| **Phosphorus** |
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| **Purpose** | This procedure provides instructions for PHOSPHORUS ON ABBOTT INSTRUMENTATION. The phosphorus method is an *in vitro* diagnostic test for the quantitative measurement of phosphorus 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** | Inorganic phosphate reacts with ammonium molybdate to form a heteropolyacid complex. The use of a surfactant eliminates the need to prepare a protein-free filtrate. The absorbance at 340 nm is directly proportional to the inorganic phosphorus level in the sample. Sample blanks must be run to correct for any non-specific absorbance in the sample.Methodology: Phosphomolybdate |
| **Clinical Significance** | The majority of the body phosphorus (80% to 85%) is present in the bones as hydroxyapatite. The remainder of the phosphate is present as inorganic phosphorus and phosphate esters. Calcium and phosphorus in serum usually exhibit a reciprocal relationship. Increased serum phosphorus may occur in hypervitaminosis D, hypoparathyroidism, and renal failure. Reduced serum phosphorus levels are seen in rickets (Vitamin D deficiency), hyperparathyroidism, and Fanconi’s syndrome. |
| **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** | **PO4**: Phosphorus in serum or plasma**UPO4**: Phosphorus in urine (MACC only) |
| **Specimen** | Sample: Plasma (lithium heparin with or without gel) preferred. Sodium heparin plasma or serum (with or without gel) are also acceptable. Refer to specimen collection procedures.Urine: sterile container; centrifuge if cloudy. **Minimum sample volume:** 200 µL preferred, 150 µL minimum**Stability when separated from cells/gel:** RT / 1 day, 2-8 °C / 4 days, < -20°C / 1 year**Rejection criteria:** Unlabeled tube, sample type other than serum or heparinized plasma. See Interferences section on handling of 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 24 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 – 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 Phosphorus ReagentCHC# 32629 | 08P40-20 | **Store at:** 2 – 8°C**Unopened:** Manufacturer’s printed expiration date**On-board: 65 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 c Multiconstituent CalibratorCHC# 32633 | 08P60-01 | **Store at:** 2 – 8°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. |

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|  | **Architect c4000:**

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| ***Product Description*** | ***Product Code*** | ***Stability*** |
| Abbott Architect Phosphorus ReagentCHC# 32552 | 07D71-22 | **Store at:** 2 – 8°C**Unopened:** Manufacturer’s printed expiration date.**On-board:** 65 Days |
| Abbott Architect Multiconstituent CalibratorCHC# 32557 | 01E65-05 | **Store at:** 2 – 8°C**Unopened:** Manufacturer’s printed expiration date**Opened:** 7 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) page.**Alinity c** and **Architect c4000:**R1 and R2 Reagents: Contains sulfuric acid and polyethylene glycol octylphenyl ether. Causes severe skin burns and eye damage. May be corrosive to metals. Harmful to aquatic life. Harmful to aquatic life with long lasting effects. Recap and dispose of in Acid waste stream.Multiconstituent Calibrator 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: | 1. – 23.0 mg/dL blood

4.39 - 186.20 mg/dL (urine) |
| Reference Material: | Abbott Alinity Multiconstituent CalibratorAbbott Architect Multiconstituent Calibrator |
| Suggested Calibration Levels: |  See lot-specific assay set point documentation |
| Calibration Scheme: | 2 levels, 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. 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 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, 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 day 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.
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| **Interferences** | **Alinity c and Architect c4000:** **Hemolysis, Icterus & Lipemia (HIL) Index Values apply to serum only:**

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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” Hemolysis in serum or plasma can increase test results. Samples that contain visible hemolysis should not be used, whenever possible. Interference studies were conducted by Abbott Diagnostics Division based on guidance from NCCLS EP7-P 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:* Hemoglobin: up to 125 mg/dL
* Bilirubin: up to 60 mg/dL
* Triglycerides: up to 1000 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.  |
|  | **Alinity c and Architect c4000:**  |
| **Reference Intervals** |

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| Age | Phosphorus, blood |
| 0 – 14 days | 5.6 – 10.5 mg/dL |
| 15 - 364 days | 4.8 – 8.4 mg/dL |
| 1 – 4 years | 4.3 – 6.8 mg/dL |
| 5 - 12 years | 4.1 – 5.9 mg/dL |
| 13 - 15 years female | 3.2 – 5.5 mg/dL |
| 13 - 15 years male | 3.5 – 6.2 mg/dL |
| 16 – 18 years | 2.9 – 5.0 mg/dL |
| Adult | 2.3 – 4.7 mg/dL |
| Urine: Random Reference Ranges not established. Phosphorus in 24 Hour Urines: 500-1500 mg/24 hours |

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| **Critical Values** | < 2.0 or > 10.0 mg/dL (blood)Critical values must be called and documented according to the critical values policy. |
| **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 phosphorus 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.Hemolysis in serum or plasma can increase test results. Samples that contain visible hemolysis should not be used, whenever possible.  |
| **Dilutions** | Do not dilute blood samples.

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| **Alinity ci (MACC) only, for Urine:**  |
| Auto Dilution: | 1:10 |
| Maximum Manual Dilution: | none |
| Diluent: | - |
| 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 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 4.39 mg/dL, do not report the result. Rerun and/or investigate for other possible causes of error. |

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| **Result Reporting** | **Alinity c and Architect c4000, blood samples:** * Results between 1.0 – 23.0 mg/dL without error messages are released
* Results < 2.0 mg/dL and > 10.0 mg/dL must be called and documented according to the critical values policy.
* Results < 1.0 mg/dL are reported as < 1.0 mg/dL.
* Results > 23.0 mg/dL are reported as > 23.0 mg/dL.

**CAUTION**: Hemolysis in serum or plasma can increase test results. Samples that contain visible hemolysis should not be used, whenever possible. Otherwise, append sample with –HP comment.**Alinity c, MACC only, urine samples:*** Results between 4.39 – 186.20 mg/dL without error messages are released
* Results < 4.39 mg/dL are reported as < 4.39 mg/dL.
* Results > 186.20 mg/dL are diluted 1:10 with automated dilution and reported as the numerical value, unless it is greater than 1862.0; in which case, report as > 1862.0 mg/dL.
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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. Jacobs & DeMott Laboratory Test Handbook, Lexi-Comp, Inc., Hudson, OH, 5th Edition, 2001
2. Architect Phosphorus Package Insert, Abbott Laboratories Diagnostics Division, Abbott Park, IL 60064, January 2016.
3. Alinity Phosphorus Package Insert, Abbott Laboratories Diagnostics Division, Abbott Park, IL 60064, December 2017.
4. Alinity c Multiconstituent Calibrator Package Insert, Abbott Laboratories Diagnostics Division, Abbott Park, IL 60064, December 2017.
5. Architect Multiconstituent Calibrator Package Insert, Abbott Laboratories Diagnostics Division, Abbott Park, IL 60064, August 2017.
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
8. CALIPER pediatric reference range database. (2019). Retrieved October 3, 2019, from https://caliper.research.sickkids.ca/#/
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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 |
|  | Elauteria Earnhardt | April 23, 2020 | Added St Paul Alinity c as an analyzer |
|  | 2 | Erin Bartos | 10/28/2020 | Added Alinity ci, Urine Phos, changes AMRs, added new QC, ref range for urine |