CALCIUM ASX

CA 0100 CH	2 x 50 ml
CA 0500 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 methabolism as well as in neuromuscular function and in hemostasis.

PRINCIPLE OF THE METHOD

Arsenazo(III) combines with calcium at slight acidic pH to form a blue complex, the absorbance of which is measured at 660 nm. The reaction has high specificity and interference from magnesium is avoided, due to pH.
For bichromatic analyzers, the reference wavelenght must be set at 700 nm.

KIT COMPONENTS

For in vitro diagnostic use only.
The components of the kit are stable until expiration date on the label.
Keep away from direct light sources.

CA ASX R1 **0100: 2 x 50 ml (liquid) blue cap**
0500: 4 x 125 ml (liquid) blue cap

Composition: arsenazo(III) 0.2 mM, Good's buffer 50 mM pH 6.8, stabilizers.

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

Use reagent ready to use.
Stability: 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

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

Serum (preferred), plasma heparinate. 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

Wavelenght:	660 nm (allowed 650 ÷ 660 nm)
Lightpath:	1 cm
Temperature:	25, 30 or 37°C

dispense:	blank	standard	sample
reagent	1 ml	1 ml	1 ml
water	10 µl	-	-
standard	-	10 µl	-
sample	-	-	10 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 0.2 mg/dl.

Interferences
no interference was observed by the presence of:

hemoglobin	≤ 450 mg/dl
bilirubin	≤ 50 mg/dl

Lipids interferences are possible performing readings at single wavelenght of 660 nm. To avoid interferences, perform a bichromatic reading at 660 / 700 nm.

Precision

intra-assay (n=10)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	8.89	0.10	1.10
sample 2	13.74	0.16	1.20

inter-assay (n=20)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	9.22	0.19	2.10
sample 2	14.04	0.23	1.70

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

Calcium ASX Chema = x
Calcium competitor = y
n = 97

$y = 0.98x + 0.17$ mg/dl $r^2 = 0.94$

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).
Clinical Chemistry vol. 38 N. 6 - 904-908 - (1992)

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SYMBOLS

IVD	*in vitro* diagnostic medical device
LOT	batch code
REF	catalogue number
	temperature limit
	use by date
	caution
	consult instructions for use

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