respons®920

Calcium P FS*

Diagnostic reagent for quantitative in vitro determination of calcium in serum or plasma on DiaSys respons®920

Order Information

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

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 a 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. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
5. In very rare cases, samples of patients with gammopathy might give falsified results [5].
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

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 controls should be assayed. Each laboratory should establish corrective actions 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 25 mg/dL calcium (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use the rerun function).	
Limit of detection**	0.2 mg/dL calcium
On-board stability	8 weeks
Calibration stability	8 weeks

Interferences < 10% by
Ascorbate up to 30 mg/dL
Hemoglobin up to 1000 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 20 mg/dL
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]	10.0	10.0	12.2
Coefficient of variation [%]	1.00	0.68	0.80
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	9.41	10.0	12.3
Coefficient of variation [%]	2.08	1.28	2.05

Method comparison (n=152)	
Test x	DiaSys Calcium P FS (Hitachi 917)
Test y	DiaSys Calcium P FS (respons®920)
Slope	0.987
Intercept	0.322 mg/dL
Coefficient of correlation	0.996

** 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]

Reference Range [3]

8.6 – 10.3 mg/dL (2.15 – 2.57 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

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

* fluid stable

respons®920

DiaSys Diagnostic Systems

Calcium P FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	CA				Auto Rerun		☐
Report Name	:	Calcium Phosphonazo				Online Calibration		☐
Unit	:	mg/dL	Decimal Places	:	2	Cuvette Wash		☐
Wavelength-Primary	:	660	Secondary	:	700	Total Reagents	:	2
Assay Type	:	2-Point	Curve Type	:	Linear	Reagent R1	:	CA R1
M1 Start	:	15	M1 End	:	15	Reagent R2	:	CA R2
M2 Start	:	20	M2 End	:	20			
Sample Replicates	:	1	Standard Replicates	:	3	**Consumables/Calibrators:**		
Control Replicates	:	1	Control Interval	:	0	Blank /Level 0		0
Reaction Direction	:	Decreasing	React. Abs. Limit	:	0.0000	Calibrator 1		*
Prozone Limit %	:	0	Prozone Check	:	Upper			
Linearity Limit %	:	0	Delta Abs./Min.	:	0.0000			
Technical Minimum	:	0.2	Technical Maximum	:	25.0			
Y = aX + b a=	:	1.0000	b=	:	0.0000			

* Enter calibrator value.

Test Details			Test Volumes	Reference Ranges
Test	:	CA		
Sample Type	:	Serum		

Sample Volumes

Normal	:	2.00 µl	Dilution Ratio	:	1	X
Increase	:	4.00 µl	Dilution Ratio	:	1	X
Decrease	:	2.00 µl	Dilution Ratio	:	2	X
Standard Volume	:	2.00 µl				

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	180 µl	R1 Stirrer Speed	:	Medium
RGT-2 Volume	:	45 µl	R2 Stirrer Speed	:	High

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	CA		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (mg/dL)	Upper Limit (mg/dL)
Normal	:	8.60	10.30
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other