Calcium P FS*

Diagnostic reagent for quantitative in vitro determination of calcium in serum, plasma or urine on BioMajesty JCA-BM6010/C

Order Information

Cat. No. 1 1181 99 10 962
R1: 6 x 315 tests
R2: 6 x 315 tests

Method

Photometric endpoint determination with Phosphonazo III

Principle

At acidic pH calcium forms a purple-blue colored complex with phosphonazo III. In a second step calcium is bound to a chelating agent whereby the specific signal is eliminated. The resulting difference in absorbance is directly proportional to the calcium concentration in the sample. This guarantees a specific measurement of calcium.

Reagents

Components and Concentrations

R1:	Malonic acid buffer	pH 5.0	150 mmol/L
	Phosphonazo III		150 µmol/L
R2:	Malonic acid		150 mmol/L
	Chelating agent		< 150 mmol/L

Storage Instructions and Reagent Stability

Reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8 °C and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions

1. Reagent 1: Warning. H319 Causes serious eye irritation. H412 Harmful to aquatic life with long lasting effects. P273 Avoid release to the environment. P280 Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention. P501 Dispose of contents/container to hazardous or special waste collection point.
2. As calcium is an ubiquitous ion, special precaution must be taken against accidental contamination. Only use disposable materials.
3. Traces of chelating agent, such as EDTA can prevent the formation of the colored complex.
4. In very rare cases, samples of patients with gammopathy might give falsified results [5].
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
6. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Specimen

Serum, heparin plasma or urine
Do not use EDTA plasma.

Stability [1]:

in Serum/Plasma	7 days	at	20 – 25 °C
	3 weeks	at	4 – 8 °C
	8 months	at	–20 °C
in Urine	2 days	at	20 – 25 °C
	4 days	at	4 – 8 °C
	3 weeks	at	–20 °C

Add 10 mL of concentrated HCl to 24 h urine and heat the specimen to dissolve calcium oxalate.

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

For calibration, DiaSys TruCal U calibrator is recommended. This method has been standardized against the reference method Atomic Absorption Spectrometry (AAS). For internal quality control DiaSys TruLab N and P or TruLab Urine controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL
TruLab Urine Level 1	5 9170 99 10 062	20 x 5 mL
	5 9170 99 10 061	6 x 5 mL
TruLab Urine Level 2	5 9180 99 10 062	20 x 5 mL
	5 9180 99 10 061	6 x 5 mL

Performance Characteristics

Measuring range up to 25 mg/dL (6.2 mmol/L) calcium (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	0.1 mg/dL (0.025 mmol/L) calcium
On-board stability	6 weeks
Calibration stability	3 weeks

Interferences < 10% by
Ascorbate up to 30 mg/dL
Hemoglobin up to 700 mg/dL
Conjugated Bilirubin up to 60 mg/dL
Unconjugated Bilirubin up to 60 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL
Magnesium up to 8 mmol/L
Strontium salts in medicine may lead to strongly increased calcium values.
For further information on interfering substances refer to Young DS [4].

Precision (Serum/plasma)			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	5.91	10.5	13.2
Mean [mmol/L]	1.47	2.62	3.28
Coefficient of variation [%]	0.84	0.84	0.85
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	5.77	9.82	12.5
Mean [mmol/L]	1.44	2.45	3.13
Coefficient of variation [%]	1.58	1.13	0.97

Method comparison (Serum/plasma; n=100)	
Test x	Competitor Calcium
Test y	DiaSys Calcium P FS
Slope	1.00
Intercept	0.120 mg/dL (0.030 mmol/L)
Coefficient of correlation	0.9965

* fluid stable

BioMajesty

Precision (Urine)			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	2.62	7.36	10.9
Mean [mmol/L]	0.65	1.84	2.73
Coefficient of variation [%]	2.05	1.11	0.61
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	2.61	7.27	11.0
Mean [mmol/L]	0.65	1.81	2.74
Coefficient of variation [%]	2.66	1.24	0.82

Method comparison (Urine; n=93)	
Test x	Competitor Calcium
Test y	DiaSys Calcium P FS
Slope	1.03
Intercept	0.409 mg/dL (0.102 mmol/L)
Coefficient of correlation	0.997

** lowest measurable concentration which can be distinguished from zero mean + 3 SD (n=20) of an analyte free specimen

Conversion factor

Calcium [mg/dL] x 0.2495 = Calcium [mmol/L]

Calcium/U [mg/24 h] x 0.025 = Calcium/U [mmol/24 h]

Reference Range

Serum/Plasma [2]:

8.6 – 10.3 mg/dL (2.15 – 2.57 mmol/L)

Urine [2]**:**

Women	< 250 mg/24 h	(< 6.24 mmol/24 h)
Men	< 300 mg/24 h	(< 7.49 mmol/24 h)

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 20-1 and p. 50-1
2. Endres DB, Rude RK. Mineral and bone metabolism. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1395-1406.
3. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 231-241.
4. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
5. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

BioMajesty

Calcium P FS

Chemistry code 10 118

Application for serum, plasma and urine samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1.0
Sample vol (U)	1.0
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	CAP
Digits	2
M-wave L.	658
S-wave.L	805
Analy.mthd.	EPA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	1.0	1.0
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	22
M-DET.P.n	23
S-DET.P.p	17
S-DET.P.r	18
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Dec

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999