PHOS2

cobas®

Phosphate (Inorganic) ver.2

Order information

REF		CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
03183793122	03183793500	Phosphate (Inorganic) ver.2 (250 tests)	System-ID 07 6614 3	**cobas c** 311, **cobas c** 501/502, COBAS INTEGRA 400 plus

Materials required (but not provided):

		cobas c 311, **cobas c** 501/502	COBAS INTEGRA 400 plus
10759350190	Calibrator f.a.s. (12 x 3 mL)	Code 401	System-ID 07 3718 6
12149435122	Precinorm U plus (10 x 3 mL)	Code 300	System-ID 07 7999 7
12149443122	Precipath U plus (10 x 3 mL)	Code 301	System-ID 07 8000 6
05117003190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 391	System-ID 07 7469 3
05947626190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 391	System-ID 07 7469 3
05117216190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 392	System-ID 07 7470 7
05947774190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 392	System-ID 07 7470 7
04489357190	Diluent NaCl 9 % (50 mL)	System-ID 07 6869 3	n.a.

English

Intended use

In vitro test for the quantitative determination of phosphorus in human serum, plasma and urine on **cobas c** and COBAS INTEGRA systems.

Summary

Phosphate measurements, performed with this assay, in human serum, plasma and urine are used as an aid in diagnosis and monitoring of phosphate imbalances such as hyper- or hypophosphatemia.

The large majority (85 %) of phosphate is contained in the skeleton combined with calcium as hydroxyapatite, about 15 % is contained in soft tissue and only < 0.1 % in the extracellular fluid. Phosphate homeostasis is a complex process involving the kidneys, intestine, and skeleton. Phosphate occurs in blood in the form of inorganic phosphate and in organically bound phosphoric acid. The small amount of extracellular organic phosphate is found almost exclusively in the form of phospholipids.[1]

The ratio of phosphate to calcium in the blood is approximately 6 : 10.[1] An increase in the level of phosphate causes a decrease in the calcium level. The mechanism is influenced by interactions between parathormone and vitamin D. Hyperphosphatemia originates from excessive phosphate intake or renal reabsorption, reduced phosphate excretion or transcellular shifting.[2] Clinical conditions such as hypoparathyroidism, vitamin D intoxication and most commonly, renal failure with decreased glomerular phosphate filtration (like in chronic kidney disease, CKD), give rise to hyperphosphatemia.[3,4,5] Hypophosphatemia is the result of inadequate phosphorus intake, reduced intestinal absorption, excessive urinary excretion, or redistribution of phosphate to the intracellular compartments.[2,6] Clinical conditions such as rickets, hyperparathyroidism and Fanconi's syndrome are associated with hypophosphatemia.[7,8,9]

The method presented here for the determination of inorganic phosphate is based on the reaction of phosphate with ammonium molybdate to form ammonium phosphomolybdate without reduction. The addition of an accelerator gives rise to a more rapid rate of reaction and the application of sample blanking yields more precise results.

Test principle[10]

Molybdate UV.

Inorganic phosphate forms an ammonium phosphomolybdate complex having the formula $(NH_4)_3[PO_4(MoO_3)_{12}]$ with ammonium molybdate in the presence of sulfuric acid.

$$\text{Phosphate} + \text{ammonium molybdate} \xrightarrow{H_2SO_4} \text{ammonium phosphomolybdate}$$

The concentration of phosphomolybdate formed is directly proportional to the inorganic phosphate concentration and is measured photometrically.

Precautions and warnings

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:
Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Warning

H290 May be corrosive to metals.

Prevention:

P234 Keep only in original packaging.

Response:

P390 Absorb spillage to prevent material damage.

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590

Reagent handling

Ready for use

Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.
Serum
Plasma: Li-heparin and K_2-EDTA plasma

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Urine

Collect in detergent-free containers. Acidify with hydrochloric acid after collection (pH < 3).[11,12]

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Stability in serum/plasma:[13]	24 hours at 15-25 °C
	4 days at 2-8 °C
	1 year at (-15)-(-25) °C

Freeze only once.

Stability in urine:[11,12]	6 months at 2-8 °C (when acidified)
24-hour urine:	Store cooled during collection.

Centrifuge samples containing precipitates before performing the assay.

See the limitations and interferences section for details about possible sample interferences.

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

- See "Order information" section
- General laboratory equipment

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator's manual for analyzer-specific assay instructions.

The performance of applications not validated by Roche is not warranted and must be defined by the user.

Calculation

The systems automatically calculate the analyte concentration of each sample.

Conversion factors:	mmol/L x 3.10 = mg/dL
	mmol/L x 31 = mg/L
	mg/L x 0.0323 = mmol/L

Expected values

Serum/plasma

Adults:[14]

0.81-1.45 mmol/L (2.5-4.5 mg/dL)

Children:[15]

Age	*Male*	*Female*
	mmol/L (mg/dL)	*mmol/L (mg/dL)*
1–30 d	1.25–2.25 (3.9–6.9)	1.40–2.50 (4.3–7.7)
1–12 m	1.15–2.15 (3.5–6.6)	1.20–2.10 (3.7–6.5)
1–3 y	1.00–1.95 (3.1–6.0)	1.10–1.95 (3.4–6.0)
4–6 y	1.05–1.80 (3.3–5.6)	1.05–1.80 (3.2–5.5)
7–9 y	0.95–1.75 (3.0–5.4)	1.00–1.80 (3.1–5.5)
10–12 y	1.05–1.85 (3.2–5.7)	1.05–1.70 (3.3–5.3)
13–15 y	0.95–1.65 (2.9–5.1)	0.90–1.55 (2.8–4.8)
16–18 y	0.85–1.60 (2.7–4.9)	0.80–1.55 (2.5–4.8)

Urine

1st morning urine[16]	13-44 mmol/L (40-136 mg/dL)
24-hour urine[11]	13-42 mmol/d (0.4-1.3 g/d)

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

cobas c systems

System information

For **cobas c** 311 analyzer:

PHOS2: ACN 714 (serum/plasma)

SPHO2: ACN 675 (STAT, reaction time: 7: serum/plasma)

PHO2U: ACN 716 (urine)

SPH2U: ACN 656 (STAT, reaction time: 7: urine)

For **cobas c** 501 analyzer:

PHOS2: ACN 714 (serum/plasma/urine)

SPHO2: ACN 675 (STAT, reaction time: 7: serum/plasma/urine)

For **cobas c** 502 analyzer:

PHOS2: ACN 8714 (serum/plasma)

SPHO2: ACN 8675 (STAT, reaction time: 7: serum/plasma)

PHO2U: ACN 8716 (urine)

SPH2U: ACN 8656 (STAT, reaction time: 7: urine)

Reagents - working solutions

R1 Sulfuric acid: 0.36 mol/L; detergent

R2 Ammonium molybdate: 3.5 mmol/L; sulfuric acid: 0.36 mol/L; sodium chloride: 150 mmol/L

R1 is in position B and R2 is in position C.

Storage and stability

Shelf life at 2-8 °C:	See expiration date on **cobas c** pack label.
On-board in use and refrigerated on the analyzer:	12 weeks

Application for serum and plasma

cobas c 311 **test definition**

Assay type	2-Point End	
Reaction time / Assay points	10 / 6-32 (STAT 7 / 6-32)	
Wavelength (sub/main)	700/340 nm	
Reaction direction	Increase	
Units	mmol/L (mg/dL, mg/L)	
Reagent pipetting		Diluent (H_2O)
R1	90 µL	28 µL
R2	38 µL	–

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	2.5 µL	–	–
Decreased	12.5 µL	15 µL	135 µL
Increased	2.5 µL	–	–

cobas c 501 **test definition**

Assay type	2-Point End	
Reaction time / Assay points	10 / 10-47 (STAT 7 / 10-47)	
Wavelength (sub/main)	700/340 nm	
Reaction direction	Increase	
Units	mmol/L (mg/dL, mg/L)	
Reagent pipetting		Diluent (H_2O)
R1	90 µL	28 µL
R2	38 µL	–

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	2.5 µL	–	–
Decreased	12.5 µL	15 µL	135 µL

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Increased	2.5 µL	–	–

cobas c 502 **test definition**

Assay type	2-Point End
Reaction time / Assay points	10 / 10-47 (STAT 7 / 10-47)
Wavelength (sub/main)	700/340 nm
Reaction direction	Increase
Units	mmol/L (mg/dL, mg/L)
Reagent pipetting	Diluent (H_2O)
R1	90 µL 28 µL
R2	38 µL –

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	2.5 µL	–	–
Decreased	12.5 µL	15 µL	135 µL
Increased	5 µL	–	–

Application for urine

cobas c 311 **test definition**

Assay type	2-Point End
Reaction time / Assay points	10 / 6-32 (STAT 7 / 6-32)
Wavelength (sub/main)	700/340 nm
Reaction direction	Increase
Units	mmol/L (mg/dL, mg/L)
Reagent pipetting	Diluent (H_2O)
R1	90 µL 28 µL
R2	38 µL –

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	2.5 µL	15 µL	150 µL
Decreased	2.5 µL	8 µL	168 µL
Increased	2.5 µL	15 µL	150 µL

cobas c 501 **test definition**

Assay type	2-Point End
Reaction time / Assay points	10 / 10-47 (STAT 7 / 10-47)
Wavelength (sub/main)	700/340 nm
Reaction direction	Increase
Units	mmol/L (mg/dL, mg/L)
Reagent pipetting	Diluent (H_2O)
R1	90 µL 28 µL
R2	38 µL –

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	2.5 µL	15 µL	150 µL
Decreased	2.5 µL	8 µL	168 µL
Increased	2.5 µL	15 µL	150 µL

cobas c 502 **test definition**

Assay type	2-Point End
Reaction time / Assay points	10 / 10-47 (STAT 7 / 10-47)
Wavelength (sub/main)	700/340 nm
Reaction direction	Increase
Units	mmol/L (mg/dL, mg/L)
Reagent pipetting	Diluent (H_2O)
R1	90 µL 28 µL
R2	38 µL –

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	2.5 µL	15 µL	150 µL
Decreased	2.5 µL	8 µL	168 µL
Increased	5 µL	15 µL	150 µL

Calibration

Calibrators	S1: H_2O S2: C.f.a.s.
Calibration mode	Linear
Calibration frequency	2-point calibration • after reagent lot change • as required following quality control procedures

Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

Traceability: This method has been standardized against NERL primary reference material.

Quality control

Serum/plasma

For quality control, use control materials as listed in the "Order information" section.

In addition, other suitable control material can be used.

Urine

Quantitative urine controls are recommended for routine quality control.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Limitations - interference[11]

Criterion: Recovery within ± 10 % of initial value at a phosphate concentration of 0.87 mmol/L (2.7 mg/dL).

Serum/plasma

Icterus:[17] No significant interference up to an I index of 40 for conjugated and 60 for unconjugated bilirubin (approximate conjugated bilirubin concentration: 684 µmol/L or 40 mg/dL and approximate unconjugated bilirubin concentration: 1026 µmol/L or 60 mg/dL).

Hemolysis:[17] No significant interference up to an H index of 300 (approximate hemoglobin concentration: 186 µmol/L or 300 mg/dL).

Note: This interference results from inorganic phosphates produced by the action of phosphatases on organic phosphates, both of which are released from the red cells upon hemolysis.

Lipemia (Intralipid):[17] No significant interference up to an L index of 1250. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Drugs: No interference was found at therapeutic concentrations using common drug panels.[18,19]

Exception: Phospholipids contained in liposomal drug formulations (eg AmBisome) may be hydrolyzed in the test due to the acidic reaction pH and thus lead to elevated phosphate results.[20]

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[21]

Urine

Drugs: No interference was found at therapeutic concentrations using common drug panels.[19]

Criterion: Recovery within ± 10 % of initial value at a phosphate concentration of 13 mmol/L (40.3 mg/dL).

Urea: No significant interference from urea up to a concentration of 1500 mmol/L (9009 mg/dL).

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

ACTION REQUIRED

Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on **cobas c** systems. The latest version of the carry-over evasion list can be found with the NaOHD-SMS-SmpCln1+2-SCCS Method Sheets. For further instructions refer to the operator's manual. **cobas c** 502 analyzer: All special wash programming necessary for avoiding carry-over is available via the **cobas** link, manual input is required in certain cases.

Where required, special wash/carry-over evasion programming must be implemented prior to reporting results with this test.

Limits and ranges

Measuring range

Serum/plasma

0.10-6.46 mmol/L (0.31-20.0 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:2 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 2.

Urine

1.1-92 mmol/L (3.4-285 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:2 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 2.

Lower limits of measurement

Lower detection limit of the test

Serum/plasma

0.10 mmol/L (0.31 mg/dL)

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 3 standard deviations above that of the lowest standard (standard 1 + 3 SD, repeatability, n = 21).

Urine

1.1 mmol/L (3.4 mg/dL)

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 3 standard deviations above that of the lowest standard (standard 1 + 3 SD, repeatability, n = 21).

Specific performance data

Representative performance data on the analyzers are given below. Results obtained in individual laboratories may differ.

Precision

Precision was determined using human samples and controls in an internal protocol.

Serum/plasma:

Repeatability (n = 21), intermediate precision (3 aliquots per run, 1 run per day, 21 days);

Urine:

Repeatability (n = 21), intermediate precision (3 aliquots per run, 1 run per day, 10 days).

The following results were obtained on the **cobas c** 501 analyzer:

Serum/plasma

Repeatability	*Mean*	*SD*	*CV*
	mmol/L (mg/dL)	*mmol/L (mg/dL)*	*%*
Precinorm U	1.24 (3.84)	0.01 (0.03)	0.7
Precipath U	2.05 (6.36)	0.01 (0.03)	0.6
Human serum 1	2.68 (8.31)	0.02 (0.06)	0.6
Human serum 2	1.56 (4.84)	0.01 (0.03)	0.7
Intermediate precision	*Mean*	*SD*	*CV*
	mmol/L (mg/dL)	*mmol/L (mg/dL)*	*%*
Precinorm U	1.23 (3.81)	0.02 (0.06)	1.4
Precipath U	2.04 (6.32)	0.02 (0.06)	1.2
Human serum 3	2.67 (8.28)	0.04 (0.12)	1.4
Human serum 4	1.55 (4.81)	0.02 (0.06)	1.4

Urine

Repeatability	*Mean*	*SD*	*CV*
	mmol/L (mg/dL)	*mmol/L (mg/dL)*	*%*
Control Level 1	10.2 (31.6)	0.1 (0.3)	1.4
Control Level 2	19.9 (61.7)	0.2 (0.6)	1.2
Human urine 1	40.9 (127)	0.4 (1)	1.0
Human urine 2	6.25 (19.4)	0.08 (0.2)	1.2
Intermediate precision	*Mean*	*SD*	*CV*
	mmol/L (mg/dL)	*mmol/L (mg/dL)*	*%*
Control Level 1	10.0 (31.0)	0.2 (0.6)	1.6
Control Level 2	19.6 (60.8)	0.3 (0.9)	1.7
Human urine 3	40.4 (125)	0.5 (2)	1.3
Human urine 4	6.23 (19.3)	0.12 (0.4)	2.0

The data obtained on **cobas c** 501 analyzer(s) are representative for **cobas c** 311 analyzer(s).

Method comparison

Inorganic phosphate values for human serum, plasma and urine samples obtained on a **cobas c** 501 analyzer (y) were compared with those determined using the corresponding reagent on a Roche/Hitachi 917 analyzer (x).

Serum/plasma

Sample size (n) = 150

Passing/Bablok[22]	Linear regression
y = 1.022x + 0.000 mmol/L	y = 1.023x - 0.002 mmol/L
τ = 0.978	r = 1.000

The sample concentrations were between 0.62 and 5.54 mmol/L (1.92 and 17.2 mg/dL).

Urine

Sample size (n) = 145

Passing/Bablok[22]	Linear regression
y = 0.976x - 0.053 mmol/L	y = 0.974x - 0.047 mmol/L
τ = 0.967	r = 0.999

The sample concentrations were between 1.61 and 91.5 mmol/L (4.99 and 284 mg/dL).

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The data obtained on **cobas c** 501 analyzer(s) are representative for **cobas c** 311 analyzer(s).

COBAS INTEGRA systems

System information

PHOS2: Test ID 0-614 (serum, plasma)
PHOU2: Test ID 0-514 (urine)

Reagents - working solutions

R1	Sulfuric acid 0.36 mol/L, detergent
SR	Ammonium molybdate 3.5 mmol/L, Sulfuric acid 0.36 mol/L, Sodium chloride 150 mmol/L

R1 is in position B and SR is in position C

Storage and stability

Shelf life at 2-8 °C	See expiration date on **cobas c** pack label
On-board in use at 10-15 °C	12 weeks

Application for serum, plasma, and urine

Test definition

Measuring mode	Absorbance
Abs. calculation mode	Endpoint
Reaction direction	Increase
Wavelength A/B	340/659 nm
Calc. first/last	33/63
Unit	mmol/L

Serum, plasma

Reaction mode	R1-S-SR

Urine

Reaction mode	D-R1-S-SR
Predilution factor	11

Pipetting parameters

Serum, plasma, and urine		Diluent (H_2O)
R1	90 µL	
Sample	2.5 µL	27.5 µL
SR	38 µL	
Total volume	158 µL	

Calibration

Serum, plasma, and urine

Calibrator	Calibrator f.a.s. Use deionized water as zero calibrator.
Calibration mode	Linear regression
Calibration replicate	Duplicate recommended
Calibration interval	Each lot and as required following quality control procedures

Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

Traceability: This method has been standardized against NERL primary reference material.
For USA: This method has been standardized against NIST traceable primary reference material.

Quality control

Quality control serum, plasma	PreciControl ClinChem Multi 1 Precinorm U plus PreciControl ClinChem Multi 2 Precipath U plus
Quality control urine	Quantitative urine controls are recommended for routine quality control.
Control interval	24 hours recommended
Control sequence	User defined
Control after calibration	Recommended

For quality control, use control materials as listed in the “Order information” section. In addition, other suitable control material can be used.

The control intervals and limits should be adapted to each laboratory’s individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Limitations - interference

Criterion: Recovery within ± 10 % of initial value.

Serum, plasma

Icterus:[17] No significant interference up to an I index of 51 (approximate conjugated bilirubin concentration: 872 µmol/L or 51 mg/dL). No significant interference with unconjugated bilirubin.

Hemolysis:[17] No significant interference up to an H index of 420 (approximate hemoglobin concentration: 261 µmol/L or 420 mg/dL).

Lipemia (Intralipid):[17] No significant interference up to an Intralipid level of 1000 mg/dL. There is poor correlation between turbidity and triglycerides concentration.

Drugs: No interference was found at therapeutic concentrations using common drug panels.[18,19] *Exception:* Phospholipids contained in liposomal drug formulations (e.g. AmBisome) may be hydrolyzed in the test due to the acidic reaction pH and thus lead to elevated phosphate results.[20]

In very rare cases, gammopathy, in particular type IgM (Waldenström’s macroglobulinemia), may cause unreliable results.[21]

Urine

Drugs: No interference was found at therapeutic concentrations using common drug panels.[19]

Criterion: Recovery within ± 10 % of initial value at a phosphate concentration of 13 mmol/L (40.3 mg/dL).

Urea: No significant interference from urea up to a concentration of 1500 mmol/L (9009 mg/dL).

For diagnostic purposes, the results should always be assessed in conjunction with the patient’s medical history, clinical examination and other findings.

ACTION REQUIRED

Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on COBAS INTEGRA analyzers. Refer to the CLEAN Method Sheet for further instructions and for the latest version of the Extra wash cycle list.
Where required, special wash/carry-over evasion programming must be implemented prior to reporting results with this test.

Limits and ranges

Measuring range

Serum/plasma

0.1-6.46 mmol/L (0.31-20 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:10 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 10.

Urine

1.1-92 mmol/L (3.41-285 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:5 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 5.

Lower limits of measurement

Serum/plasma

Lower detection limit of the test:

0.1 mmol/L (0.31 mg/dL)

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 3 standard deviations above that of the lowest standard (standard 1 + 3 SD, repeatability, n = 21).

Urine

Lower detection limit of the test:

1.1 mmol/L (3.41 mg/dL)

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 3 standard deviations above that of the lowest standard (standard 1 + 3 SD, repeatability, n = 21).

Specific performance data

Representative performance data on the analyzers are given below. Results obtained in individual laboratories may differ.

Precision

Precision was determined using human samples and controls in an internal protocol with repeatability (n = 21) and intermediate precision (1 aliquot per run, 1 run per day, 21 days). The following results were obtained on the COBAS INTEGRA 700 analyzer:

Serum and plasma

	Level 1	Level 2
Mean	1.17 mmol/L (3.63 mg/dL)	2.01 mmol/L (6.23 mg/dL)
CV repeatability	1.3 %	1.4 %
Mean	1.17 mmol/L (3.63 mg/dL)	2.00 mmol/L (6.20 mg/dL)
CV intermediate precision	2.5 %	2.4 %

Precision was determined using human samples and controls in an internal protocol with repeatability (n = 21) and intermediate precision (1 aliquot per run, 1 run per day, 10 days). The following results were obtained:

Urine

	Level 1	Level 2
Mean	13.9 mmol/L (43.1 mg/dL)	27.6 mmol/L (85.6 mg/dL)
CV repeatability	1.0 %	0.7 %
Mean	13.9 mmol/L (43.1 mg/dL)	27.7 mmol/L (85.9 mg/dL)
CV intermediate precision	1.7 %	1.1 %

The data obtained on COBAS INTEGRA 700 analyzer(s) are representative for COBAS INTEGRA 400 analyzer(s).

Method comparison

Inorganic phosphate values obtained on a COBAS INTEGRA 700 analyzer with the COBAS INTEGRA Phosphate (Inorganic) ver.2 reagent (y) were compared with those determined using the same reagent on a Roche/Hitachi 917 analyzer (x) and with the previous reagent (PHOS) on a COBAS INTEGRA 700 analyzer (x).

Serum and plasma

Roche/Hitachi 917 analyzer	Sample size (n) = 100
Passing/Bablok[22]	Linear regression
y = 1.043x + 0.022 mmol/L	y = 1.040x + 0.025 mmol/L
τ = 0.955	r = 1.000
SD (md 95) = 0.040	Sy.x = 0.018

The sample concentrations were between 0.572 to 5.69 mmol/L (1.77 to 17.7 mg/dL).

COBAS INTEGRA 700 analyzer	Sample size (n) = 96
Passing/Bablok[22]	Linear regression
y = 1.029x - 0.047 mmol/L	y = 1.040x - 0.067 mmol/L
τ = 0.942	r = 0.999
SD (md 95) = 0.077	Sy.x = 0.032

The sample concentrations were between 0.619 to 4.76 mmol/L (1.92 to 14.9 mg/dL).

Urine

Roche/Hitachi 917 analyzer	Sample size (n) = 86
Passing/Bablok[22]	Linear regression
y = 1.052x - 0.0235 mmol/L	y = 1.044x - 0.028 mmol/L
τ = 0.983	r = 1.000
SD (md 95) = 0.743	Sy.x = 0.349

The sample concentrations were between 6.08 to 89.4 mmol/L (18.9 to 277 mg/dL).

COBAS INTEGRA 700 analyzer	Sample size (n) = 68
Passing/Bablok[22]	Linear regression
y = 1.000x - 0.399 mmol/L	y = 1.002x - 0.405 mmol/L
τ = 0.989	r = 1.000
SD (md 95) = 0.396	Sy.x = 0.180

The sample concentrations were between 6.08 to 44.8 mmol/L (18.9 to 139 mg/dL).

The data obtained on COBAS INTEGRA 700 analyzer(s) are representative for COBAS INTEGRA 400 analyzer(s).

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A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see navifyportal.roche.com for definition of symbols used):

CONTENT	Contents of kit
→	Volume for reconstitution
GTIN	Global Trade Item Number
Rx only	For USA: Federal law restricts this device to sale by or on the order of a physician.

CE 0123

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