

# CALCIUM

|            |            |
|------------|------------|
| CA 0305 CH | 6 x 50 ml  |
| CA 0405 CH | 4 x 100 ml |
| CA 0505 CH | 4 x 125 ml |

## INTENDED USE

Reagent for quantitative in vitro determination of calcium in biological fluids.

## SUMMARY OF TEST

In human body, circulating calcium is used for several functions, in skeletal metabolism as well as in neuromuscular function and in hemostasis.

## PRINCIPLE OF THE METHOD

o-cresolphthalein complexone combines with calcium at alkaline pH to form a red-violet complex, the absorbance of which is measured at 575 nm. The reaction has high specificity and interference from magnesium is avoided, due to selective complexing agent.

## KIT COMPONENTS

### For in vitro diagnostic use only.

The components of the kit are stable until expiration date on the label at 15-25°C.

Keep away from direct light sources.

**CA R1**      **0305: 3 x 50 ml (liquid) blue cap**  
**0405: 2 x 100 ml (liquid) blue cap**  
**0505: 2 x 125 ml (liquid) blue cap**

Composition: AMP buffer 1 M pH 11.00, surfactant.

**CA R2**      **0305: 3 x 50 ml (liquid) red cap**  
**0405: 2 x 100 ml (liquid) red cap**  
**0505: 2 x 125 ml (liquid) red cap**

Composition: CPC 0.14 mM, 8-quinolinol 26 mM, HCl pH 1.20

**Standard:**      **calcium solution 10 mg/dl - 5 ml**

Store all components at 15-25°C.

## MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

## REAGENT PREPARATION

Mix equal quantities of both reagents R1 and R2.

Stability of working reagent: 14 days at 2-8°C and 7 days at room temperature, well closed.

Stability of unopened vials: up to expiration date on labels at 15-25°C.

Stability since first opening of vials: preferably within 60 days at 15-25°C.

## PRECAUTIONS

**CA R1: Warning.** Causes serious eye irritation (H319). Causes skin irritation (H315). Wear protective gloves. Eye protection (P280). IF ON SKIN: Wash with plenty of water (P302+P352). IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305+P351+P338). If eye irritation persists: get medical advice (P337+P313).

**CA R2:** It is not classified as hazardous.

**Standard:** It is not classified as hazardous.

## SPECIMEN

Serum (preferred), heparin plasma. Urine. Do not use citrate, oxalate and EDTA as anticoagulant.

Total calcium is stable 7 days at 2-8°C and for several months when frozen at -20°C.

Urine specimens should be collected in 20 to 30 ml of HCl 6M per 24/h specimen (1-2 ml for random urine) in order to prevent calcium salt precipitation.

Dilute sample urine 1:2 with redistilled water and multiply results by two.

## TEST PROCEDURE

Wavelength: 575 nm (allowed 570 ÷ 580 nm)  
Lightpath: 1 cm  
Temperature: 25, 30 or 37°C

| dispense: | blank | standard | sample |
|-----------|-------|----------|--------|
| reagent   | 3 ml  | 3 ml     | 3 ml   |
| water     | 50 µl | -        | -      |
| standard  | -     | 50 µl    | -      |
| sample    | -     | -        | 50 µl  |

Mix, incubate at 25, 30 or 37°C for 2 minutes.  
Read absorbances of standard (As) and samples (Ax) against reagent blank.

## RESULTS CALCULATION

serum/plasma sample:

calcium mg/dl = Ax/As x 10 (standard value)

urine sample:

calcium mg/dl = Ax/As x 10 x 2 (standard value and dilution factor)

24 hours urine sample:

calcium mg/24h = Ax/As x 10 x 2 x urine volume (standard value, dilution factor and diuresis in decilitres)

## EXPECTED VALUES

serum/plasma: 8.6 - 10.3 mg/dl (2.15 - 2.57 mmol/l)  
urine (men): up to 300 mg/24h (7.49 mmol/24h)  
urine (women): up to 250 mg/24h (6.24 mmol/24h)

Each laboratory should establish appropriate reference intervals related to its population.

## QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:

### QUANTINORM CHEMA

with normal or close to normal control values

### QUANTIPATH CHEMA

with pathological control values.

If required, a multiparametric, human based calibrator is available:

### AUTOCAL H

Please contact Customer Care for further information.

## TEST PERFORMANCE

### Linearity

the method is linear up to 20 mg/dl.

If the limit value is exceeded, it is suggested to dilute sample 1+9 with distilled water and to repeat the test, multiplying the result by 10.

### Sensitivity/limit of detection (LOD)

the limit of detection is 0.1 mg/dl.

### Interferences

no interference was observed by the presence of:

hemoglobin ≤ 350 mg/dl  
bilirubin ≤ 40 mg/dl  
lipids ≤ 400 mg/dl

### Precision

| intra-assay (n=10) | mean (mg/dl) | SD (mg/dl) | CV%  |
|--------------------|--------------|------------|------|
| sample 1           | 8.99         | 0.08       | 0.90 |
| sample 2           | 14.50        | 0.18       | 1.20 |

| inter-assay (n=20) | mean (mg/dl) | SD (mg/dl) | CV%  |
|--------------------|--------------|------------|------|
| sample 1           | 8.96         | 0.21       | 2.40 |
| sample 2           | 14.72        | 0.27       | 1.80 |

### Methods comparison

a comparison between Chema and a commercially available product gave the following results:

Calcium Chema = x  
Calcium competitor = y  
n = 96

y = 0.95x + 0.158 mg/dl      r<sup>2</sup> = 0.957

## WASTE DISPOSAL

This product is made to be used in professional laboratories.

P501: Dispose of contents according to national/international regulations.

## REFERENCES

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).

## MANUFACTURER

Chema Diagnostica

Via Campania 2/4

60030 Monsano (AN) - ITALY - EU








phone +39 0731 605064

fax +39 0731 605672

e-mail: mail@chema.com

website: http://www.chema.com

## SYMBOLS

|   |                                    |
|---|------------------------------------|
|  | in vitro diagnostic medical device |
|  | batch code                         |
|  | catalogue number                   |
|  | temperature limit                  |
|  | use-by date                        |
|  | caution                            |
|  | consult instructions for use       |