CALCIUM (2-8°C)

(O-Cresolpthalein Complexone)

CATALOGUE NUMBER	KIT SIZE (ML)
MPRCAL8	2x100ml / 2x100ml / 1x5ml

Intended Use:
For *In Vitro* diagnostic use by trained professionals only.
Calcium OCPC reagent is intended to be used for the quantitative detection of Calcium in human serum and plasma.

Clinical Significance:
Calcium is the most abundant and one of the most important minerals in the human body. Approximately 99% of body calcium is found in bones. A decrease in albumin levels causes a decrease in calcium levels in the human body. Among causes of hypercalcemia are cancers, large intake of vitamin D, enhanced renal retention, osteoporosis, sarcosidosis, thyrotoxicosis, hyperparathyroidism.
Low levels of calcium are found in hypoparathyroidism, pseudohypoparathyroidism, Vitamin D deficiency, malnutrition and intestinal malabsorption.

Test Principle:
In an alkaline medium a colour complex forms between sample-derived calcium and o-cresolphthalein. The intensity of colour development can be measured photometrically and is proportional to the concentration of calcium in the sample.

Reagent Composition

REAGENT	COMPONENT	CONCENTRATION
R1 - Buffer	Ethanolamine	500 mmol/l
R2 - Chromogen	o-cresolphthalein	0.62 mmol/l
	8-hydroxyquinolein	69 mmol/l
Calcium Standard	Calcium aqueous primary standard	10 mg/dl

Precautions: R1 and R2 are corrosive, cause severe burns.

Reagent Preparation and Stability:
R1: Liquid, ready to use.
R2: Liquid, ready to use.
Standard: Liquid, ready to use.
R1, R2 and Standard are stable to the expiry date when stored unopened at 2 - 8°C.
Reagent deterioration is indicated by the presence of particles and turbidity and a Blank absorbance at 570nm of > 0.22.
Exercise the normal precautions associated with the handling of laboratory reagents and dispose of carefully according to local guidelines.

Sample Preparation and Stability:
Collect serum and heparin plasma by standard venepuncture technique. Do not use oxalate or EDTA as anticoagulants.
Stability: 10 days at 2 – 8°C.
Urine: 24 hour urine. Put 10 ml dilute HNO_3 (50% v/v) in a calcium-free collection bottle to dissolve calcium salts. Dilute urine ½ in distilled water before assay.
Stability: 10 days at 2 – 8°C.
Centrifuge samples containing precipitate before performing the assay.
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Assay Procedure:

WAVELENGTH	570 nm
TEMPERATURE	37°C
CUVETTE	1cm Path Length
BLANK	Reagent Blank

	Blank	Standard	Sample
R1 – Buffer	1000 µl	1000 µl	1000 µl
R2 - Chromogen	1000 µl	1000 µl	1000 µl
Sample	-	-	20 µl
Standard	-	20 µl	-
Mix and incubate 5 minutes at assay temperature. Read absorbance of Sample/Standard against the Reagent Blank. The colour is stable for 40 minutes.			

Calculation:
Serum / Plasma

$$\text{Calcium Concentration (mg/dl)} = \frac{\Delta\text{Abs Sample}}{\Delta\text{Abs Standard}} \times \text{Concentration of Standard}$$

Urine 24 hours

$$\text{Calcium (mg/24h)} = \frac{\Delta\text{Abs Sample}}{\Delta\text{Abs Standard}} \times \text{Concentration of Standard x vol urine}$$

Conversion factor: mg/dl x 0.25 = mmol/l

Performance Characteristics:

Measuring range:
0.07 to 35 mg/dl
If sample results are higher than 35 mg/dl, dilute the sample 1+1 with normal saline and multiply the result by 2.

Analytical Sensitivity: (Lowest detection limit):
0.07 mg/dl

Intra-Assay Precision:

Sample	Mean (mg/dl)	SD (mg/dl)	CV %
Pool 1	9.14	0.07	0.74
Pool 2	16.02	0.11	0.68

Inter-Assay Precision:

Sample	Mean (mg/dl)	SD (mg/dl)	CV %
Pool 1	9.34	0.20	2.16
Pool 2	16.27	0.37	2.27

Method Comparison:
A comparison of the AMS Calcium kit (y) with a commercial assay (x) gave the following result:
Y = 0.8234x + 1.5484, r = 0.981

Interferences:
No interference observed with triglycerides up to 1.25 g/l.
A list of drugs and other interfering substances with calcium determination has been reported.

Reference Range:

Serum / Plasma	
Adults	8.5 – 10.5 mg/dl (2.1 – 2.6 mmol/l
Children	10 – 12 mg/dl (2.5 – 3.0 mmol/l)
New born	8 – 13 mg/dl (2.0 – 3.25 mmol/l)
Urine	
Adults	50 – 300 mg/24h (1.25 – 7.50 mmol/24 h)
Children	80 – 160 mg/24h (2.0 – 4.0 mmol/l 24h)

Each laboratory should establish its own mean reference range according to the population.

Application for Automated systems:
For applications on automated systems – contact technical department. Use of a serum calibrator to standardise the assay on automated systems.

Quality Control and Calibration Material:
It is recommended that laboratories use reference control sera to verify the reagent performance. Results obtained should fall within the specified ranges. If results fall outside these ranges actions should be taken in line with the laboratory's internal quality procedures.
AMS recommend the following calibrator and controls
Calibration Serum: **QCCCAL1 / QCCCAL2**
Human Assayed Control Normal: **QCCHAN1 / QCCHAN2**
Human Assayed Control Elevated: **QCCHAE1 / QCCHAE2**

Precautions:
- This product is easily contaminated, handle with care.
- Use of disposable laboratory ware is recommended. If glassware is used the material should be well cleaned with diluted ½ nitric acid in water and then thoroughly rinsed with distilled water.
- Do not exchange reagents from different lots or use reagents from other commercially available kits. The components of the kit are precisely matched for optimal performance of the tests.
- All specimens from human origin should be considered as potentially infectious. Adhere to strict Good Laboratory Practice regulations to ensure personal safety.
- The result from this test should not be used as the sole criteria for diagnosis, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

References:

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4. Young DS Effects of drugs on clinical lab tests, 4th ed, AACC 2001.
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6. Burtis A et al. Tietz textbook of clinical chemistry, 3rd ed. AACC 1999
7. Tietz NW et all. Clinical Guide to Laboratory tests, 3rd ed., AACC 1995.

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		

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