**CHEM.DIMENSION.ASSAY.29.0 PHOSPHORUS BY DIMENSION**

**INTENDED USE**

The PHOS method used on the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended for the quantitative determination of phosphorus in serum and plasma.

**PRINCIPLE**

Inorganic phosphate combines with molybdate in an acid solution to form a complex which is reduced by p-methylaminophenol sulfate (PMAPS) and bisulfite. The 340 nm absorbance of the reduced phosphomolybdate solution is proportional to the inorganic phosphorus concentration and is measured using a bichromatic endpoint technique.

**DOCUMENT OWNER**

Manager, St. Vincent Jennings Hospital Laboratory

**RELATED DOCUMENTS**

CHEM.DIMENSION.1.0 *Operation of the Siemens Dimension RxL MAX, Xpand and EXL Clinical Chemistry*

*Systems*

CHEM.DIMENSION.2.0 *Dimension Calibration Procedure*

**SPECIMEN**

A. Patient Preparation: None.

B. Sample Size:

 1. Primary tube: Compare the tube to the filling gauge supplied with the Dimension.

 2. SSC or Dimension sample cup: 3 µL plus 50 µL dead space volume.

C. Specimen Type:

1. Serum: SST® and Corvac® collection tubes do not affect the PHOS method.

2. Plasma: Lithium heparin is the preferred anticoagulant.

D. Specimen Preparation:

1. Complete clot formation should be allowed to take place before centrifugation to obtain

serum samples.

2. Serum or plasma samples should be separated from the red cells within 1 hour of collection.

E. Storage and Stability for Separated Specimens:

 1. 8 hours at room temperature

 2. 2 days at 2 – 8⁰ C

 3. For longer storage, specimens may be frozen at -20⁰ C or colder.

**REAGENTS**

A. PHOS Flex® reagent cartridge, Cat. No. DF61A

1. Preparation: All reagents are liquid and ready to use.

2. Storage and Stability:

a. Unopened reagent cartridges are stable until the date given on the packaging

when stored at 2 – 8 ⁰C.

 b. On board stability:

1) Sealed cartridge wells are stable for 30 days.

2) Open well stability is 3 days for wells 1 – 6 and 30 days for wells 7 – 8.

**EQUIPMENT**

Siemens Dimension® RxL MAX®, Xpand® or EXL™Clinical Chemistry System

**CALIBRATION**

A. Calibration Material: CHEM II Calibrator, Cat. No. DC20

 1. Three levels: typical calibrator levels are 2.0, 5.0, and 8.0 mg/dL; see the package

insert for exact values for the lot in use.

 2. See the package insert for preparation, storage and stability.

B. Calibration Frequency:

 1. For each new lot of Flex® reagent cartridges.

 2. Every 3 months for any one lot of reagent cartridges.

 3. After major maintenance or service if indicated by quality control results.

 4. When indicated by unacceptable QC data.

C. Procedure: See CHEM.DIMENSION.2.0 *Dimension Calibration Procedure*

**QUALITY CONTROL**

A minimum of two levels of controls spanning the medical decision range are to be run once every 24 hours of assay use. See QC procedure, HBL.GEN.7.0 for specific details.

**PROCEDURE**

Sampling, reagent delivery, mixing and processing are automatically performed by the Dimension® System. For details of this processing, refer to the Dimension® Operator’s Guide.

**RESULTS**

A. The instrument automatically calculates and prints the concentration of phosphorus in mg/dL using the calculation scheme outlined in your Dimension® Operator’s Guide.

B. Results of the test should always be interpreted in conjunction with the patient’s medical history, clinical presentation and other findings.

**REPORTING RESULTS**

1. Expected values (mg/dl):

0 Days 3.1 – 7.5

29 Days 3.1 – 6.6

3 M 3.1 – 6.6

13 M 3.1 – 6.2

2 Y 3.1 – 5.9

13 Y 3.1 – 5.3

16 Y 3.1 – 5.1

19 Y 2.5 – 4.8

B. Critical values:

1. Phosphorus results less than 1.2 mg/dl or greater than 8.9 mg/dl are considered critical.

2. Per MACL Policy QA.REPORT.1.0 *Critical Values--Reporting of Significant Results*, all

 critical values must be called and documented.

C. Sunquest Computer Entry

1. Manual Entry

Function: MEM

Worksheet: Site specific

Test Code: PHOS

1. Online Entry

Function: OEM

Device: Site specific

Test Code: PHOS

D. QLS Computer Entry

1. Enter: 3, 3, 1
2. Worksheet: Enter worksheet from QLS label.
3. Accession number: Enter JI number.

E. If the HIS or LIS system is down, see the appropriate Laboratory Computer Downtime Policy.

**PROCEDURE NOTES**

A. Expected Turnaround Time (TAT): Nursing units are to be notified if the turnaround time is unable to be met per current MACL network turnaround time standards.

B. Backup method: When testing cannot be performed, the testing site’s backup policy should be followed.

**LIMITATIONS**

A. AMR: 0.5 – 9.0 mg/dL

1. Patient samples with PHOS levels that exceed 8.0 mg/dL will autodilute. If a valid result cannot be obtained a manual dilution should be made.

2. If a manual dilution is required, the specimen should be handled as follows:

a. Make an appropriate dilution with reagent grade water to obtain results within the assay range.

b. Enter the dilution factor into the instrument when programming the sample.

c. Reassay. The resulting readout will be corrected for the dilution.

3. Specimens with PHOS levels greater than 12.0 mg/dL should be reported as >12.0 mg/dL.

B. Interfering Substances:

1. The PHOS method was evaluated for interference from hemolysis, icterus and lipemia according to CLSI/NACCLS EP7-P. Bias exceeding 10% is considered “interference”.

a. Hemoglobin (hemolysate):

1) Hemoglobin at 50 mg/dL did **not** interfere with a PHOS result of 1.1 mg/dL.

2) Hemoglobin at 200 mg/dL increases a PHOS result of 1.1 mg/dL by 27%.

3) Hemolyzed samples may give spuriously elevated phosphorus results. Bias from hemolysis may result from inorganic phosphates produced by the action of phosphatases on organic phosphates, both of which are relased from red blood cells upon hemolysis.

b. Bilirubin (unconjugated):

1) Bilirubin at 5 mg/dL did **not** interfere with a PHOS result of 1.0 mg/dL.

2) Bilirubin at 20 mg/dl decreases a PHOS result of 1.0 mg/dl by 21%.

c. Lipemia (Intralipid):

1) Lipemia at 200 mg/dL did **not** interfere with a PHOS result of 1.1 mg/dL.

2) Lipemia at 600 mg/dL decreases a PHOS result of 1.0 mg/dl by 16%.

2. Other substances: The PHOS package insert contains a lengthy list of common drugs and other substances that do not interfere.

**CLINICAL SIGNIFICANCE**

Phosphorus, as phosphate, is distributed throughout the body. Causes of high serum phosphorus include dehydration, hypoparathyroidism, hypervitaminosis, metastases to bone, sarcoidosis, pulmonary embolism, renal failure, and diabetes mellitus with ketosis. Low serum phosphorus is found in primary hyperpapathyroidism and other causes of serum calcium elevation, sepsis, vitamin D deficiency and vomiting.

**REFERENCES**

A. Siemens Dimension® Clinical Chemistry System PHOS Flex® reagent cartridge package insert #717061.001 – US , Siemens Healthcare Diagnostics, Inc., Newark, DE, 3/27/2008.

B. Anderson, S. C. & Cockayne, S. (1993). *Clinical Chemistry Concepts and Applications*. Philadelphia, PA: W. Saunders Company.