

Calcium P FS*

Order Information

Cat. No.

1 1181 99 10 920

Kit size

 800 (4 x 200)

Intended Use

Diagnostic reagent for quantitative in vitro determination of calcium in human serum or heparin plasma on automated respons[®]910.

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

R1:	Malonic acid	pH 5.0	150 mmol/L
	Phosphonazo III		150 µmol/L
R2:	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.
- To avoid contamination and carryover, special care should be taken in combination with Rheumatoid factor FS reagent.
- 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 or heparin plasma

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 [4]:

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

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 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

Performance Characteristics

Measuring range from 0.35 mg/dL up to 16 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**	0.35 mg/dL
Limit of quantitation**	0.35 mg/dL
Onboard stability	4 weeks
Calibration stability	4 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ascorbic acid	30 mg/dL	9.47
Bilirubin (conjugated)	70 mg/dL	9.10
	70 mg/dL	16.2
Bilirubin (unconjugated)	70 mg/dL	9.10
	70 mg/dL	16.2
Hemolysis	1000 mg/dL	7.81
	1000 mg/dL	12.3
Lipemia (triglycerides)	1900 mg/dL	7.75
	1900 mg/dL	13.8
Magnesium	20 mg/dL	10.3

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=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	7.11	9.87	12.1
CV [%]	2.94	1.39	1.50
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	7.84	9.86	11.3
CV [%]	2.99	3.28	3.36

Method comparison (n=97)	
Test x	DiaSys Calcium P FS (Hitachi 911)
Test y	DiaSys Calcium P FS (respons [®] 910)
Slope	1.02
Intercept	-0.097 mg/dL
Coefficient of correlation	0.998

** according to CLSI document EP17-A, Vol. 24, No. 34

Conversion Factor

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

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

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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- Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
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Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.



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* Fluid Stable

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Application for serum and plasma 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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	CA
Shortcut:	
Reagent barcode reference:	021
Host reference:	021

Technic	
Type:	End point
First reagent:[μ L]	180
Blank reagent	Yes
Sensitive to light	
Second reagent:[μ L]	45
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	660
Secondary wavelength:[nm]	800
Polychromatic factor:	1.0000
1 st reading time [min:sec]	(04:24)
Last reading time [min:sec]	07:00
Reaction way:	Decreasing
Linear Kinetics	
Substrate depletion: Absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics	
Substrate depletion: Absorbance limit	
Endpoint	
Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [μ L]	0 (no hemolysis)
Cleaner	
Sample [μ L]	0
Technical limits	
Concentration technical limits-Lower	0.3500
Concentration technical limits-Upper	16.000
SERUM	
Normal volume [μ L]	5.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	5.0
Above normal dilution (factor)	6
URINE	
Normal volume [μ L]	5.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	5.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [μ L]	5.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	5.0
Above normal dilution (factor)	6
CSF	
Normal volume [μ L]	5.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	5.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [μ L]	5.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	5.0
Above normal dilution (factor)	6

Results	
Decimals	2
Units	mg/dL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	#
URINE	
PLASMA	#
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants	
Please refer to r910 Carryover Pair Table	

Calibrators details	
Calibrator list	Concentration
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
	Max delta abs.
Cal. 1	0.003
Cal. 2	0.015
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.80

Calculations	
Model	X
Degree	1

* Enter calibrator value
Editable by user