CALCIUM - CRESOLPHTHALEIN

COD 12513 5 x 50 mL
Only for *in vitro* use in the clinical laboratory

Automated Systems

BioSystems

CALCIUM-CRESOLPHTHALEIN
O-CRESOLPHTHALEIN COMPLEXONE

INTENDED USE

Reagent for the measurement of calcium concentration in human serum, plasma or urine. The obtained values are useful as an aid in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

This reagent is for use in the BioSystems A25 and A15 analyzers.

CLINICAL SIGNIFICANCE

Calcium is the most prevalent cation found in the body, distributed in bone (99%), soft tissues and extracellular fluid. Its concentration in plasma is regulated by parathyroid hormone, vitamin D and calcitonin.

Calcium ion is important in the transmission of nerve impulses, in the maintenance of normal muscle contractility, as a cofactor in certain enzyme reactions, and in the coagulation of the blood.

Hypercalcemia can be due to vitamin D intoxication, enhanced renal retention, osteoporosis, sarcosidosis, thyrotoxicosis, hyperparathyroidsm, multiple mieloma, idiopathic hypercalcemia of infancy, and carcinoma metastasic to bone[1,2].

Elevated calcium concentration in urine is found in nephrolithiasis and metabolic acidosis[1,2].

Hypocalcemia may be caused by primary and secondary hypoparathyroidism, pseudohypoparathyroidism, vitamin D deficiency, malnutrition and intestinal malabsorption[1,2].

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

PRINCIPLE OF THE METHOD

Calcium in the sample reacts with o-cresolphthalein complexone (o-CPC) forming a coloured complex that can be measured by spectrophotometry[3].

CONTENTS AND COMPOSITION

A. Reagent. 5 x 40 mL. Ethanolamine 900 mmol/L.

B. Reagent. 5 x 10 mL. o-Cresolphthalein Complexone 0.3 mmol/L, 8 hydroxyquinoline 28 mmol/L, hydrochloric acid 100 mmol/L.

DANGER: H314: Causes severe skin burns and eye damage. P280: Wear protective gloves/protective clothing/eye protection/face protection. P303+P361+P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

STORAGE AND STABILITY

Store at 2-30ºC.

Components are stable once opened until the expiry date marked in the label if they are stored well closed and care is taken to prevent contamination during their use.

On board stability: Reagents open and kept in the refrigerated compartment of the analyzer are stable 7 weeks

Indications of deterioration: Absorbance of the blank over the limit indicated in "Test Parameters".

WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents. Safety data sheet available for professional user on request. Disposal of all waste material should be in accordance with local guidelines. Any serious incident that might occur in relation to the device shall be reported to BioSystems S.A.

ADDITIONAL MATERIALS REQUIRED (NOT PROVIDED)

Biochemistry Calibrator (BioSystems cod. 18011) or Biochemistry Calibrator Human (BioSystems cod. 18044).

REAGENT PREPARATION

Reagents are provided ready to use.

SAMPLES

Serum, heparinized plasma or urine collected by standard procedures.

Calcium in serum or plasma is stable for 10 days at 2-8ºC. Anticoagulants other than heparin should not be used.

Collect a 24-hour urine specimen in a bottle containing 10 mL of 50 % (v/v) nitric acid. Stable for 10 days at 2-8ºC. Centrifuge or filter before testing.

CALIBRATION

A reagent blank should be done every day and a calibration at least every 7 weeks, after reagent lot change or as required by quality control procedures.

QUALITY CONTROL

It is recommended to use the Biochemistry Control Serum level I (cod. 18005, cod. 18009 and cod. 18042), level II (cod. 18007. cod. 18010 and cod. 18043) and and the Biochemistry Control Urine (cod. 18054 and cod. 18066) to verify the accuracy of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if control results are not within the acceptable limits.

REFERENCE VALUES

Serum and plasma[1]: 8.6 - 10.0 mg/dL = 2.15 - 2.50 mmol/L.

Urine[1]: 100 - 300 mg/24-h = 2.5 - 7.5 mmol/24-h.

These ranges are given for orientation only; each laboratory should establish its own reference ranges.

METROLOGICAL CHARACTERISTICS

The metrological characteristics described below have been obtained using an A25 analyzer. Results are similar with A15.

- Detection limit: 0.26 mg/dL = 0.06 mmol/L.
- Linearity limit: 20 mg/dL = 5 mmol/L. For samples with higher values, dilute manually or refer to the Test Parameterization for Automatic dilution (note that all these samples will be diluted with the same dilution ratio).
- Precision:

Mean concentration	Repeatability (CV)	Within-laboratory (CV)
9.58 mg/dL = 2.40 mmol/L	1.7 %	2.2 %
13.6 mg/dL = 3.40 mmol/L	1.4 %	1.6 %

- Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

LIMITATIONS OF THE PROCEDURE

- Interferences: bilirubin (up to 20 mg/dL), hemolysis (hemoglobin up to 1000 mg/dL) and lipemia (triglycerides up to 3000 mg/dL) do not interfere. Other drugs and substances may interfere[4].

BIBLIOGRAPHY

1. K. Lorentz. Improved determination of serum calcium with 2-cresolphthalein comlpexone. Clin Chim Acta 1982; 126:327-334.
2. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 3th ed. Burtis CA, Ashwood ER, Bruns DE. WB Saunders Co, 1987.
3. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.
4. Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press, 2001.

TEST PARAMETERS

R1: use Reagent A.

R2: use Reagent B.

	A25	A15
GENERAL		
Name	**CALCIUM-CPC**	**CALCIUM-CPC**
Sample type	SER/URI	SER/URI
Analysis mode	differential bir.	differential bir.
Units	mg/dL	mg/dL
Turbidimetry test	no	no
Decimals	2	2
Type of reaction	increasing	increasing
PROCEDURE		
Reading mode	monoch.	monoch.
Main filter	560	560
Reference filter	-	-
Sample	4	4
Vol. R1	240	240
Vol. R2	60	60
Washing	1.2	1.2
Reading 1 (cycle)	6	4
Reading 2 (cycle)	21	14
Reagent 2 (cycle)	7	5
Predilution factor	- / 2	- / 2
Predilution reduced factor	2	2
CALIBRATION AND BLANK		
Calibration type	multiple	multiple
Number of calibrators	-	-
Calibration curve	-	-
OPTIONS		
Blank absorbance limit	0.500	0.300
Kinetic blank limit	-	-
Linearity limit	20 / 40	20 / 40
Substrate depletion	-	-

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