Clinical Chemistry

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REAGENT 2 x 29 mL

IVD CE 2797

HORIBA ABX SAS
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FRANCE

Yumizen C560 Phosphorus

- Yumizen C560

Diagnostic reagent for quantitative *in vitro* determination of Phosphorus in serum, plasma and urine by colorimetry.

Intended Use

Yumizen C560 Phosphorus reagent is intended for the quantitative *in vitro* diagnostic determination of phosphorus in human serum, plasma and urine based on a UV method using phosphomolybdate.
Clinical laboratories use.
Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.
Assessing the physiologic and pathologic variations of Phosphorus (inorganic) concentration in human serum and plasma is useful for screening or follow-up of these diseases.

Clinical Interest (1)

The phosphorus contained in the human body (80% at bone level) exists solely in the form of inorganic phosphate. The necessary level of phosphates is provided via nutrition. Phosphate plays an important role in the storage and distribution of the energy needed for cell metabolism. Mainly located in the extracellular liquids, the phosphate ions also have a buffering capacity.
An increase of seric phosphate ions can occur during hypervitaminosis D, hypoparathyroidism and renal insufficiency. A reduction of the serum phosphate rates is observed at the time of deficiency in vitamins D and during hyperparathyroidism.
Plasmatic concentration of mineral phosphorus depends upon diet and intestinal absorption, renal elimination, tubular re-absorption and bone metabolism. While inorganic phosphorus levels are most commonly performed on blood samples, timed urine phosphorus measurements also may be used to monitor phosphorus elimination by the kidneys.
All these phenomena are under the influence of regulatory hormones and calcium concentration (parathormone PTH, calcitonin, and vitamin D). As a consequence, the regulation of plasmatic phosphate is closely related to that of calcium. The variations from phosphataemia (PTH stimulating the kidneys to eliminate any phosphate and retain the calcium), which results from a malfunction of the mechanisms mentioned above, are often inverse to those of calcaemia.

Method (2)

UV method using phosphomolybdate.
Phosphate reacts in acid medium with ammonium molybdate to form a yellow colored phosphomolybdate complex:

Ammonium Molybdate+Sulphuric Acid $\xrightarrow{\text{Phosphorus}}$ Phosphomolybdate complex

The intensity of the coloration is proportional to the concentration of inorganic phosphorus in the sample.

Reagents

Yumizen C560 Phosphorus is ready-to-use.

Reagent:	
Sulphuric acid	210 mmol/L
Ammonium molybdate	650 µmol/L

Yumizen C560 Phosphorus should be used according to this notice. The manufacturer cannot guarantee its performance if used otherwise.

Handling

1. Remove the cap of the cassette.

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2. If present, remove foam by using a plastic pipette.
3. Place the reagent R1 in the inner ring of the refrigerated reagent compartment.

Calibrator

For calibration, use:
ABX Pentra Multical (A11A01652) (not included)
10 x 3 mL (lyophilisate)

Control

For internal quality control, use:

- **ABX Pentra N MultiControl** (1300054414) (not included)
  10 x 5 mL (lyophilisate)
- **ABX Pentra P MultiControl** (1300054415) (not included)
  10 x 5 mL (lyophilisate)
- **Yumizen C Urine Level 1 Control** (1300023946) (not included)
  6 x 5 mL
- **Yumizen C Urine Level 2 Control** (1300023947) (not included)
  6 x 5 mL

Each control should be assayed daily and/or after a calibration.
The frequency of controls and the confidence intervals should correspond to laboratory guidelines and country-specific directives. You should follow federal, state and local guidelines for testing quality control materials. The results must be within the range of the defined confidence limits. Each laboratory should establish a procedure to follow if the results exceed these confidence limits.

Materials Required but not Provided

- Automated clinical chemistry analyzer: Yumizen C560
- Calibrator: **ABX Pentra Multical** (A11A01652)
- Controls:
  ABX Pentra N MultiControl (1300054414)
  ABX Pentra P MultiControl (1300054415)
  Yumizen C Urine Level 1 Control (1300023946)
  Yumizen C Urine Level 2 Control (1300023947)
- Standard laboratory equipment.

Specimen

This device intended testing population is general population.

Specimen types

- Non-haemolysed serum.
- Plasma in lithium heparin.
- Fresh centrifuged urine.
  24h urines have to be collected with HCl 6N.

Anticoagulants other than those listed have not been tested by HORIBA and are therefore not recommended for use with this assay.

Stability

Serum, plasma (3)

- At 2-8°C: 1 week

Urine (4, 5)

- at 20-25°C: 2 days if pH < 5.0

Reference Range

Each laboratory should establish its own reference ranges. The values given here are used as guidelines only.

Serum, plasma (1)	27 - 45 mg/L 2.7 - 4.5 mg/dL 0.87 - 1.45 mmol/L
Urine (6)	Adults: 12.9 - 42.0 mmol/24h (0.4 -1.3 g/24h)

Clinical sensitivity and specificity, positive predictive value and negative predictive value are not commonly reported for this analyte. This is largely attributed to the fact that this analyte is not sole indicator for the intended purpose and patient treatment decision making. To arrive at a diagnosis and a course of treatment, results from others routine clinical chemistry tests should be used in conjunction with other diagnostic information and the attending health-care professional's evaluation of the patient's condition.

Storage and Stability

Stability before opening:

Stable up to the expiry date on the label if stored at 2-8°C.

Stability after opening:

Refer to the paragraph "Performance on Yumizen C560".

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Waste Management

Please refer to local legal requirements.

General Precautions

- This reagent is for professional *in vitro* diagnostic use only.
  For laboratory use.
- For prescription use only.
- This reagent is classified as hazardous in compliance with regulation (EC) N°.1272/2008.
- **Warning**
  H290: May be corrosive to metals.
  H315: Causes skin irritation.
  H319: Cause serious eye irritation.
  P280: Wear protective gloves/protective clothing/eye protection/face protection.
  P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
  P332 + P313: If skin irritation occurs: Get medical advice/attention.
  P337 + P313: If eye irritation persists: Get medical advice/attention.
  P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  P390: Absorb spillage to prevent material damage.
  P406: Store in corrosive resistant container with a resistant inner liner.
- The reagent cassettes are disposable and should be disposed of in accordance with the local legal requirements.
- Please refer to the SDS associated with the reagent.
- Do not use the product if there is visible evidence of biological, chemical or physical deterioration.
- Do not use the product if the recommended storage conditions, including temperature, are not followed.
- User must be trained by a HORIBA representative before attempting to operate the device.
- It is the user's responsibility to verify that this document is applicable to the reagent used.
- For technical assistance, you can call +33 (0)4 67 14 15 16.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the country in which the user and/or the patient is established.

Performance on Yumizen C560

Serum, plasma

The performance data listed below have been obtained on the Yumizen C560 analyzer.

Number of tests: approximately 2 x 127 tests

On Board Reagent Stability

Once opened, the reagent cassette placed in the refrigerated Yumizen C560 compartment is stable for 50 days.

Sample volume: 2 µL/test

Lowest Detectable Level

The lowest detectable level represents the lowest measurable level of analyte that can be distinguished from zero. It is calculated as the absolute mean plus three standard deviations of 20 replicates of an analyte free sample. The lowest detectable level is estimated at 0.01 mmol/L (0.03 mg/dL).

Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A2 protocol (7) and equals 0.10 mmol/L (0.31 mg/dL).

Accuracy and Precision

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (8) with samples tested 20 times:

- 2 controls
- 3 specimens (low / medium / high levels)

	Mean value mmol/L	Mean value mg/dL	CV %
Control specimen 1	1.38	4.28	0.4
Control specimen 2	2.81	8.70	0.4
Specimen 1	0.50	1.54	0.7
Specimen 2	1.52	4.71	0.9
Specimen 3	2.90	9.00	0.6

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP05-A3 protocol (9) with samples tested in duplicate for 20 days (2 series per day):

- 2 controls
- 3 specimens (low / medium / high levels)

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	Mean value mmol/L	Mean value mg/dL	CV %
Control specimen 1	1.38	4.28	1.7
Control specimen 2	2.80	8.68	1.5
Specimen 1	0.48	1.49	2.0
Specimen 2	1.56	4.84	1.7
Specimen 3	2.94	9.11	1.8

Measuring Range

The assay confirmed a measuring range from 0.10 mmol/L (0.31 mg/dL) to 8.10 mmol/L (25.11 mg/dL).
The measuring range is extended up to 32.40 mmol/L (100.44 mg/dL) with the automatic post-dilution.
The reagent linearity has been assessed up to 8.10 mmol/L (25.11 mg/dL) according to the recommendations found in the CLSI (NCCLS), EP06-Ed2 protocol (10).

Correlation

Patient samples: Serum
Number of patient samples: 100
Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (11).
Values ranged from 0.14 mmol/L (0.43 mg/dL) to 8.05 mmol/L (24.96 mg/dL).
The equation for the allometric line obtained using Passing-Bablok regression procedure (12) is:
Y = 0.9776 X - 0.003 (mmol/L)
Y = 0.9776 X - 0.009 (mg/dL)
with a correlation coefficient r^2 = 0.999.

Interferences

Haemoglobin: Do not use hemolysed samples.
Triglycerides: Do not use lipemic samples.
Total Bilirubin: No significant influence is observed up to 165.93 µmol/L (9.71 mg/dL).
Direct Bilirubin: No significant influence is observed up to 195.75 µmol/L (11.45 mg/dL).

Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (13, 14).

Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 35 days.
Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.

Conversion Factor

mmol/L x 31 = mg/L
mmol/L x 3.1 = mg/dL

Urine

The performance data listed below have been obtained on the Yumizen C560 analyzer.

Number of tests: approximately 2 x 127 tests

On Board Reagent Stability

Once opened, the reagent cassette placed in the refrigerated Yumizen C560 compartment is stable for 50 days.

Sample volume: 2 µL/test

Lowest Detectable Level

The lowest detectable level represents the lowest measurable level of analyte that can be distinguished from zero. It is calculated as the absolute mean plus three standard deviations of 20 replicates of an analyte free sample. The lowest detectable level is estimated at 0.10 mmol/L (0.31 mg/dL).

Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A2 protocol (7) and equals 0.15 mmol/L (0.47 mg/dL).

Accuracy and Precision

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (8) with samples tested 20 times:

- 2 controls
- 3 specimens (low / medium / high levels)

	Mean value mmol/L	Mean value mg/dL	CV %
Control specimen 1	8.17	25.31	0.8
Control specimen 2	13.33	41.33	0.8
Specimen 1	1.58	4.88	2.3
Specimen 2	9.97	30.91	1.0
Specimen 3	19.46	60.33	1.0

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Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP05-A3 protocol (9) with samples tested in duplicate for 20 days (2 series per day):

- 2 controls
- 3 specimens (low / medium / high levels)

	Mean value mmol/L	Mean value mg/dL	CV %
Control specimen 1	8.21	25.45	1.8
Control specimen 2	13.54	41.97	1.9
Specimen 1	2.01	6.23	3.1
Specimen 2	8.99	27.87	4.3
Specimen 3	19.32	59.89	1.9

Measuring Range

The assay confirmed a measuring range from 0.15 mmol/L (0.47 mg/dL) to 60.00 mmol/L (186.00 mg/dL).
The measuring range is extended up to 240 mmol/L (744 mg/dL) with the automatic post-dilution.
The reagent linearity has been assessed up to 60 mmol/L (186 mg/dL) according to the recommendations found in the CLSI (NCCLS), EP06-Ed2 protocol (10).

Correlation

Patient samples: urine
Number of patient samples: 100
Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (11).
Values ranged from 0.62 mmol/L (1.92 mg/dL) to 57.40 mmol/L (177.94 mg/dL).
The equation for the allometric line obtained using Passing-Bablok regression procedure (12) is:
Y = 0.9762 X – 0.188 (mmol/L)
Y = 0.9762 X – 0.583 (mg/dL)
with a correlation coefficient r^2 = 0.998.

Interferences

Haemoglobin: No significant influence is observed up to 579 µmol/L (1000 mg/dL).
Triglycerides: No significant influence is observed up to a triglyceride concentration of 6.15 mmol/L (538 mg/dL).
Direct Bilirubin: No significant influence is observed up to 711.90 µmol/L (41.65 mg/dL).

Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (13, 14).

Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 35 days.
Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.

Conversion Factor:

mmol/L x 31 = mg/L
mmol/L x 3.1 = mg/dL

Reference

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