reagent  CHC# 32642 | 07P53-20 | **Store at:** 15 - 30 °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.) | | Abbott Alinity ***and*** Architect ICT Module  CHC# 32595  NOTE: this ICT module is used on both Alinity and Architect systems. | 09D28-04 | **Store at: 15 - 30 °C**  **Unopened:** Manufacturer’s printed expiration date  **On-board:** 60,000 tests (15,000 each for Na, K, Cl-). The module can still be used onboard past the printed expiration date provided the slope of the ICT calibration is above 45% and the quality controls are all acceptable. ICT modules are expected to last between 3-6 months or more. | | Abbott Alinity c ICT Serum Calibrator  CHC# 32636 | 01E46-03 | **Store at:** 15 - 30°C  **Unopened:** Manufacturer’s printed expiration date  **On board expiration: 5 days when stored onboard.** The Alinity c tracks time on the system.  **Opened expiration: 7 days** when opened and stored off the system at 2 – 8 °C. | | | | |
|  | **Architect c4000:**   |  |  |  | | --- | --- | --- | | ***Product Description*** | ***Product Code*** | ***Stability*** | | Abbott Architect ICT Sample Diluent (ICTD5) Reagent  CHC# 32550 | 02P32-11 | **Store at:** 15 - 30°C  **Unopened:** Manufacturer’s printed expiration date.  **On-board:** 30 Days | | Abbott Architect ICT Serum Calibrator  CHC# 32563 | 01E46-03 | **Store at:** 15 - 30°C  **Unopened:** Manufacturer’s printed expiration date  **Opened:** 7 Days at 2 - 8°C | | | | |
| **Risk and Safety** | |  | | --- | | **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) page  Dispose of used reagent and calibrators in regular trash. | | | | |
| **Calibration** | **Alinity c** and **Architect c4000:**   |  |  | | --- | --- | | Assay Range: | 100- 200 mEq/L (mmol/L) blood  20 – 300 mEq/L (mmol/L) urine | | Reference Material: | Abbott Alinity ICT Serum Calibrator  Abbott Architect ICT Serum Calibrator | | Suggested Calibration Levels: | CAL L: 120 mmol/L(mEq/L)  CAL H: 160 mmol/L(mEq/L | | Calibration Scheme: | 2 levels, Potentiometric data reduction method | | Calibration Frequency: | 24 Hours | | AMR | AMR is verified twice annually using the Maine Standards GC1, Product # 1100ab, and UC1, Product # 701 db, 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™ Multiqual Unassayed Chemistry Control Levels 1 & 3  **Frequency:** Two levels each shift  **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.   **Bio-Rad Liquichek™ Urine Chemistry Levels 1 & 2**  **Frequency:** Two levels each shift of use  **Stability:** Once opened store tightly capped at 2 to 8°C, this product has a stability of 30 days once open unless vial expiration date comes first  **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.   * The product **MUST** be gently swirled and inverted several times to ensure homogeneity. * For optimal analyte stability 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. | | | |
| **Interferences** | **Alinity c and Architect c4000:**  **Hemolysis, Icterus & Lipemia (HIL) Index Values apply to serum/plasma only:**   |  |  |  | | --- | --- | --- | | **H** | **I** | **L** | | **-** | **-** | **4** |   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”  Interference studies were conducted by Abbott Diagnostics Division using CLSI protocol NCCLS  EP7-P14 and EP7-A2.15, and effects were assessed by Dose Response and Paired Difference methods at the medical decision levels of the analyte. Interference is less than 10% at sodium concentration levels of approximately 120-140 mmol/L:   * Hemoglobin: up to 2000 mg/dL * Bilirubin: up to 60 mg/dL * Lipemia (Intralipid®): up to 2000 mg/dL * Benzalkonium Chloride up to 10 mg/dL   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.  Do not dilute ICT tests for any reason. | | | |
|  | **Alinity c and Architect c4000:** | | | |
| **Reference Intervals** | |  |  | | --- | --- | | Age | Sodium (mEq/L = mmol/L) | | Premature newborns, first 48 hours of life | 128 - 148 mEq/L | | 0 - 28 days | 133 - 146 mEq/L | | 28 days - 364 days | 139 - 146 mEq/L | | 1 – 17 years | 138 - 145 mEq/L | | Adult | 136 - 145 mEq/L | | No reference range for random urines. 24 hour urine sodium collection: 40-220 mEq/L | | | | | | |
| **Critical Values** | < 124 or > 156 mEq/L or mmol/L. (plasma/serum)  Call result and document according to Critical Results Policies | | | |
| **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 sodium 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. | | | |
| **Dilutions** | Do not dilute. | | | |
| **Result Reporting** | **Alinity c and Architect c4000:**   * Results between 124 – 156 mEq/L without error messages are released * Results below 124 mEq/L and above 156 mEq/L must be called and documented according to critical value policies. * Results below 100 mEq/L: without error message are reported as < 100 mEq/L instead of the numerical value. * Results > 200 mEq/L without error messages are reported as > 200 mEq/L rather than the numerical value. * Urine values between 20 mEq/L and 300 without error messages are released. <20 and >300 mEq/L are reported as such. | | | |
| **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 ICT Sample Diluent (ICTD5) Package Insert, Abbott Laboratories Diagnostics Division, Abbott Park, IL 60064, May 2016. 3. Alinity ICT Sample Diluent (ICTD5) Package Insert, Abbott Laboratories Diagnostics Division, Abbott Park, IL 60064, January 2018. 4. Alinity ICT Serum Calibrator Package Insert, Abbott Laboratories Diagnostics Division, Abbott Park, IL 60064, January 2018. 5. Architect ICT Serum Calibrator Package Insert, Abbott Laboratories Diagnostics Division, Abbott Park, IL 60064, November 2012. 6. Bio-Rad Liquichek Multiqual Unassayed Chemistry Control Product Insert, Bio-Rad Laboratories, Irvine, CA 92618 7. Bio-Rad Liquichek Urine Chemistry Control Product Insert, Bio-Rad Laboratories, Irvine, CA 92618 | | | |
| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | Erin Bartos | 10/15/2019 | New Procedure for Abbott analyzers |
|  | Elauteria Earnhardt | April 23, 2020 | Added St Paul Alinity c as an analyzer |
| 2 | Erin Bartos | 10/28/2020 | Added Alinity ci, urine sodium, new controls, HIL box. |
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