

## Calcium P FS\*

### Order Information

#### Cat. No.

1 1181 99 10 962

#### Kit size



1890 (R1: 6 x 315, R2: 6 x 315)

### Intended Use

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

### Summary

Calcium is the most abundant mineral in the body. Around 99% is found in bones, while the rest is distributed in various tissues and extracellular fluids, where it plays an essential role in numerous physiological processes: intracellular in muscle contraction and glycogen metabolism, extracellular in bone mineralization, in blood coagulation and in transmission of nerve impulses. In the human body, calcium exists in three forms: ionized calcium (the biologically active form), protein-bound calcium (primarily to albumin), and calcium complexed with small anions such as phosphate or citrate. Ionized calcium accounts for approximately 50% of total calcium in bloodstream and is tightly regulated to maintain homeostasis [1]. Calcium determination in serum, plasma and urine is commonly performed for screening, monitoring, and routine health assessments including osteoporosis, kidney diseases, and disorders of calcium metabolism such as parathyroidism. Hypercalcemia describes an elevated calcium level and is often associated with conditions such as primary hyperparathyroidism, certain types of cancer (e.g., metastatic bone disease), and excessive intake of vitamin D. In contrast, decreased calcium levels, which are also known as hypocalcemia, can result from vitamin D deficiency, hypoparathyroidism, or chronic kidney disease. In addition, persistent hypocalcemia weakens the bones and by this contributes to the development of osteoporosis [1,2].

### Method

Photometric endpoint determination with Phosphonazo III

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

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

### Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 18 months until expiry date.

### Warnings and Precautions

- Components contained in Calcium P FS are classified according to EC regulation 1272/2008 (CLP) as follows:



⚠ 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. 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.

- As calcium is a ubiquitous ion, essential precaution must be taken against accidental contamination. Only use disposable materials.
- Traces of chelating agent, such as EDTA can prevent the formation of the colored complex.
- In very rare cases, samples of patients with gammopathy might give falsified results [3].
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
- Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
- Please refer to the safety data sheets (SDS) 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.
- For professional use only.

### Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

### Reagent Preparation

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

### Materials Required

General laboratory equipment

### Specimen

Human serum, heparin plasma or urine

Do not use EDTA or citrate plasma.

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability in serum/plasma [4]:

7 days	at	20 – 25°C
3 weeks	at	4 – 8°C
8 months	at	-20°C

Stability in urine [4]:

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.

Only freeze once. Discard contaminated specimens.

### Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the reference method Atomic Absorption Spectrometry (AAS). Use DiaSys TruLab N and TruLab P or TruLab Urine Level 1 and Level 2 for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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

### Serum/Plasma

Measuring range up to 25 mg/dL, linearity is given within ± 5%. 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
Onboard stability	6 weeks
Calibration stability	3 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
<b>Ascorbic acid</b>	30 mg/dL	8.20
<b>Bilirubin</b> (conjugated)	60 mg/dL	8.16
<b>Bilirubin</b> (unconjugated)	60 mg/dL	8.18
<b>Hemolysis</b>	700 mg/dL	8.15
<b>Lipemia</b> (triglycerides)	2000 mg/dL	8.15
<b>Magnesium</b>	8 mmol/L	8.16

**Strontium salts** in medicine may lead to strongly increased calcium values.

For further information on interfering substances, refer to the literature [5,6].

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	5.91	10.5	13.2
CV [%]	0.837	0.837	0.850
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	5.77	9.82	12.5
CV [%]	1.58	1.13	0.966

Method comparison (n=100)	
Test x	Competitor Calcium P (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Calcium P FS (BioMajesty® JCA-BM6010/C)
Slope	1.00
Intercept	0.120 mg/dL
Coefficient of correlation	0.997

### Urine

Measuring range up to 25 mg/dL, linearity is given within ± 5%. 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
Onboard stability	6 weeks
Calibration stability	3 weeks

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	2.62	7.36	10.9
CV [%]	2.05	1.11	0.613
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	2.61	7.27	11.0
CV [%]	2.66	1.24	0.820

Method comparison (n=93)	
Test x	Competitor Calcium P (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Calcium P FS (BioMajesty® JCA-BM6010/C)
Slope	1.03
Intercept	0.409 mg/dL
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 [2]

#### Serum/Plasma

Adults	8.6 – 10.3 mg/dL	2.15 – 2.58 mmol/L
Newborns, 0 – 5 days	7.9 – 10.7 mg/dL	1.96 – 2.66 mmol/L
Children 1 – 3 years	8.7 – 9.8 mg/dL	2.17 – 2.44 mmol/L
Children 4 – 13 years	8.8 – 10.6 mg/dL	2.19 – 2.64 mmol/L
Children 14 – 19 years	8.9 – 10.7 mg/dL	2.22 – 2.66 mmol/L

<b>Urine</b>	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

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\* Fluid Stable

## 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.l	0
M-DET.P.m	22
M-DET.P.n	23
S-DET.P.p	17
S-DET.P.r	18
Check D.P.l.	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