

# Calcium AS FS\*

## Order Information

Cat. No.	Kit size
1 1130 99 10 021	6 x 25 mL
1 1130 99 10 026	6 x 100 mL
1 1130 99 10 023	1 x 1000 mL
1 1130 99 10 704	8 x 50 mL

Kits for use in conjunction with DiaSys CE applications.

## Intended Use

Diagnostic reagent for quantitative in vitro determination of calcium in human serum, heparin plasma or urine on automated photometric systems.

## Summary

Calcium plays an essential role in many cell functions: intracellularly in muscle contraction and glycogen metabolism, extracellularly, in bone mineralization, in blood coagulation and in transmission of nerve impulses. Calcium is present in plasma in three forms: free, bound to proteins or complexed with anions as phosphate, citrate and bicarbonate. Decreased total calcium levels can be associated with diseases of the bone apparatus (especially osteoporosis), kidney diseases (especially under dialysis), defective intestinal absorption and hypoparathyroidism. Increased total calcium can be measured in hyperparathyroidism, malignant diseases with metastases and sarcoidosis. Calcium measurements also help in monitoring calcium supplementation mainly in the prevention of osteoporosis. [1,2]

## Method

Photometric test using arsenazo III

Calcium with arsenazo III at neutral pH yields a blue colored complex, whose intensity is proportional to the calcium concentration. Interference by magnesium is eliminated by adding 8-hydroxyquinoline-5-sulfonic acid.

## Reagent

### Components and Concentrations

Phosphate buffer	pH 7.5	50 mmol/L
8-Hydroxyquinoline-5-sulfonic acid		5 mmol/L
Arsenazo III		120 µmol/L

## Storage and Stability

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

The open-vial stability of the reagent is 24 months until expiry date.

## Warnings and Precautions

1. The reagent contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. As calcium is an ubiquitous ion, essential precautions 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 [3].
5. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
6. 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.
7. 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.
8. 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 reagent is ready to use.

## Materials Required

General laboratory equipment

## Specimen

Human serum, heparin plasma or urine

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

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

Do not use EDTA plasma.

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.

## Assay Procedure

### Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	658/694 nm
Temperature	37°C
Measurement	Endpoint
Sample/Calibrator	1.0 µL
Reagent	100 µL
Addition reagent	Cycle 19 (286 s)
Absorbance	Cycle 17/18 (231 s/244 s)
Calibration	Linear

## Calculation

### With Calibrator

$$\text{Calcium [mg/dL]} = \frac{A_{\text{Sample}}}{A_{\text{Cal}}} \times \text{Conc. Cal. [mg/dL]}$$

### Conversion Factor

$$\text{Calcium [mg/dL]} \times 0.2495 = \text{Calcium [mmol/L]}$$

$$\text{Calcium/U [mg/24 h]} \times 0.025 = \text{Calcium/U [mmol/24 h]}$$

## Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the reference method Atomic Absorption Spectrometry (AAS). Calcium Standard FS may be used alternatively for calibration. Use DiaSys TruLab N and 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
Calcium Standard FS	1 1100 99 10 030	6 x 3 mL

## Performance Characteristics

Data evaluated on BioMajesty® JCA-BM6010/C

### Serum/Plasma

Measuring range from 2.1 mg/dL up to 30 mg/dL. Linearity ≤ 3 mg/dL is given within ± 10%, > 3 mg/dL within ± 5%. When values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Limit of detection**	0.9 mg/dL
Limit of quantitation**	0.9 mg/dL

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
<b>Ascorbic acid</b>	60 mg/dL	8.96
	60 mg/dL	13.4
<b>Bilirubin (conjugated)</b>	60 mg/dL	11.1
	60 mg/dL	14.5
<b>Bilirubin (unconjugated)</b>	60 mg/dL	8.98
	60 mg/dL	13.4
<b>Hemolysis</b>	1000 mg/dL	9.26
	1000 mg/dL	11.9
<b>Lipemia (triglycerides)</b>	2000 mg/dL	10.2
	2000 mg/dL	13.2
<b>Magnesium</b>	10 mmol/L	9.30
	10 mmol/L	12.3

**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=80)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	4.78	8.55	10.0
CV [%]	1.41	1.73	1.08
Within-laboratory (n=80)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	4.78	8.55	10.0
CV [%]	2.60	2.78	2.35

Method comparison (n=155)	
Test x	Competitor Calcium (cobas c 501)
Test y	DiaSys Calcium AS FS (BioMajesty® JCA-BM6010/C)
Slope	1.01
Intercept	-0.588 mg/dL
Coefficient of correlation	0.996

### Urine

Measuring range from 1 mg/dL up to 30 mg/dL. Linearity ≤ 3 mg/dL is given within ± 10%, > 3 mg/dL within ± 5%. When values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Limit of detection**	0.5 mg/dL
Limit of quantitation**	0.5 mg/dL

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
<b>Ascorbic acid</b>	60 mg/dL	6.59
	60 mg/dL	16.7
<b>Bilirubin (conjugated)</b>	60 mg/dL	4.58
	60 mg/dL	14.5
<b>Hemolysis</b>	1000 mg/dL	7.47
	1000 mg/dL	16.8
<b>Magnesium</b>	7 mmol/L	6.52
	10 mmol/L	16.8
<b>Urobilinogen</b>	40 mg/dL	5.96
	40 mg/dL	15.8

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

Precision			
Repeatability (n=80)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	5.31	10.6	13.7
CV [%]	1.69	1.51	2.20
Within-laboratory (n=80)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	5.31	10.6	13.7
CV [%]	2.18	1.77	2.97

\*\* according to CLSI document EP17-A2, Vol. 32, No. 8

## Reference Range

**Serum/Plasma [2]** 8.6 – 10.3 mg/dL 2.15 – 2.57 mmol/L

**Urine [1]** 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. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 231-241.
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3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 20-1 and p. 50-1.
5. 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.
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\* Fluid Stable