CALCIUM OCP - Liquid

O-cresolphtalein Method

R1:1 x 100 + ml R2: 1 x 25 ml **CL16-125S**

INTENDED USE

Kit for quantitative determination of calcium in serum, plasma and urine.

CLINICAL MEANING

In the human body, calcium has different purposes: it is used in skeletal metabolism, in neuromuscular functions and in haemostasis.
Higher levels of calcium may indicate hyperparathyroidism (caused by parathyroid adenoma or by secondary hyperplasia), metastatic bone tumors or tumors that produce parathyroid hormone, Paget bone disease, excessive consumption of vitamin D, milk or antacids etc.
Lower calcium levels are commonly associated to: hypoparathyroidism caused by surgical removal of parathyroids or by radiation therapy; increase of phosphates caused by kidney failure, by consumption of laxatives, phosphates or magnesium; acute pancreatitis; vitamin D deficiency; rickets etc.

PRINCIPLE

In an alkaline environment, calcium forms a red-violet complex with o-creosolphtaleine (read at 570 nm). The reaction is highly specific and a suitable chelating agent present in the reagent avoids magnesium interferences. The intensity of the colour is directly proportional to the quantity of calcium in the sample.

SAMPLE

Fresh, non hemolysed serum, plasma with heparin.
Do not use citrate, oxalate or EDTA as anticoagulant.
STABILITY: 7 days at 2-8°C, one month at -20°C.
Urine 24/h, diluted 1:2 with distilled water, acidified with 2-3 drops of HCl 23%.

REAGENTS

Only for in Vitro diagnostics.
Liquid reagents ready to use. Reagents marked by an asterisk are considered dangerous.

Package contents	**CL16-125S**
***REAGENT 1** Buffer pH 11	1 x 100 ml
REAGENT 2 o-cresolphtaleine complexone , 8 oxyquinoline.	1 x 25 ml
Standard: Calcium solution 10 mg/dl (2.5 mmol/L)	1 x 4 ml

STABILITY: if stored at 15-25°C and away from light, kit components are stable up to the expiration date on the label.

NECESSARY ITEMS – NOT PROVIDED

Usual laboratory equipment: UV/VIS Spectrophotometer with temperature control; automatic micropipettes; Optical glass cuvettes or, alternatively, disposable ones in optical polystyrene; Saline solution.

PREPARATION OF WORKING REAGENT

(only for monoreagent procedure)

Mix 4 volumes of Reagent 1 with 1 volume of Reagent 2.

Stability: 5 days at 20-25°C or 14 days at 2-8°C if stored away from light (and tightly closed).

MANUAL ASSAY PROCEDURE

Wavelength:	570 nm (550 ÷ 580 nm)
Optical path:	1 cm
Temperature:	37°C – 25°C
Reading:	against blank reagent
Method:	End point
Sample/reagent Ratio (monoreagent)	1/120
Sample/reagent Ratio (bireagent):	1/96/24

Monoreagent procedure

Pipette into cuvette:

	Blank	Standard	Sample
Working reagent	1200 µl	1200 µl	1200 µl
Distilled water	10 µl	-	-
Standard	-	10 µl	-
Sample	-	-	10 µl

Bireagent procedure

	Blank	Standard	Sample
Reagent 1	1920 µl	1920 µl	1920 µl
Reagent 2	480 µl	480 µl	480 µl
Distilled water	20 µl	-	-
Standard	-	20 µl	-
Sample	-	-	20 µl

Stir and incubate for 2 minutes at 37°C or 5 minutes at room temperature. Read the absorbance of the sample (AC) and of the standard (Astd) against blank.

The coloration is stable for at least 15 minutes at room temperature. Volumes may be varied proportionally.

CALCULATION

Serum and plasma: calcium mg/dl = Ac/As x 10 (value of the standard)

Urine: calcium mg/dl = Ac/As x 10 x 2
(value of the standard + dilution factor)

24 hours urine: calcium mg/24h = Ac/As x 10 x 2 x volume urine
(value of the standard + dilution factor and diuresis in dl).

REFERENCE VALUES

Serum and plasma: 8.6 - 10.3 mg/dl (2.15 - 2.57 mmol/l)

urine (men): ≤ 300 mg/24h (7.49 mmol/24h)

urine (women): ≤ 250 mg/24h (6.24 mmol/24h)

Each laboratory should define its own reference values for this method.

QUALITY CONTROL - CALIBRATION

All Clinical Chemistry laboratories should implement a quality control program. Control serums of human origin are available for this purpose on request:

PRE-NORM serums with normal values

PRE-PATH serums with pathological values

If the method requires it, a multi-parameter calibrator of human origin is available.

PERFORMANCE CHARACTERISTICS

Sensitivity
This method discriminates up to 0.1 mg/dl.
Linearity
This method is linear up to (at least) 25 mg/dl.
For higher values, dilute the sample 1:9 with distilled water and repeat the test, multiplying the result by 10.
Precision

Within run (n=20)	Average (mg/dl)	CV%
Sample 1	4.35	4.35
Sample 2	9.18	2.75

Between run (n=20)	Average (mg/dl)	CV%
Sample 1	4.51	3.61
Sample 2	8.98	2.20

Interferences
Bilirubin (20 mg/dl), Triglycerides (1250 mg/dl), Haemoglobin (100 mg/dl), Magnesium (20 mg/dl) do not interfere.
Correlation against a reference method
The correlation of method (Y) with reference method (X) highlighted the following equation (in sample=90) :

$y = 0.9x + 0.47$ $R^2 = 0.996$

DISPOSAL

The product must be used for professional analysis only. The product must be disposed of according to national/international laws.

WARNINGS AND PRECAUTIONS

REAGENT 1 **WARNING:** Causes severe eye irritation (H319). Wear protective gloves. Protect your eyes (P280).

REFERENCES

1. Zak B., Epstein E., Babinski E.S., Review of Calcium Methodologies, Annals of Clinical and Laboratory Science 5, 195-212 (1975). Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994). Clinical Chemistry, vol. 38 n. 6 - 904-908 - (19

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KEY SYMBOLS

IVD	In Vitro diagnostic medical device
LOT	batch number
REF	catalog number
	temperature limits
	use by
	caution
	consult accompanying documents

Issue 01 - Jan 2021 RR