

ANA BIO CLR CALCIUM

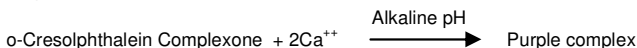
(o-Cresolphthalein Complexone (CPC) method)

Intended Use

CALCIUM is used for the quantitative determination of calcium in serum or plasma based on o-Cresolphthalein Complexone method. The reagents are for *in-vitro* diagnostic use.

Principle

Calcium forms a purple colour complex with o-Cresolphthalein complexone in an alkaline medium. This complex absorbs light at 578 nm (570 - 580 nm). The intensity of the colour is directly proportional to the calcium concentration in specimen.



Reagents provided

1. R1- CPC Reagent (Ready to use).
2. R2- Diluent reagent (Ready to use).
3. Standard - Calcium (8 mg/dl).

Working solution preparation

Prepare working solution by mixing equal volume of CPC reagent and diluent reagent.

Reagent storage and stability

The reagents are stable till the expiry date stated on the bottle label; when stored at 2° - 8°C. The working solution is stable for 7 days at 2° - 8°C.

Specimen collection and preservation

Blood should be collected in a clean dry container. Avoid the use of plastic or siliconized container which may prolong clotting time. Serum is preferred but heparinized (200 IU/ml of blood) plasma can also be used; Heparin should be without calcium salt. EDTA, Citrate, Oxalate and calcium salt of heparin interfere in the assay and should not be used as anticoagulant. Calcium is stable in serum or plasma for 5 days when stored at 2° - 8°C and 20 days when stored at -20°C.

Assay guidelines for Analyzers

Reaction Type	End Point with Standard
Reaction slope	Increasing
Incubation time	5 min. at RT (25° - 30°C)
Wave length	578 nm (570 - 580 nm)
Blank	Reagent Blank
Sample Volume	20 µl (0.02 ml)
Working solution Volume	1000 µl (1.0 ml)
Calcium Standard Concentration	8 mg/dl
Factor Calculation	8 mg/dl ÷ Absorbance of Standard
Low normal	8.5 mg/dl
High normal	11 mg/dl
Linearity	Up to 15 mg/dl

Assay guidelines for Manual Procedure

Bring the reagents to room temperature (25° - 30°C) and perform the assay as given below.

Reagents	Blank	Standard	Sample
Working solution	1000 µl (1.0 ml)	1000 µl (1.0 ml)	1000 µl (1.0 ml)
Standard	-	20 µl (0.02 ml)	-
Sample	-	-	20 µl (0.02 ml)

1. Mix thoroughly and incubate at room temperature (25° - 30°C) for 5 minutes.
2. Read the absorbance against reagent blank at 578 nm (570 - 580 nm).
3. The final colour is stable for 60 minutes if not exposed to direct light.

Calculation

Calcium con. in sample (mg/dl) = $\frac{\text{Sample OD}}{\text{Standard OD}} \times \text{Con. of Standard}$

Note:

- Avoid the contamination of reagent into standard during its repeated use.
- Glassware is the most common source of contamination in the calcium assay. It is strongly recommended that glassware required for assay be rinsed with 0.1N HCl followed by repeated rinsing with demineralized water.
- The specimen and reagent volumes can proportionally be altered without affecting the final results.

Normal Range

Guidance Value : 8.5 - 11 mg/dl

Note: Expected range varies from population to population and each laboratory should establish its own normal range

Limitation

1. Patients receiving EDTA treatment cannot be assayed for calcium correctly.
2. Reaction is linear up to 15 mg/dl. For higher values dilute sample with normal saline and perform the assay. Multiply the final result by dilution factor to get the real value.

Quality Control

To ensure adequate quality control measures, it is recommended that each batch should include a normal and an abnormal commercial reference control serum. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glassware and accuracy of pipetting.

References

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

Symbols

 IVD	In Vitro Diagnostics.	 Caution.	 Keep away from sun light.	 Date of Manufacture.
 LOT	Batch No.	 Read Instructions.	 Fragile.	 Product Expiry Date.
 CONT	Content.	 Storage Temperature.	 Keep Dry.	 Manufactured By.
 REF	Catalogue No.			



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