CALCIUM (Ca)

Colorimetric Method
RX SERIES

INTENDED USE

A calcium test system is a device intended for the quantitative *in vitro* determination of calcium concentration in serum, plasma or urine. This product is suitable for use on RX **series** instruments which includes the RX **daytona** and the RX **imola**.

Cat. No.		
CA 3871	R1. Arsenazo Reagent	9 x 51ml

GTIN: 05055273200904

CLINICAL SIGNIFICANCE [1,2]

Calcium is the most abundant mineral element in the body with about 99% in the bones primarily as hydroxyapatite. The remaining calcium is distributed between the various tissues and extracellular fluids. Calcium is involved in blood coagulation, neuromuscular conduction, excitability of skeletal and cardiac muscle and enzyme activation.

Serum calcium levels are believed to be controlled by parathyroid hormone and vitamin D. An imbalance in any of these modulators can lead to alterations of the body and serum calcium levels. Increases in serum PTH or vitamin D are usually associated with hypercalcemia, which may lead to multiple myeloma and other neoplastic diseases. Hypocalcemia may be observed in hypoparathyroidism, nephrosis and pancreatitis.

PRINCIPLE

Arsenazo III specifically binds to calcium forming a coloured complex at 660 nm.

Ca^{++} + Arsenazo III ——— Coloured complex

The amount of calcium present in the sample is directly proportional to the intensity of the coloured complex formed.

SAMPLE [3]

Serum/Plasma: (Lithium heparinzed)	DO NOT use sodium oxalate, EDTA or Sodium fluoride as anticoagulants, as they have been found to interfere. Serum is stable for 8 hours at room temperature or 24 hours when stored at +2°C to +8°C.
Urine:	It is recommended that urine is assayed within two hours of collection.

REAGENT COMPOSITION

Contents	Initial Concentration of Solutions
R1. Arsenazo III Reagent	
Sodium acetate	54.2 mmol/l pH 5.9
Arsenazo	approx. 250 µmol/l
Non-Reactive Stabilizers	

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Health and Safety Data Sheets are available on request.

Please dispose of all biological and chemical materials according to local guidelines.

The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

STABILITY AND PREPARATION OF REAGENTS

R1. Arsenazo Reagent
Reagent supplied ready for use. Stable up to the expiry date when stored at +15°C to +25°C.

MATERIALS PROVIDED

Arsenazo Reagent

MATERIALS REQUIRED BUT NOT PROVIDED

Randox Assayed Multi-sera Level 2 (Cat. No. HN 1530) and Level 3 (Cat. No. HE 1532)
Randox Calibration Serum Level 3 (Cat. No. CAL 2351)

PROCEDURE NOTES

To avoid the potential for reagent carryover, it is recommended that the testing order of the reagents is confirmed. Please consult the reagent carryover document available on www.randox.com under support and documentation - Reagent product inserts or by contacting Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

The Chemistry parameters for Randox Dedicated RX **series** Assays are predefined on the hard drive of the analyser PC. The required programs should be downloaded to the analyser software. Please note that the predefined chemistry parameters use SI units. If alternative units are required, these can be edited by the user. In this case, the technical range should be edited in accordance with the users selected units. All necessary instructions are encoded on the bar code. If the barcode cannot be read by the analyser, enter manually the series of numbers given beneath the barcode. If problems continue, contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 94451070.

Important Note

This assay may only be performed on analysers with a 660nm optical filter installed. Please contact Randox Technical Services for further details.

LIMITATIONS

Results should be interpreted taking into consideration patient clinical history, examination and other findings.

A number of substances cause physiological changes in serum, plasma, or urine analyte concentrations. Consult the listed reference for details on known potential interfering substances. However as with any clinical chemistry test you must be alert to the possible effect on results of unknown interferences from medications or endogenous substances. (4)

CALIBRATION

0.9% NaCl solution and Randox Calibration Serum Level 3 are recommended for calibration.

QUALITY CONTROL

Randox Assayed Multi-sera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check cleanliness of all equipment in use.
3. Check water, contaminants i.e. bacterial growth may contribute to inaccurate results.
4. Check reaction temperature.
5. Check expiry date of kit and contents.
6. Contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 94451070.

Quality control requirements should be determined in conformance with government regulations or accreditation requirements.

NORMAL VALUES(5)

Serum: 2.02 - 2.60 mmol/l (8.10 - 10.4 mg/dl)
Urine: 2.5-6.2 mmol/24 hours (100-249 mg/24hours)

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

The following performance characteristics were obtained using a RX **daytona** analyser.

SERUM

INTERFERENCE

The analytes below were tested up to the following levels and were found not to interfere:

Haemoglobin	1000 mg/dl
Free Bilirubin	25 mg/dl
Conjugate Bilirubin	25 mg/dl
Triglycerides	1000 mg/dl
Intralipid®	800 mg/dl

Gadodiamide (Omniscan: used in MR imaging) interferes with serum calcium causing low levels (6).

LINEARITY

This method is linear up to 4.3 mmol/l (17.24 mg/dl). In the event of a rerun, this is extended to 6.45 mmol/l (25.8 mg/dl).

SENSITIVITY

The minimum level of calcium detectable has been determined as 0.09 mmol/l (0.36 mg/dl).

PRECISION

Within run precision

	Level 1	Level 2	Level 3
Mean (mmol/l)	1.66	2.29	3.21
SD	0.03	0.04	0.12
CV (%)	2.00	1.90	3.60
n	88	87	88

Total precision

	Level 1	Level 2	Level 3
Mean (mmol/l)	1.66	2.29	3.21
SD	0.05	0.06	0.14
CV (%)	3.20	2.60	4.20
n	88	87	88

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

Y = 0.98 X - 0.03
and a correlation coefficient of r = 1.00

110 patient samples were analyzed spanning the range 0.31 to 4.27 mmol/l.

URINE

INTERFERENCE

The analytes below were tested up to the following levels and found not to interfere:

Bilirubin	30 mg/dl
Intralipid®	1000 mg/dl
Triglycerides	1000 mg/dl
Haemoglobin	1000 mg/dl

LINEARITY

This method is linear up to 5.91 mmol/l (23.69 mg/dl). In the event of a rerun, this is extended to 8.87 mmol/l (35.54 mg/dl).

SENSITIVITY

The minimum level of calcium detectable has been determined as 0.1 mmol/l (0.4 mg/dl).

PRECISION

Intra run precision

	Level 1	Level 2	Level 3
Mean (mmol/l)	1.57	2.16	4.02
SD	0.01	0.03	0.03
CV (%)	0.88	1.51	0.83
n	20	20	20

Inter run precision

	Level 1	Level 2	Level 3
Mean (mmol/l)	1.66	2.13	3.98
SD	0.07	0.06	0.09
CV (%)	4.35	2.99	2.16
n	20	20	20

CORRELATION

This method (Y) was compared with a Hitachi 717 method (X) and the following linear regression equation obtained:

Y = 1.02 X - 0.09
and a correlation coefficient of r = 0.99

78 patient samples were analyzed spanning the range 0.28 to 4.22 mmol/l.

REFERENCES

1. Tietz, N.W., Fundamentals of Clinical Chemistry 2nd ed. N.B. Saunders Co., Philadelphia (1976).
2. Michaylova, V., and Illkova, P., Anal Chem Acta, 53: **194** (1971).
3. Young, D. Pestaner L., Clin Chem. 21: **5** (1975).
4. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Washington, DC: AACC Press; 2000.
5. Barnett, R.N., *et al.* (1973) Amer. J. Clin. Path. **59:**836.
6. Prince *et al*, Radiology 2003; **227**: 639-646.

The presence of a vertical bar in the margin indicates a technical update from the previous revision.

EC REP

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