Tài liệu hướng dẫn sử dụng tiếng Anh của trang thiết bị y tế

Tài liệu được xác nhận bằng chữ ký số

Hà Nội, ngày 27 tháng 10 năm 2022

Người đại diện hợp pháp của cơ sở

GIÁM ĐỐC

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Calcium
CPC

Diagnostic reagent for quantitative in vitro determination of calcium in human serum, plasma or urine on photometric systems

Reagents with ATCS*

REF	Kit Size	Configuration
D03108B	1 x 1.25 L	1 x 1 L R1 + 1 x 0.25 L R2
D99097	5 x 100 mL	4 x 100 mL R1 + 1 x 100 mL R2
D95098	5 x 50 mL	4 x 50 mL R1 + 1 x 50 mL R2
D00102	5 x 25 mL	4 x 25 mL R1 + 1 x 25 mL R2
D00100	5 x 10 mL	4 x 10 mL R1 + 1 x 10 mL R2
D60911	10 x 50 mL	10 x 40 mL R1 + 4 x 25 mL R2
D0413917	5 x 62.5 mL	4 x 62.5 mL R1 + 1 x 62.5 mL R2
DA0812	5 x 50 mL	5 x 40 mL R1 + 5 x 10 mL R2
DT1012	4 x 62.5 mL	4 x 50 mL R1 + 4 x 12.5 mL R2
DK0711	5 x 50 mL	4 x 50 mL R1 + 1 x 50 mL R2
DE1812	2 x 62.5 mL	2 x 50 mL R1 + 2 x 12.5 mL R2
DB20309	4 x 62.5 mL	4 x 50 mL R1 + 4 x 12.5 mL R2

* Advanced Turbidity Clearing System; minimizes turbidity caused by lipemia.

Additionally available:

D95094	1 x 3 mL	Calcium Standard	
D98485	5 x 3 mL	Calibrator	Diacal Auto
D98485SV	1 x 3 mL	Calibrator	Diacal Auto
D98481	12 x 5 mL	Control normal	Diacon N
D14481	5 x 5 mL	Control normal	Diacon N
D98481SV	1 x 5 mL	Control normal	Diacon N
D98482	12 x 5 mL	Control abnormal	Diacon P
D14482	5 x 5 mL	Control abnormal	Diacon P
D98482SV	1 x 5 mL	Control abnormal	Diacon P
D08581	12 x 5 mL	Urine Ctrl. normal	Diacon Urine Level 1
D08581SV	1 x 5 mL	Urine Ctrl. normal	Diacon Urine Level 1
D08582	12 x 5 mL	Urine Ctrl. abnormal	Diacon Urine Level 2
D08582SV	1 x 5 mL	Urine Ctrl. abnormal	Diacon Urine Level 2

For professional in vitro diagnostic use only.

GENERAL INFORMATION

Method	Colorimetric, endpoint, increasing reaction, CPC
Wavelength	570 nm (550 – 590 nm), Hg 578 nm
Temperature	20 – 25 °C, 37 °C
Sample	Serum or heparin plasma (do not use EDTA plasma), acidified urine

INTENDED USE
Diagnostic reagent for quantitative in vitro determination of calcium in human serum, plasma or urine on photometric systems.

DIAGNOSTIC SIGNIFICANCE [1, 2]
Calcium plays an essential role in many cell functions: intracellularly in muscle contraction and glycogen metabolism, extracellularly, in bone mineralization, in blood coagulation and in transmission of nerve impulses. Calcium is present in plasma in three forms free, bound to proteins or complexed with anions as phosphate, citrate and bicarbonate. Decreased total calcium levels can be associated with diseases of the bone apparatus (especially osteoporosis), kidney diseases (especially under dialysis), defective intestinal absorption and hypoparathyroidism. Increased total calcium can be measured in hyperparathyroidism, malignant diseases with metastases and sarcoidosis. Calcium measurements also help in monitoring of calcium supplementation mainly in the prevention of osteoporosis.

TEST PRINCIPLE
Cresolphtalein complexone (CPC) reacts with calcium ions in alkaline solution forming a red-violet colour. The intensity of the violet color is proportional to the calcium concentration in the sample.
Interference by magnesium is eliminated by addition of 8-hydroxy-quinoline.

REAGENT COMPOSITION

COMPONENTS		CONCENTRATION	
Reagent 1	pH 10.7		
Ethanolamine		750	mmol/L
Reagent 2	pH 1.1		
2-Cresolphtalein complexone		0.13	mmol/L
8-Hydroxychinoline		35	mmol/L
Hydrochloric acid		100	mmol/L

MATERIAL REQUIRED BUT NOT PROVIDED
- NaCl solution (9 g/L).
- Clinical chemistry analyser.

REAGENT PREPARATION
Substrate Start:
Reagents are ready to use.

Sample Start:
Mix 4 parts of Reagent 1 with 1 part of Reagent 2.
(= working reagent)

STORAGE AND STABILITY
Conditions: Close immediately after use, otherwise the pH decreases because of CO2 absorption from the air.
Do not freeze the reagent.
Avoid contamination.

Substrate Start:
Storage: at 2 – 8 °C
Stability: up to the expiration date
Sample Start (Working Reagent):
Stability in closed vials: at 2 – 8 °C 3 days
at 15 – 25 °C 3 days

WARNINGS AND PRECAUTIONS
1. Reagent 1: Danger

H315: Causes skin irritation.
H318: Causes serious eye damage.
P102: Keep out of reach of children.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352: IF ON SKIN: Wash with plenty of water/soap.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313: If skin irritation occurs: Get medical advice/attention.
P362: Take off contaminated clothing and wash before reuse.
Special labelling: Contains Ethanolamine.

2. Reagent 2: Warning

H290: May be corrosive to metals.
P234: Keep only in original container.
P390: Absorb spillage to prevent material damage.

3. As calcium is an ubiquitous ion, essential precaution must be taken against accidental contamination. Only use disposable materials.
4. In very rare cases, samples of patients with gammopathy might give falsified results [7].
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
6. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
7. For professional use only!

SPECIMEN COLLECTION AND STORAGE
Sample preparation (Urine): add 10 ml of concentrated HCl to 24 h Urine and heat the specimen to dissolve calcium oxalate.

Do not use EDTA plasma.

Stability [5]:

In serum/plasma	at 20 – 25 °C	7 days
	at 4 – 8 °C	3 weeks
	at - 20 °C	8 months
In urine:	at 20 – 25 °C	2 days
	at 4 – 8 °C	4 days
	at - 20 °C	3 weeks

Discard contaminated specimens. Freeze only once!

STANDARD
(not included in the kit; has to be ordered separately)
Concentration 10 mg/dL (2.5 mmol/L)
Storage: 2 – 8 °C
Stability: up to the indicated expiration date
Protect from light! Close immediately after use!

TEST PROCEDURE
Bring reagents and samples to room temperature.
Note: For measurement of coloured or lipemic samples use substrate start.

Substrate Start:

Pipette into test tubes	Blank	Std./Cal.	Sample
Sample	-	-	20 µL
Std./Cal.	-	20 µL	-
Dist. water	20 µL	-	-
Reagent 1	1000 µL	1000 µL	1000 µL
Mix and read absorbance A1 against reagent blank after 5 - 30 min. at 20 – 25 °C / 37 °C.Then add:			
Reagent 2	250 µL	250 µL	250 µL
Mix and read absorbance A2 against reagent blank after 5 - 30 min. at 20 – 25 °C / 37 °C. ΔA = (A2 – A1) sample or Std./Cal.			

Sample Start:

Pipette into test tubes	Blank	Std./Cal	Sample
Sample	-	-	20 µl
Std./Cal.	-	20 µl	-
Dist. water	20 µl	-	-
Working Reagent	1000 µl	1000 µl	1000 µl
Mix and read absorbance against reagent blank after 5 - 30 min at 20 – 25 °C / 37 °C.			

Automation
Special adaptations for automated analysers can be made on request.

INTERPRETATION OF RESULTS
Calculation

$$\text{Calcium [mg/dL]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std./Cal.}} \times \text{Conc. Std./Cal.[mg/dL]}$$

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Unit Conversion
Calcium [mg/dL] x 0.2495 = Calcium [mmol/L]
Calcium (urine) [mg/24h] x 0.025 = Calcium (urine) [mmol/24h]

QUALITY CONTROL AND CALIBRATION

All controls with Calcium values determined by this method can be used.
We recommend the Dialab serum controls **Diacon N** (control serum with values in the normal range) and **Diacon P** (control serum with values in the abnormal range) as well as the Dialab urine controls **Diacon Urine Level 1** (control urine normal) and **Level 2** (control urine abnormal).
Each laboratory should establish corrective action in case of deviations in control recovery.

Calibration
The assay requires the use of a Calcium Standard or a Calcium Calibrator.
We recommend the Dialab Calcium Standard and the Dialab multi calibration serum Diacal Auto.

PERFORMANCE CHARACTERISTICS

LINEARITY, MEASURING RANGE

The test has been developed to determine calcium concentrations within a measuring range from 0.2 – 20 mg/dL (0.05 – 5.0 mmol/L). When values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and re-assayed multiplying the result by 2.

SENSITIVITY/LIMIT OF DETECTION

The lower limit of detection is 0.2 mg/dL (0.05 mmol/L).

PRECISION (at 37 °C)

Intra-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	6.18	0.05	0.84
Sample 2	9.94	0.10	1.02
Sample 3	13.5	0.11	0.81

Inter-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	6.31	0.09	1.38
Sample 2	10.1	0.10	1.04
Sample 3	13.4	0.08	0.63

SPECIFICITY/INTERFERENCES

No interference up to:

Ascorbic acid	30 mg/dL
Bilirubin	40 mg/dL
Hemoglobin	500 mg/dL
Triglycerides	2000 mg/dL
Magnesium	15 mg/dL

Strontium salts in medicine may lead to strongly increased calcium values.
For further information on interfering substances refer to Young DS [6].

METHOD COMPARISON

A comparison between Dialab Calcium (y) and a commercially available test (x) using 82 samples gave following results: y = 0.98 x + 0.11 mg/dL; r= 0.999.

TRACEABILITY

This method has been standardized against the reference method Atomic Absorption Spectrometry (AAS).

EXPECTED VALUES

Serum/plasma [2]:	mg/dL	mmol/L
	8.6 - 10.3	2.15 – 2.57
Urine [1]:	mg/24h	mmol/24h
Females:	< 250	< 6.24
Males:	< 300	< 7.49

* Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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