DIAGNOSTICA PRODUCTS

Liquid Reagent – ready to use

CALCIUM

Arsenazo with ATCS*

Single Reagent

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

Ref.No.	Kit Size	Content
DIA010032	5 x 25 ml	Single Reagent
DIA010033	5 x 50 ml	Single Reagent
DIA010034	5 x 100 ml	Single Reagent

Additionally offered:

DIA060060	1 x 3 mL	**Calcium STANDARD**
DIA040012	1 x 3 mL	**Diacal Auto** (Calibrator)
DIA030012	1 x 5 mL	**Diacon N** (Control Normal)
DIA030022	1 x 5 mL	**Diacon P**(Control Abnormal)
DIA030030	1 x 5 mL	**Diacon Urine Level 1** (Control Normal)
DIA030035	1 x 5 mL	**Diacon Urine Level 2** (Control Abnormal)

* **A**dvanced **T**urbidity **C**learing **S**ystem; minimzes turbidity caused by lipemia.

TEST PARAMETERS

Method: Colorimetric, Endpoint, increasing reaction, Arsenazo III.

Wavelength: 650 nm, Hg 623 nm, (630 – 670 nm).

Temperature: 20 – 25 °C, 37 °C

Sample: Serum, heparin plasma or urinedo not use EDTA plasma.

Linearity: up to 20 mg/dL (5 mmol/L)

Sensitivity: The lower limit of detection 0.04 mg/dL (0.01 mmol/L)

REAGENT COMPOSITION

COMPONENTS	CONCENTRATION	
Phosphate buffer, pH 7.5	50	mmol/L
8–Hydroxyquinoline-5-sulfonic acid	5	mmol/L
Arsenazo III	120	µmol/L
Detergents		

REAGENT PREPARATION

The reagent is ready for use.

MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution (9 g/L)
General laboratory equipment

REAGENT STABILITY AND STORAGE

Conditions: Close immediately after use
Avoid contamination
Do not freeze the reagent.
Storage: at 2 – 8 °C
Stability: up to the indicated expiration date

SAMPLE PREPARATION

Urine: add 10 ml of concentrated HCl to 24 h Urine and heat the specimen to dissolve calcium oxalate.

SAMPLE STABILITY AND STORAGE [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 – 25 °C
Stability: up to the indicated expiration date
CLOSE IMMEDIATELY AFTER USE!

INTERFERING SUBSTANCES

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 [5].

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Pipette into test tubes	Blank	Std./Cal.	Sample
Reagent	1000 µL	1000 µL	1000 µL
Sample	-	-	10 µL
Std./Cal.	-	10 µL	-
Dist. water	10 µL	-	-
Mix, Incubate for 5 minutes at 20 – 25 °C / 37 °C and read absorbance against reagent blank.			

CALCULATION

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

UNIT CONVERSION

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

REFERENCE RANGE [4] *

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.

DIAGNOSTIC IMPLICATION [1,2]

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 halp in monitoring of calcium supplementation mainly in the prevention of osteoporosis.

TEST PRINCIPLE

At neutral pH, calcium forms a blue coloured complex with arsenazo III. The intensity of the colour is proportional to the calcium concentration. Interference by magnesium is eliminated by addition of 8-hydroxyquinoline-5-sulfonic acid.

PERFORMANCE CHARACTERISTICS

LINEARITY

The test has been developed to determine calcium concentrations

DIAGNOSTICA PRODUCTS, RTE DE GABES KM 9 Z.I THYNA AL JADIDA SFAX, TUNISIA.
Tel. +216 74 68 79 40 Fax. +216 74 68 79 32

REV. 01,
23.10.2017

within a measuring range from 0.04 – 20 mg/dL (0.01 – 5 mmol/L). When values exceed this range samples should be diluted 1+1 with NaCl solution (9 g/L) and the results multiplied by 2.

PRECISION (at 20 – 25 °C)

Intra-assay n = 20	**Mean [mg/dL]**	**SD [mg/dL]**	**CV [%]**
Sample 1	8.79	0.09	1.04
Sample 2	12.5	0.15	1.20
Sample 3	14.0	0.24	1.73

Inter-assay n = 20	**Mean [mg/dL]**	**SD [mg/dL]**	**CV [%]**
Sample 1	8.82	0.18	2.01
Sample 2	12.3	0.11	0.90
Sample 3	13.7	0.26	1.92

METHOD COMPARISON

A comparison of Diagnostica Calcium (y) with a commercially available assay (x) using 70 samples gave following results:
y = 1.02 x – 0.20 mg/dL; r = 0.999.

QUALITY CONTROL

All control sera with Calcium values determined by this method can be used.
We recommend the Diagnostica 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 Diagnostica 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 Diagnostica **Calcium Standard** and the Diagnostica multi calibration serum **Diacal Auto**.
This method has been standardized against the reference method Atomic Absorption Spectrometry (AAS).

AUTOMATION

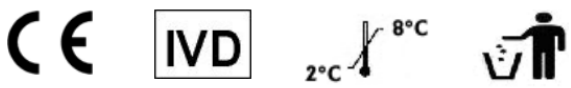
Special adaptations for automated analyzers can be made on request.

WARNINGS AND PRECAUTIONS

1. As calcium is an ubiquitous ion, essential precaution must be taken against accidental contamination. Only use disposable materials.
2. Traces of chelating agent, such as EDTA can prevent the formation of the coloured complex.
3. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
4. In very rare cases, samples of patients with gammopathy might give falsified results.
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.

WASTE MANAGEMENT

Please refer to local legal requirements.



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