respons®910

Calcium P FS*

Diagnostic reagent for quantitative in vitro determination of calcium in serum or plasma on DiaSys respons®910

Order Information

Cat. No. 1 1181 99 10 920
4 twin containers for 200 tests each

Method

Photometric endpoint determination with Phosphonazo III

Principle

In acidic medium 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 a ubiquitous ion, special precaution must be taken against accidental contamination.
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. To avoid contamination and carryover, special care should be taken in combination with Rheumatoid factor FS reagent.
6. 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.
7. 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 or heparin plasma
Do not use EDTA plasma.

Stability [1]:

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

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. This method has been standardized against the reference method Atomic Absorption Spectrometry (AAS). DiaSys TruLab N and P should be assayed for internal quality control. 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 up to 16 mg/dL 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**	0.35 mg/dL calcium
On-board stability	4 weeks
Calibration stability	4 weeks

Interfering substance	Interferences < 10%	Calcium [mg/dL]
Ascorbate	up to 30 mg/dL	9.47
Hemoglobin	up to 1000 mg/dL	7.81
	up to 1000 mg/dL	12.3
Bilirubin, conjugated	up to 70 mg/dL	9.10
	up to 70 mg/dL	16.2
Bilirubin, unconjugated	up to 70 mg/dL	9.10
	up to 70 mg/dL	16.2
Lipemia (triglycerides)	up to 1900 mg/dL	7.75
	up to 1900 mg/dL	13.8
Magnesium	up to 20 mg/dL	10.3
Strontium salts in medicine may lead to strongly increased calcium values.		
For further information on interfering substances refer to Young DS [2].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	7.11	9.87	12.1
Coefficient of variation [%]	2.94	1.39	1.50
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	7.84	9.86	11.3
Coefficient of variation [%]	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	1.017
Intercept	–0.097 mg/dL
Coefficient of correlation	0.998

** according to NCCLS document EP17-A, vol. 24, no. 34

Conversion factor

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

Reference Range [3]

8.6 — 10.3 mg/dL (2.15 — 2.57 mmol/L)

Each laboratory should check if 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.
2. 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.
3. 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.
4. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 231-241
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

respons®910

Calcium P FS

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:	CAP
Shortcut:	
Reagent barcode reference:	021
Host reference:	

Technic	
Type:	End point
First reagent:[µL]	180
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	45
Blank reagent	Yes
Sensitive to light	
Main wavelength:[nm]	660
Secondary wavelength:[nm]	800
Polychromatic factor:	1.000
1 st reading time [min:sec]	(04:24)
Last reading time [min:sec]	07:00
Reaction way:	Decreasing
Linear Kinetics	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics	
Endpoint	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	0.35
Concentration technical limits-Upper	16
SERUM	
Normal volume [µL]	5
Normal dilution (factor)	1
Below normal volume [µL]	8
Below normal dilution (factor)	1
Above normal volume [µL]	5
Above normal dilution (factor)	6
URIN	
Normal volume [µL]	5
Normal dilution (factor)	1
Below normal volume [µL]	8
Below normal dilution (factor)	1
Above normal volume [µL]	5
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	5
Normal dilution (factor)	1
Below normal volume [µL]	8
Below normal dilution (factor)	1
Above normal volume [µL]	5
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	5
Normal dilution (factor)	1
Below normal volume[µL]	8
Below normal dilution (factor)	1
Above normal volume [µL]	5
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	5
Normal dilution (factor)	1
Below normal volume[µL]	8
Below normal dilution (factor)	1
Above normal volume [µL]	5
Above normal dilution (factor)	6

Results	
Decimals	2
Units	mg/dL
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Gender	All
Age	
SERUM	>=8.60 <=10.3
URINE	
PLASMA	>=8.60 <=10.3
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants	
Contaminant 1	Please refer to r910 Carryover Pair Table
Wash with	
Cycle	
Volume [µL]	
Contaminant 2	
Wash with	
Cycle	
Volume [µL]	
Contaminant 3	
Wash with	
Cycle	
Volume [µL]	

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 [%]	0.8
Calculations	
Model	X
Degree	1

* Enter calibrator value