CALCIUM o-CPC

METHOD – o-CPC
PRODUCT CODE – LC02

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of Calcium in serum / plasma using o-CPC method.

SUMMARY AND PRINCIPLE

Elevated Calcium levels are associated with primary hyperparathyroidism, breast cancer, bronchial cancer, pancreatic tumour, osteoporosis, Paget's disease and Adison's disease. Calcium o-CPC is a single reagent with a one-step reconstitution set for determination of Calcium in human serum and plasma.
It involves mixing of CPC and diluent reagent.

Ca^{2+} + Cresolphthalein Complexone $\xrightarrow{\text{Alkaline pH}}$ Purple complex

KIT COMPONENTS

Reagent1: Calcium CPC Reagent
Reagent 2: Calcium Diluent
Reagent 3: Calcium Standard (10 mg/dL)

REAGENT PREPARATION, STORAGE & STABILITY

Mix equal volume of CPC reagent and diluent reagent (1:1 ratio) to get desired working reagent. Working Reagent is stable for 7 days at 2 - 8 ^{0}C. The reagent kit should be stored at 2 - 8 ^{0}C and is stable till the expiry date indicated on the label.

PRECAUTIONS & HANDELING

The reagents/samples should be handled by qualified personnel only. Patients receiving EDTA treatment cannot be assayed for calcium correctly. A thorough rinsing of glass wares by 0.1N HCl followed by distilled water is recommended for calcium assay. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent. Do not shake the reagent vigorously. Discard the reagent if the absorbance of the reagent exceeds 0.200 O.D. against D/W at 575 nm. Contamination of the reagent should be avoided.

TEST PARAMETERS

Name	Cal CPC
Reaction Type	End Point
Wavelength	575 nm
Flow Cell Temp.	37 °C
Blank setting	Reagent
Blank abs. limit	< 0.200

Reagent Volume	1000 µl
Sample Volume	20 µl
Incubation Temperature	R.T.
Incubation Time	5 min.
Standard Conc.	10 mg/dL
Linearity	16 mg/dL

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls, Incubation chamber.

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Serum or heparinized plasma can be used. Do not use citrate, oxalate or EDTA as anticoagulant. Avoid venous stasis. Calcium in the serum/plasma is stable for 5 days when stored at 2 - 8 ^{0}C and 20 days when stored at -20 ^{0}C.

COMPONENTS OF REAGENT

Component	Concentration
Diethanolamine Buffer , pH 10.7	500 mmol/l
o-Cresolphthalein Complexone	63 mol/l
Quinolinol	17 mmol/l
Stabilizers and inactive ingredients.	-

ASSAY PROCEDURE

	Blank	Standard	Test
Reagent	1000 µl	1000 µl	1000 µl
Standard	NA	20 µl	NA
Sample	NA	NA	20 µl
Mix the reagent and sample/standard in the above-mentioned ratio.			
Incubate the assay mixture for 5 minutes at room temperature.			
Aspirate reaction mixture into flow cell and measure the absorbance.			
The final colour is stable for 1 hour if not directly exposed to light.			

CALCULATION

$$\text{Calcium (mg/dL)} = \frac{\text{Abs. of sample} \times 10}{\text{Abs. of standard}}$$

REFERENCE VALUES FOR NORMAL PEOPLE

8.5 - 10.5 mg/dL

PERFORMANCE CHARACTERISTICS

Measuring Range: The assay is linear between 0.6 - 16 mg/dL. If the Calcium value exceeds linearity limit (above 16 mg/dL), dilute the specimen suitably with normal saline and repeat the assay. In that case, assay value should be multiplied with the dilution factor to obtain correct Calcium value of the specimen.

Interference: There is no significant interference in samples containing Bilirubin upto 20 mg/dL and Haemoglobin upto 500 mg/dL.

Precision: Precision studies has been carried out using quality control sera as shown below:

(n=10)	Within Run			Between Run		
Specimen Material	Mean (mg/dL)	SD (mg/dL)	CV %	Mean (mg/dL)	SD (mg/dL)	CV %
Low Value Serum	9.31	0.09	0.9	9.01	0.08	0.8
High Value Serum	11.08	0.18	1.6	10.8	0.29	2.6

Note: We recommend all the laboratories to establish its own accuracy and precision data.

QUALITY CONTROL

Inclusion of a normal value and abnormal value chemistry control serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides between run precision and accuracy data for Calcium. We recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

PRECAUTIONS

1. Patients receiving EDTA treatment cannot be assayed for calcium correctly.
2. If Calcium value exceeds 16 mg/dL then dilute the specimen suitably with normal saline & repeat the assay. In such case the results obtained should be multiplied by dilution factor to obtain the correct calcium value.
3. A thorough rinsing of glass wares by 0.1N HCl followed by distilled water is recommended for calcium assay.

BIBLIOGRAPHY

1. Kessler G.et al, Clin. Chem. 10. 686 (1964).
2. Harold Varley, "Practical Clinical Biochemistry" V. ed. pp. 858.

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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ISO 9001: 2015
ISO 13485 : 2016
GMP
CE