

Ca

Calcium

cobas®

● Indicates Roche/Hitachi analyzer(s) on which kit(s) can be used

Cat. No.	Bottle	Contents	902	904	911 912	917	MODULAR	
							P	D
11730240 216	1	REAGENT 6 x 63 mL				●	●	
	2	REAGENT 6 x 29 mL						
04580664 190	1	REAGENT 6 x 250 mL					●	●
04580699 190	2	REAGENT 6 x 112 mL						
11929801 216	1	REAGENT 4 x 653 mL						●
11929828 216	2	REAGENT 4 x 273 mL						
11489216 216	1	REAGENT 12 x 50 mL	●	●	●			
	2	REAGENT 6 x 43 mL						
11125621 216	1	REAGENT 7 x 100 mL		●	●			
	2	REAGENT 3 x 100 mL						

Some analyzers and kits shown may not be available in all countries. For additional system applications, contact your local Roche Diagnostics representative.

English

System Information

For Roche/Hitachi 904/911: ACN 043.

For Roche/Hitachi 912: ACN 431 (US code 180).

For Roche/Hitachi 917: ACN 706 (US codes 180, 521, 522); ACN 726.

For Roche/Hitachi MODULAR P: ACN 706; ACN 726 (not for US).

For Roche/Hitachi MODULAR D: ACN 726 (US code 706).

Other applications available on request:

For Roche/Hitachi 912: ACN 450 (not for US).

For Roche/Hitachi 917: ACN 298; ACN 749 (not for US).

Intended use

In vitro test for the quantitative determination of calcium in human serum, plasma and urine on Roche automated clinical chemistry analyzers.

Summary^{1,2,3,4,5}

The calcium content of an adult is somewhat over 1 kg (25000 mmol), i.e. about 2% of the body weight. Of this, 99% is present as calcium hydroxyapatite in bones and less than 1% is present in the extra-osseous ICS (intracellular space) or ECS (extracellular-space). The calcium level in the ECS (approx. 100 mmol) is in dynamic equilibrium with the rapidly exchangeable fraction of bone calcium. Calcium ions affect the contractility of the heart and the skeletal musculature and are essential for the function of the nervous system. In addition, calcium ions play an important role in blood clotting and bone mineralization. In plasma, calcium is bound to a considerable extent to proteins (approx. 40%), 10% is in the form of inorganic complexes and 50% is present as free (ionized) calcium. The body's calcium balance is regulated by the parathyroid hormone (PTH), calcitriol (CT) and calcitonin.

The test is used for the diagnosis and monitoring of hypocalcemia (calcium deficiency) and hypercalcemia (excess calcium) in serum. The characteristic symptom of hypocalcemia is latent or manifest tetany and osteomalacia. Hypocalcemia is due to the absence or impaired function of the parathyroid or impaired vitamin D-synthesis. Hypercalcemia is brought about by increased mobilization of calcium from the skeletal system (osteoporosis) or increased intestinal absorption. The majority of cases are due to primary hyperparathyroidism (pHPT) or bone metastasis of carcinoma of the breast, prostate or thyroid and bronchial carcinoma.

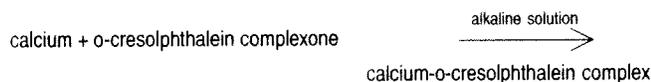
The main significance of determining urinary calcium lies in the differentiation between hypercalciuria and hypocalciuria and the differential diagnosis of nephrolithiasis.

Complexometric methods are used in addition to atomic absorption spectrometry (AAS) for determining calcium. The following calcium determination is based on the reaction of calcium with o-cresolphthalein complexone in alkaline solution. Magnesium is masked with 8-hydroxyquinoline.

Test principle⁵

Colorimetric assay with endpoint determination and sample blank

- Sample and addition of R1 (buffer)
- Addition of R2 (chromogen) and start of reaction:



The color intensity of the purple complex formed is directly proportional to the calcium concentration and is measured photometrically.

Reagents – working solutions

R1 Ethanolamine buffer: 1 mol/L, pH 10.6

R2 o-cresolphthalein complexone: 0.3 mmol/L; 8-hydroxyquinoline: 13.8 mmol/L; hydrochloric acid: 122 mmol/L

Precautions and warnings

For in vitro diagnostic use.

Exercise the normal precautions required for handling all laboratory reagents.

This kit contains components classified as follows according to the European directive 88/379/EEC.

Xi – Irritant (bottle 1 contains ethanolamine).

R 36/37/38; S 26, S 36/37/39, S 45

Irritating to eyes, respiratory system and skin. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable protective clothing, gloves and eye/face protection. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

For US users: Warning. Bottle 1 contains ethanolamine and Bottle 2 contains hydrochloric acid; corrosive. In the event of contact, flush affected areas with copious amounts of water. Get immediate attention for eyes, or if ingested.

Contact phone: all countries: +49-621-7590, USA: +1-800-428-2336

Safety data sheet available for professional user on request.

Disposal of all waste material should be in accordance with local guidelines.

Reagent handling

R1: Ready for use

R2: Ready for use

Storage and stability

Unopened kit components: Up to the expiration date at 15–25°C

R1: 42 days opened and refrigerated on the analyzer

R2: 90 days opened and refrigerated on the analyzer

Please note reduced on-board stability for additional applications available on request:

ACN 450 for Roche/Hitachi 912:

R1: 3 days opened and refrigerated on the analyzer

R2: 14 days opened and refrigerated on the analyzer

ACN 298 and ACN 749 for Roche/Hitachi 917:

R1: 3 days opened and refrigerated on the analyzer

R2: 3 days opened and refrigerated on the analyzer

Specimen collection and preparation

For specimen collection and preparation, only use suitable tubes or collection containers.



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Only the specimens listed below were tested and found acceptable.

Serum

Plasma: Heparin plasma.

Do not use oxalate, EDTA or citrate plasma.

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Stability:⁶ 7 days at 15–25°C
3 weeks at 2–8°C
8 months at (-15)–(-25)°C

Urine: 24-hour urine: Place 10 mL hydrochloric acid (6 mol/L) in a collection bottle, or acidify (pH < 2.0) after urine collection, in order to dissolve calcium salts.⁷

Stability:⁶ 2 days at 15–25°C
4 days at 2–8°C
3 weeks at (-15)–(-25)°C

Centrifuge samples containing precipitates before performing the assay.

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

- Calibrator: C.f.a.s. (Calibrator for automated systems), Cat. No. 10759350
- Controls: Precinorm U, e.g. Cat. No. 10171743, or Precinorm U plus, Cat. No. 12149435; Precipath U, e.g. Cat. No. 10171778, or Precipath U plus, Cat. No. 12149443
- Chimneys, Cat. No. 11930630
- 0.9% NaCl
- General laboratory equipment

Assay

For optimal performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator manual for analyzer-specific assay instructions.

The performance of applications not validated by Roche is not warranted and must be defined by the user.

Calibration

Absorption of atmospheric CO₂ by the opened reagent bottle R1 leads to impaired calibration stability. This kit therefore requires the use of color-coded chimneys which reduce the uptake of CO₂ by the reagents. The chimneys should be placed directly into the appropriate reagent(s): white for R1. The chimneys can be reused for reagent bottles within the same kit. Chimneys are used on all systems.

Traceability: This method has been standardized by atomic absorption spectrometry.

For the USA, this method has been standardized against SRM 909b (IDMS).

S1: 0.9% NaCl

S2: C.f.a.s. (Calibrator for automated systems)

Calibration frequency

Two-point calibration is recommended:

- every 3 days if the reagent bottles are onboard the analyzer for more than 3 days
- after reagent bottle change if the previous bottles were onboard the analyzer for more than 3 days
- after reagent lot change
- as required following quality control procedures

Quality control

Serum/plasma

For quality control use the control material as listed in the "Materials required" section. Other suitable control material can be used in addition.

Urine

Use suitable control material.

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The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Calculation

The analyzer automatically calculates the analyte concentration of each sample.

Conversion factors: mmol/L x 4.01 = mg/dL
mg/dL x 0.249 = mmol/L

In studies with 24-hour urine, multiply the value obtained by the 24-hour volume in order to obtain a measurement in mg/24 h or mmol/24 h.

Limitations – interference^{8,9}

Criterion: Recovery within ±10% of initial value.

Serum/plasma

Icterus: No significant interference up to an I index of 60 (approximate conjugated and unconjugated bilirubin concentration: 60 mg/dL or 1026 µmol/L).

Hemolysis: No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 1000 mg/dL or 621 µmol/L).

Lipemia (Intralipid): No significant interference up to an L index of 1000. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Drugs containing strontium salts may lead to significantly increased calcium results.

Intravenously administered contrast media for MRI (magnetic resonance imaging) contain chelating complexes which may interfere with the determination of calcium. A sharp decrease in calcium values was observed when gadodiamide (GdDTPA-BMA) was administered. Follow the instructions of the manufacturer with regard to the retention time of the contrast medium. In very rare cases gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Urine

Drugs containing strontium salts may lead to significantly increased calcium results.

Measuring range

Serum/plasma

Roche/Hitachi MODULAR analyzers

0.05–5.00 mmol/L (0.2–20 mg/dL)

Other Roche/Hitachi analyzers

Measuring range: 0.05–4.00 mmol/L (0.2–16 mg/dL)

Determine samples having higher concentrations via the rerun function.

On instruments without rerun function, manually dilute with 0.9% NaCl or distilled/deionized water (e.g. 1 + 1). Multiply the result by the appropriate dilution factor (e.g. 2).

Calculated extended ranges:

Roche/Hitachi MODULAR analyzers

Up to 8.75 mmol/L (35 mg/dL)

Roche/Hitachi 917 analyzer

Up to 7.0 mmol/L (28 mg/dL)

Roche/Hitachi 904/911/912 analyzers

Up to 8.0 mmol/L (32 mg/dL)

Urine

Roche/Hitachi MODULAR analyzers

Measuring range: 0.12–12 mmol/L (0.48–48 mg/dL)

Roche/Hitachi 917 analyzer

Measuring range: 0.12–9.25 mmol/L (0.48–37 mg/dL)

Measuring range: 0.12–8.0 mmol/L (0.48–32 mg/dL) (US users only)

Roche/Hitachi 902/904/911/912 analyzers

Measuring range: 0.12–8.0 mmol/L (0.48–32 mg/dL)

Determine samples having higher concentrations via the rerun function.

On instruments without rerun function, manually dilute with 0.9% NaCl or distilled/deionized water (e.g. 1 + 1). Multiply the result by the appropriate dilution factor (e.g. 2).

Calculated extended ranges:

Roche/Hitachi MODULAR analyzers



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Roche/Hitachi 902

No.	<Chemistry>	Serum/Plasma	Urine
1	Test Name	CA	
2	Assay Code (Mthd)	2 Point End	
3	Assay Code (2. Test)	0	
4	Reaction Time	5	
5	Assay Point 1	5	
6	Assay Point 2	17	
7	Assay Point 3	0	
8	Assay Point 4	0	
9	Wavelength (SUB)	700	
10	Wavelength (MAIN)	600	
11	Sample Volume	10.0	5.0
12	R1 Volume	250	
13	R1 Pos.	
14	R1 Bottle Size	Large	
15	R2 Volume	100	
16	R2 Pos.	
17	R2 Bottle Size	Large	
18	R3 Volume	0	
19	R3 Pos.	0	
20	R3 Bottle Size	Large	
21	Calib. Type (Type)	Linear	
22	Calib. Type (Wght)	0	
23	Calib. Conc. 1	0.00	
24	Calib. Pos. 1	
25	Calib. Conc. 2	
26	Calib. Pos. 2	
27	Calib. Conc. 3	0	
28	Calib. Pos. 3	0	
29	Calib. Conc. 4	0	
30	Calib. Pos. 4	0	
31	Calib. Conc. 5	0	
32	Calib. Pos. 5	0	
33	Calib. Conc. 6	0	
34	Calib. Pos. 6	0	
35	S1 ABS	0	
36	K Factor	10000	
37	K2 Factor	10000	
38	K3 Factor	10000	
39	K4 Factor	10000	
40	K5 Factor	10000	
41	A Factor	0	
42	B Factor	0	
43	C Factor	0	
44	SD Limit	0.1	
45	Duplicate Limit	290	150
46	Sens. Limit	2100	1200
47	S1 Abs. Limit (L)	500	
48	S1 Abs. Limit (H)	4000	
49	Abs. Limit	0	
50	Abs. Limit (D/I)	Increase	
51	Prozone Limit	32000	
52	Proz. Limit (Upp/Low)	Upper	
53	Prozone (Endpoint)	35	
54	Expect. Value (L)	
55	Expect. Value (H)	
56	Instr. Fact. (a)	1.0	
57	Instr. Fact. (b)	0.0	
58	Key setting	

For further information please refer to the appropriate operator manual for the analyzer concerned, the respective application sheets, the product information and the package inserts of all necessary components.

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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