DXC 600 (PHS) PHOSPHORUS

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☒ St. Francis Hospital Federal Way, WA ☒ St. Anthony Hospital Gig Harbor, WA ☐ Highline Medical Center Burien, WA ☐ PSC

PURPOSE

To provide instructions for the quantitative determination of phosphorus on the DXC 600.

PRINCIPLE

PHS reagent, in conjunction with SYNCHRON LX® System(s), UniCel® DxC 600/800 System(s) and SYNCHRON® Systems Multi Calibrator, is intended for the quantitative determination of inorganic phosphorus concentration in human serum, plasma or urine.

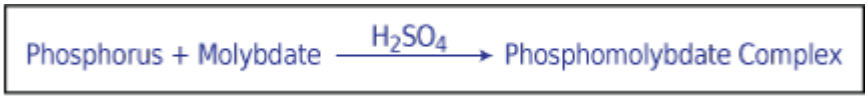
BACKGROUND

Clinical Significance

Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

Methodology

PHS reagent is used to measure the phosphorus concentration by a timed endpoint method. In the reaction, inorganic phosphorus reacts with ammonium molybdate in an acidic solution to form a colored phosphomolybdate complex.
The SYNCHRON® System(s) automatically proportions the appropriate sample and reagent volumes into a cuvette. The ratio used is one part sample to 67 parts reagent. The system monitors the change in absorbance at 340 nanometers. This change in absorbance is directly proportional to the concentration of phosphorus in the sample and is used by the system to calculate and express the phosphorus concentration.



RELATED DOCUMENTS

R-PO-CH-0810	Quality Control Program General Laboratory
R-PO-CH-0809	Quality Control Westgard Rules Statistics
R-PR-AD-0540	Specimen Rejection/Cancellation Protocol
M-F-CH-0820	Chemistry Controls
M-F-CH-0826	Chemistry Calibrators
M-F-CH-1940	DXC 600 (AMR) Analytical Measurement Range

SPECIMEN

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum or plasma is the preferred specimen. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood is not recommended for use as a sample.

Note: *Urine testing for phosphorus is performed only at SJMC.*

Specimen Storage and Stability

1. Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.

2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at +2°C to +8°C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.

Sample Type	Volume	Sample Stability
Plasma/Serum	0.5mL	• Separate serum from cells within 2 hours • Room Temp 8 hours • Refrigerated 48 hours • After 48 hrs, Freeze

Sample Preparation

Sample preparation is not required prior to analysis on SYNCHRON® System(s).

Criteria for Unacceptable Specimens

See Specimen Rejection/Cancellation Protocol

Sample Volume

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

REAGENTS

Contents

Each kit contains the following items:
Two PHS Reagent Cartridges (2 x 300 tests)

Volume per Test	
Sample Volume	4 µL
Total Reagent Volume	267 µL
Cartridge Volumes	A 243 µL B 24 µL C – –

Reactive Ingredients	
Ammonium Molybdate	2.5 mmol/L
pH	< 1.0

Also non-reactive chemicals necessary for optimal system performance.

Reagent Preparation

No preparation is required.

Acceptable Reagent Performance

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within your facility`s acceptance criteria.

Reagent Storage and Stability

PHS reagent, when stored unopened at room temperature, will remain stable until the expiration date indicated on the cartridge label. Once opened, the reagent is stable for 30 days at +2°C to +8°C. Do not use beyond the manufacturer's expiration date. DO NOT FREEZE.

CALIBRATION

Calibrator Required

SYNCHRON® Systems Multi Calibrator

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

If unopened, the SYNCHRON® Systems Multi Calibrator may be stored at -15°C to -20°C until the expiration date printed on the calibrator bottle. Opened calibrators that are resealed and stored at +2°C to +8°C are stable for 20 days. Do not use beyond the manufacturer's expiration date.

Calibration Information

1. The system must have a valid calibration curve in memory before control or patient samples can be run.

2. Under typical operating conditions the PHS reagent cartridge must be calibrated every 14 days and also with certain parts replacements or maintenance procedures, as defined in the SYNCHRON LX *Maintenance Manual and Instrument Log*, or the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual. This assay has within-lot calibration available. Refer to the SYNCHRON LX *Operations Manual*, or the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual for information on this feature.

3. For detailed calibration instructions, refer to the SYNCHRON LX *Operations Manual*, or the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

4. The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will be printed with error codes and the system will alert the operator of the failure. For information on error codes, refer to the SYNCHRON LX *Diagnostics and Troubleshooting Manual*, or the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

TRACEABILITY

For Traceability information refer to the Calibrator instructions for use.

QUALITY CONTROL

See Related Documents J-F-CH0820 DXC 800 Controls & M-F-CH0820 Chemistry Controls

STEPS

1. If necessary, load the reagent onto the system.

2. After reagent load is completed, calibration may be required.

3. Program controls for analysis.

4. After loading controls onto the system, follow the protocols for system operation. To load samples manually refer to the FHS DXC Series Manual Sample Programming procedure. For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

CALCULATIONS

The system performs all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

ANTICOAGULANT TEST RESULTS

If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of at least 40 healthy volunteers:

Anticoagulant	Level Tested for In Vitro Interference
Lithium Heparin	14 Units/mL
Sodium Heparin	14 Units/mL

PERFORMANCE CHARACTERISTICS

Reference Range

Sample Type	Male		Female		Critical Low	Critical High
	Age	Range	Age	Range		
Serum/Plasma	0-10 days	4.2 – 9.6 mg/dL	0-10 days	4.2 – 9.6 mg/dL	< 1.0 mg/dL	> 15.0 mg/dL
Serum/Plasma	10 days-2 years	4.2 – 7.2 mg/dL	10 days-2 years	4.2 – 7.2 mg/dL		
Serum/Plasma	2-12 years	4.2 – 5.9 mg/dL	2-12 years	4.2 – 5.9 mg/dL		
Serum/Plasma	12-60 years	2.3 – 4.8 mg/dL	12-60 years	2.3 – 4.8 mg/dL		
Serum/Plasma	>60 years	2.1 – 3.9 mg/dL	>60 years	2.6 – 4.4 mg/dL		

For Critical Value reporting protocol, refer to FHS Critical Policy

Analytic Range

The SYNCHRON® System(s) method for the determination of this analyte provides the following analytical range:

Sample Type	Conventional Units
Serum or Plasma	1.0 – 12.0 mg/dL

Samples with concentrations exceeding the high end of the analytical range should be diluted with saline and reanalyzed. The appropriate dilution factor should be applied to the reported result.

Reporting results outside of analytical range

Lower limit of range: serum / plasma	1.0 mg/dL	Result below 1.0, report as <1.0mg/dL
Upper limit of range: serum / plasma	12.0 mg/dL	Results >12.0 should be diluted with 0.9% saline, reanalyzed and dilution factor applied. The maximum allowable dilution is X2. Results >24.0 are reported as >24.0 mg/dL.

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for the PHS determination is 1.0 mg/dL (0.3 mmol/L) for serum or plasma.

LIMITATIONS

None identified.

Interferences

1. The following substances were tested for interference with this methodology:

Substance	Source	Level Tested	Observed Effect
Bilirubin	Porcine	7.5 mg/dL INDEX of 5	NSI
Hemoglobin	RBC Hemolysate	125 mg/dL INDEX of 4	NSI
		375 mg/dL	+0.5 mg/dL

Substance	Source	Level Tested	Observed Effect
Lipemia	Human	500 mg/dL INDEX of 10	NSI
Cefotaxime	Cefotaxime sodium salt	50 mg/dL	NSI
Ascorbic Acid	L-Ascorbic Acid	20 mg/dL	NSI
Fluorescein	Fluorescein Disodium Salt	75 mg/dL	+0.7 mg/dL
Methotrexate	NA[c]	2 mmol/L	NSI
Nafcillin	NA	2.5 mg/dL	NSI
		3.75 mg/L	+ 0.7 mg/dL
Methylbenzethonium Chloride	NA	5 mg/dL	NSI
Rifampin	NA	10 mg/dL	NSI

2. Interference may occur with serum samples from patients diagnosed as having plasma cell dyscrasias and lymphoreticular malignancies associated with abnormal immunoglobulin synthesis, such as multiple myeloma, Waldenstöm`s macroglobulinemia, and heavy chain disease. Some of these samples may precipitate when mixed with reagent. Results for these samples may be suppressed. An accurate result may be obtained as follows.
   - Prepare a 12% aqueous solution of trichloroacetic acid (TCA).
   - Combine one part of the original patient sample with one part of the prepared TCA solution and mix well.
   - Centrifuge for 10 minutes at 1200 x g at room temperature.
   - Analyze the supernatant. Multiply the result by 2.

3. Phosphorus determinations made in plasma are frequently subject to nonspecific interferences.[9]

4. Refer to References (10,11,12,13,14) for other interferences caused by drugs, disease and preanalytical variables.

ADDITIONAL INFORMATION

For more detailed information on SYNCHRON LX Systems or UniCel DxC Systems, refer to the appropriate system manual.

REFERENCES

1. Fiske, C. H., Subbarow, Y., *J. Biol. Chem.*, 66:375 (1925).
2. Dryer, R. L., Routh, J. I., "Determination of Serum Inorganic Phosphorus", *Clin. Chem.*, 4:191 (1963).
3. Tietz, N. W., "Specimen Collection and Processing; Sources of Biological Variation", *Textbook of Clinical Chemistry*, 2nd Edition, W. B. Saunders, Philadelphia, PA (1994).
4. National Committee for Clinical Laboratory Standards, *Procedures for the Handling and Processing of Blood Specimens*, Approved Guideline, NCCLS publication H18-A, Villanova, PA (1990).
5. Tietz, N. W., *Clinical Guide to Laboratory Tests*, 3rd Edition, W. B. Saunders, Philadelphia, PA (1995).
6. National Committee for Clinical Laboratory Standards, *Routine Urinalysis and Collection, Transportation and Preservation of Urine Specimens*, Tentative Guideline, NCCLS publication GP16-T, Villanova, PA (1992).
7. CDC-NIH manual, *Biosafety in Microbiological and Biomedical Laboratories*, U.S. Government Printing Office, Washington, D.C. (1984).
8. National Committee for Clinical Laboratory Standards, *How to Define, Determine, and Utilize Reference Intervals in the Clinical Laboratory*, Approved Guideline, NCCLS publication C28-A, Villanova, PA (1994).

9. Tietz, N. W., ed., *Fundamentals of Clinical Chemistry*, 3rd Edition, W. B. Saunders, Philadelphia, PA (1987).
10. Henry, J. B., *Clinical Diagnosis and Management by Laboratory Methods*, 18th Edition, W. B. Saunders Company, Philadelphia, PA (1991).
11. Sonnenwirth, A. C., Jarett, L., *Gradwohl`s Clinical Laboratory Methods and Diagnosis*, C. V. Mosby, St. Louis, MO (1980).
12. Young, D. S., *Effects of Drugs on Clinical Laboratory Tests*, 3rd Edition, AACC Press, Washington, D.C. (1990).
13. Friedman, R. B., Young, D. S., *Effects of Disease on Clinical Laboratory Tests*, 2nd Edition, AACC Press, Washington, D.C. (1989).
14. Young, D. S., *Effects of Preanalytical Variables on Clinical Laboratory Tests*, AACC Press, Washington, D.C. (1993).
15. National Committee for Clinical Laboratory Standards, *Method Comparison and Bias Estimation Using Patient Samples*, Tentative Guideline, NCCLS publication EP9-T, Villanova, PA (1993).
16. National Committee for Clinical Laboratory Standards, *Precision Performance of Clinical Chemistry Devices*, 2nd Edition, Approved Guideline, Vol. 19, No. 2, NCCLS publication EP5-A, Villanova, PA (1999).

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