

IN VITRO DIAGNOSTIC USE



REF	01016	2 x 125 ml (250 T)	R1: 1 x 125 ml	R2: 1 x 125 ml	R3: 1 x 3 ml
REF	01023	2 x 160 ml (320 T)	R1: 2 x 80 ml	R2: 2 x 80 ml	R3: 1 x 3 ml
REF	01030	1 x 160 ml (160 T)	R1: 1 x 80 ml	R2: 1 x 80 ml	R3: 1 x 2 ml

CLINICAL SIGNIFICANCE

Calcium is the most abundant mineral in the human body. In the blood, calcium is present in a non-diffusible and diffusible form. In the non-diffusible form, calcium is bound to plasma proteins (mainly albumin). In its diffusible form, 50% of the serum level is ionized and 5% is complexed (citrate, phosphate...).

Hypercalcemia can be due to many disorders, such as hyperparathyroidism (often linked to chronic renal failure) and neoplastic states manifested by osteolytic metastases. On the other hand, hypocalcemia may be associated with renal failure, hypoparathyroidism and sometimes with a deficiency or failure to resorb calcium or Vitamin D.

PRINCIPLE

Calcium measurement is based on the o-cresolphthalein complexon (CPC) method. In an alkaline medium, calcium forms a violet complex with o-cresolphthalein, the intensity of the colour being directly proportional to the calcium concentration of the test sample.

REAGENT COMPOSITION

Reagent 1 Buffer Solution	2-Amino-2-methyl 1-Propanol	500 mmol/l
Reagent 2 Solution Chromogen	Cresolphthalein Complexon Hydroxy 8 quinoline	0.62 mmol/l 69 mmol/l
Reagent 3 Standard	Standard calcium	10 mg/dl 100 mg/l 2.5 mmol/l

SAFETY CAUTIONS

Biomaghreb reagents are intended for use by qualified personnel for in vitro use (do not pipette by mouth).

- Consult the current MSDS available on request or on www.biomaghreb.com.
- Check the integrity of the reagents before use.
- Disposal of waste: comply with the legislation in force.

For safety reasons, treat any specimen or reagent of biological origin as potentially infectious. Observe the applicable legislation.

REAGENT PREPARATION

Working Solution :

Mix 1 volume of reagent R1 with 1 volume of reagent R2.

SAMPLE PREPARATION

Serum or heparinized plasma.

Urine diluted 1/3 with distilled water, acidified to pH: 3.4 with diluted HCl.

PRESERVATION AND STABILITY

- Before opening: Until the expiry date indicated on the label of the box at +4°C.
- After opening (Working Solution) :
4 hours at 20 -25°C;
20 hours at 2-8°C.

ADDITIONAL EQUIPMENT

- Basic equipment of the medical analysis laboratory ;
- Spectrophotometer or Clinical Biochemistry Analyzer.

LIMITS

Use disposable plastic material for all handling. The presence in some detergents of chelating agents such as EDTA may in some cases prevent the formation of the color complex.

QUALITY CONTROL

External quality control program.

It is recommended to control in the following cases:

- At least one test per series.
- Change of reagent bottle.
- After maintenance work on the analyzer.

If a control value is outside the confidence limits, repeat the procedure using the same control.

Use normal and pathological control sera.

CALIBRATION

The standard of the kit (Reagent 3) or any calibrator connected to a method or reference material.

The frequency of calibration depends on analyzer performance and reagent storage conditions.

Recalibration is recommended in the following cases:

1. Changing the reagent lot ;
2. After maintenance work on the analyzer; and
3. Control values are outside the confidence limits.

LINEARITY

The method is linear up to 150 mg/l (3.75 mmol/l). If the concentration is high, dilute the sample 1/2 with 9 g/l NaCl. Multiply the result by 2.

PROCEDURE

Wavelength: 570 nm (550-590) ;

Temperature : 20 -25°C ;

Tank: 1 cm thick

Adjust the spectrophotometer zero on the reagent blank.

	Blank	Standard	Sample
Standard	--	20 µl	--
Sample	--	--	20 µl
Work Solution	1 ml	1 ml	1 ml

Mix and incubate 5 minutes at room temperature.
Read optical densities. Staining is stable for 1 hour.

CALCULATION

$$\text{Calcium} = \frac{\text{DO. Sample}}{\text{DO Standard}} \quad n = \text{standard Value}$$

n =100 mg/l;

n =10 mg/dl;

n =2,5 mmol/l.

REFERENCE VALUES

Serum	Newborns	7.5 - 12 mg/dl 1.87 - 3 mmol/l
	Children	10 -11 mg/dl 2.50 - 2.74 mmol/l
	Adults	9.0 - 10.6 mg/dl 2.25 - 2.65 mmol/l

Urine	Newborns	1 - 8 mg/kg/24h 0.025 - 0.2 mmol/kg/24h
	Children	2 - 6 mg/kg/24h 2.50 0.05 - 0.150 mmol/kg/24h
	Adults	150 - 300 mg/24h 3.75 - 7.5 mmol/24h

REFERENCES

Stern J., Lewis W.H.P., Clin. Chim. Acta 2, 576 (1957)



Manufacturer

Use by

In Vitro Diagnostic

Temperature
Limitation

Catalogue number

See insert

Store away from light

Sufficient

for < n > essais

Batch number