Phosphorus, Serum, Plasma, or Urine

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Purpose

This procedure provides instructions for PHOSPHORUS on Abbott Instrumentation. The Alinity c PHOS2 assay is used for the quantification of Phosphorus in human serum, plasma, or urine on the Alinity c analyzer.

The Phosphorus2 assay is used for the quantitation of phosphorus in human serum, plasma, or urine on the Alinity c Systems. Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.[1]

Policy Statements

This procedure applies to all personnel responsible for operating the Abbott Alinity c at Children's Minnesota Laboratory.

Principle

Methodology: Phosphomolybdate

The Phosphorus2 assay is an automated clinical chemistry assay. Inorganic phosphate reacts with ammonium molybdate to form a heteropolyacid complex. The absorbance at 340 nm is directly proportional to the inorganic phosphorus level in the sample.[1]

Clinical Significance

Phosphorus is a major component of bone mineral, phospholipids in cell membranes, and nucleic acids. Phosphorus acts as a major pH buffer in serum and urine. Phosphorus is essential for normal muscle contractility, neurologic function, electrolyte transport, and oxygen carrying by hemoglobin (2,3 diphosphoglycerate). Serum phosphate is filtered at the glomerulus and is reabsorbed primarily in the proximal tubule. Parathyroid hormone (PTH) increases renal phosphate excretion by inhibiting the sodiumphosphate cotransporter in the proximal tubule, whereas vitamin D genhances intestinal phosphate absorption.

Hypophosphatemia may be caused by decreased intake, impaired intestinal absorption, redistribution into cells or bones, and renal losses (as in Fanconi syndrome). Clinical manifestation of severe hypophosphatemia include encephalopathy, dilated cardiomyopathy, generalized muscle weakness leading to respiratory failure, destruction of muscles (rhabdomyolysis), and hemolysis. Hemolysis of red blood cells may be seen with serum phosphorus levels < 0.5 mg/dL. Hyperphosphatemia is caused by excessive phosphate intake, increased intestinal absorption, redistribution from intracellular stores, or impaired renal excretion. Acute levels can increase the risk for precipitation of calcium phosphate in the kidney and soft tissues. In chronic hyperphosphatemia (renal insufficiency) with a phosphate level > 6.5 mg/dL, mortality is higher due to the increased risk for the development of coronary and other vascular calcification, leading to increased systolic blood pressure and left ventricular hypertrophy. A rapid increase in serum phosphorus can result in hypocalcemia, which can cause tetany, hypotension, seizures, and cardiac arrhythmias. A urine phosphorus-creatinine ratio and urine fractional excretion of phosphorus may provide useful information about therapies altering intestinal absorption or urine phosphorus handling.[1]

Materials

Product Description	*Product Code*	*Stability*
Phosphoru2 Reagent (1120 tests per box; each box contains 4 reagent sets of 280 tests). Each reagent set consists of an R1 and R2 component. Alinity c **R2:** Active ingredient: ammonium molybdate tetrahydrate 2.90 g/L. Preservative: ProClin 300. Abbott Diagnostics	**MFR#** 04U0320 **CHC#** 32629	**Store at:** 2-8 °C **Unopened:** Until Expiration **Opened:** Stable 28 days onboard the analyzer. Stable until expiration if returned to 2-8 °C storage with replacement caps tightly secured and in upright position.
Phosphorus2 Reagent (400 tests per box; each box contains 2 reagent sets of 200 tests). Each reagent set consists of an R1 and R2 component. Architect **R2:** Active ingredient: ammonium molybdate tetrahydrate 2.90 g/L. Preservative: ProClin 300. Abbott Diagnostics	**MFR#** 04T0720 **CHC#** 32552	**Store at:** 2-8 °C **Unopened:** Until Expiration **Opened:** Stable 28 days onboard the analyzer. Stable until expiration if returned to 2-8 °C storage with replacement caps tightly secured and in upright position.
Consolidated Chemistry Calibrator (ConCC) Each calibrator set consists of 6 lyophilized calibrator vials, and 6 empty barcode labeled vials. Abbott Diagnostics	**Alinity** **MFR#** 04V6201 **CHC#** 37653 **Architect** **MFR#** 04V1501 **CHC#** TBD	**Store at:** 2-8 °C **Unopened:** Until Expiration **Reconstituted:** Stable 7 days if returned to 2-8 °C storage with replacement caps tightly secured and in upright position.
Biorad MultiQual Controls Levels 1 and 3 Each box contains 12 5mL vials of control material. Biorad Laboratories	**Level 1 MFR#** 697 **Level 1 CHC#** 34574 **Level 3 MFR#** 699 **Level 3 CHC#** 34575	**Store at:** -20°C or colder **Unopened:** Until Expiration **Opened:** Stable 7 days at 2-8 °C storage with caps tightly secured.
Biorad Urine Chemistry Controls Level 1 and 2 Each box contains 6 4mL vials of control material.	**Level 1 MFR#** 397 **Level 1 CHC#** 29079 **Level 2 MFR#** 398	**Store at:** 2-8°C **Unopened:** Until Expiration

Biorad Laboratories	**Level 2 CHC#** 35362	**Opened:** Stable 30 days at 2-8 °C storage with caps tightly secured.

Special Safety Precautions

The following warnings and precautions apply to: R1 **DANGER** Contains sulfuric acid. H314 Causes severe skin burns and eye damage. H290 May be corrosive to metals. **Prevention** P234 Keep only in original container. P260 Do not breathe mist / vapors / spray. P264 Wash hands thoroughly after handling. P280 Wear protective gloves / protective clothing / eye protection. **Response** P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water / shower. P310 Immediately call a POISON CENTER or doctor / physician. P390 Absorb spillage to prevent material damage. **Disposal** P501 Dispose of contents / container in accordance with local regulations.

The following warnings and precautions apply to: R2 **WARNING** Contains methylisothiazolones. H317 May cause an allergic skin reaction. H402* Harmful to aquatic life. H412 Harmful to aquatic life with long lasting effects. **Prevention** P261 Avoid breathing mist / vapors / spray. P272 Contaminated work clothing should not be allowed out of the workplace. P273 Avoid release to the environment. P280 Wear protective gloves / protective clothing / eye protection. **Response** P302+P352 IF ON SKIN: Wash with plenty of water. P333+P313 If skin irritation or rash occurs: Get medical advice / attention. P362+P364 Take off contaminated clothing and wash it before reuse. **Disposal** P501 Dispose of contents / container in accordance with local regulations.[1]

Calibration material contains human-sourced and/or potentially infectious components.[3]

Sample

Sample: Plasma collected with lithium heparin with or without gel barrier is preferred. Alternatively, serum collected with or without gel barrier is also accepted. For random urine collections, collect in a clean glass or plastic container.

Stability: Serum or plasma: 24 hours at room temperature, 3 days at 2-8 C, or up to 30 days frozen at –20 C or colder. Urine: Test upon receipt in the lab. If acidified to pH less than 5, urine may be stored at room temperature for 4 days, 2-8 C for 7 days, or up to 1 month at –20 C or colder.

Test Code

LIS Test code: PO4 for Phosphorus in Serum or Plasma.
UPO4 for Phosphorus in Random Urine.

Analyzer

Primary Analyzer or Method: MACC or MALIC (Minneapolis), SALIC or ARCH4 (St. Paul). Urine phosphorus is only available on MACC.

Backup: Each analyzer may act as a backup for the other. For urine phosphorus, hold specimens unless downtime is expected to last >24 hours then send to MML.

Calibration

Calibration Information[3]

Reference Material	ConCC; 04V6201 or 04V1501
Calibration Frequency	Calibration is due every 14 days and with each new reagent lot.
Calibration Scheme	3-Point Calibration; 3 replicates per level. The PHOS2 assay utilizes the Linear data reduction method to generate a calibration and results.

Quality Control

Material: Biorad Multiqual, Levels 1 and 3. Biorad Urine Chemistry, Levels 1 and 2.
Frequency: Run 2 levels Multiqual, once per day on all analyzers. Run 2 levels Urine Chemistry on MACC once per day.
Acceptable Ranges: Acceptable ranges are set in Unity Real Time software.

Procedure

For a detailed description of how to run an assay, refer to the Alinity ci-series Operations Manual, Section 5.

- If using primary or aliquot tubes, refer to the Alinity ci-series Operations Manual, section 4 to ensure sufficient specimen is present.
- Minimum sample cup volume is calculated by the system and printed on the Order List report.
- To minimize the effect of evaporation, verify that adequate sample cup volume is present prior to running the test.
- Maximum number of replicates sampled from the same sample cup: 10
    - Sample volume for the first test: 3.6 uL + 50 uL for over-aspiration and dead volume
    - Sample volume for each additional test from the same sample cup: 3.6 uL
    - Urine samples require 16 uL + 50 uL for over-aspiration and dead volume

Dilutions

Urine samples with a Phosphorus value exceeding 186.2 mg/dL are flagged with the code ">186.2 mg/dL" and may be diluted with the Manual Dilution Protocol. Do not dilute serum or plasma samples.

Available Auto Dilutions:	None
Maximum Auto Dilution:	None
Maximum Manual Dilution:	Urine only 1:10
Diluent:	Normal Saline

Manual Dilution Instruction:	Urine only -- Add 50 uL patient sample to 450 uL normal saline in a labeled sample cup. Mix well and program manually for manual 1:10 dilution. Discard dilution after testing.

Calculations

Not applicable.

Interpretation and Resulting

Results will be reported to the first decimal (xx.x).

Serum:
Results between 0.5 and 25.3 mg/dL without error messages are released.
Results below 0.5 mg/dL without error messages are reported as <0.5 mg/dL.
Results greater than 25.3 mg/dL without error messages are reported as >25.3 mg/dL.

Urine:
Results between 2.4 and 186.2 mg/dL without error messages are released.
Results below 2.4 mg/dL without error messages are reported as <2.4 mg/dL.
Results greater than 186.2 mg/dL are diluted 1:10 by manual dilution and the reported value up to 1862 mg/dL is released.
Results greater than 1862 mg/dL without error messages are reported as >1862 mg/dL.

Reference Intervals

Critical Values:

Sample Type	*Critical Values*
Serum or Plasma	<2.0 or >10.0 mg/dL
Urine	None defined

Critical values must be called and documented according to the Critical Results or Critical Test Notification and Documentation policy.

Serum or Plasma Reference Ranges[2]

Age	*Reference Interval (mg/dL)*
0 to <15 days	5.6-10.0
15 days to <1 year	4.8-8.4
1 to <5years	4.3-6.8
5 to <13 years	4.1-5.9
13 to <16 years, female	3.2-5.5
13 to <16 years, male	3.5-6.2
16 to 18 years	2.9-5.0
Adult	2.3-4.7

Random Urine Reference Range: Not established.

Method Performance Specifications

Analytical Measuring Range: 0.5-25.3 mg/dL serum or plasma; 2.4-186.2 mg/dL urine.

AMR/Calibration Verification Frequency: Not Required, 3 point calibration every 14 days or less

AMR recommended verification product: Maine Standards GC1 or UC4
AMR proximity budget serum or plasma: 0.5 mg/dL (low) or 3.o mg/dL (high)
AMR proximity budget urine: 50% (low) or 20% (high)
AMR systematic error budget: 50%

Allowable Error: Serum or plasma 0.3 mg/dL or 10% (CAP). Urine 2.0 mg/dL or 25% (CAP).

Precision: Serum or plasma: 0.06 mg/dL SD or 4.0% CV, whichever is greater. Urine: 0.3 mg/dL SD or 4.6% CV, whichever is greater.

Limitations

HIL Indices Cutoff Values[1,4]				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"
Interpretation	H	I	L	
Quant (Index)	250	40	1500	
Semi Quant	3+	4+	4+	

Results should be used in conjunction with other data; e.g., symptoms, results of other tests, and clinical impressions.

Substances that demonstrated interference with the Phosphorus2 assay are listed in the SPECIFIC PERFORMANCE CHARACTERISTICS, Analytical Specificity, Interference section of the package insert.[1]

Potential interference has not been evaluated for substances other than those described in the SPECIFIC PERFORMANCE CHARACTERISTICS, Analytical Specificity, Interference section of the package insert.[1]

In very rare cases, gammopathy may cause unreliable results.[1]

Additional interference information can be found in reagent package insert, pages 4-6.[1]

References

1. Total Phosphorus2 for Alinity c Reagent Package Insert, Abbott Laboratories Diagnostic Division, Abbott Park, IL 60064, Revised January 2023
2. CALIPER Reference Interval Studies, accessed October 27 2020
3. ConCC for Alinity c Calibrator Package Insert, Abbott Laboratories Diagnostic Division, Abbott Park, IL 60064, Revised December 2020
4. Hemolysis, Icterus, and Lipemia/Turbidity Indices as Indicators of Interference in Clinical Laboratory Analysis. CLSI guideline C56-A, 1st Ed, Wayne, PA: CLSI, 2012
5. Total Phosphorus2 for Architect Reagent Package Insert, Abbott Laboratories Diagnostic Division, Abbott Park, IL 60064, Revised January 2023

Appendices

Not applicable.

Training Plan/Competency Assessment

CH 1.04.T1 Abbott Alinity Training
QP 2.30 Orientation and Training
QP 2.40 Competency Assessment

Historical Record

Version	Author	Effective Date	Summary
1	Matt Johnson	1/7/2026	Initial Version