



Ca Reagent Kit (Arsenazo III Colorimetric Method)

Instructions for Use

REF CC1017

PRODUCT NAME

Ca Reagent Kit (Arsenazo III Colorimetric Method)

PACKAGE SPECIFICATION

R: 1×10 mL	R: 1×20 mL	R: 1×50 mL	R: 2×30 mL
R: 2×35 mL	R: 2×40 mL	R: 2×45 mL	R: 2×50 mL
R: 2×55 mL	R: 2×60 mL	R: 4×20 mL	R: 4×30 mL
R: 4×35 mL	R: 4×40 mL	R: 4×45 mL	R: 4×50 mL
R: 4×55 mL	R: 4×60 mL	R: 5×20 mL	R: 6×20 mL
R: 6×30 mL	R: 6×35 mL	R: 6×40 mL	R: 6×45 mL
R: 6×50 mL	R: 6×55 mL	R: 6×60 mL	R: 8×20 mL
R: 10×20 mL	R: 6×100 mL	R: 5×120 mL	R: 1×1000 mL
R: 1×2000 mL	2×300 T (R: 2×100 mL)	12×72 T (R: 12×25 mL)	Calibrator (optional): 1×1 mL

INTENDED USE

This test kit is intended for the *in vitro* quantitative determination of calcium in human serum, plasma and urine and it is mainly used clinically for the auxiliary diagnosis of disorders of calcium metabolism. For professional and laboratory use only.

TEST PRINCIPLE

Calcium ions react with Arsenazo III to form a blue-purple colored Calcium–Arsenazo III complex, which has an absorbance peak at a wavelength of 660 nm. Within a certain range, the absorbance (ΔA) of the reaction mixture is directly proportional to the calcium concentration in the sample.

MAIN COMPONENTS

Kit composition	Reagent components	Content
Reagent	Arsenazo III	0.5 g/L
	Phosphate buffered saline (pH 7.0)	6.3882 g/L
Calibrator (optional)	Calcium chloride and an aqueous matrix	2.0-2.5 mmol/L

The components in different batches of a multi-component kit are not interchangeable.

Calibrator traceability: Traceable to international Standard Reference Material (SRM) 909c.

STORAGE AND SHELF LIFE

Unopened reagents should be stored at 2°C-8°C away from light, with a shelf life of 18 months. Opened reagents are stable for 42 days when stored at 2°C-8°C.

Please refer to the label on the reagent kit for the production date and expiration date.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from

Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000F01, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc. models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480.

If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

Fasting is required before sample collection. Serum should be separated from blood cells after sample collection as soon as possible to avoid hemolysis.

Serum or plasma calcium is stable for 7 days at 15-25°C, 3 weeks at 2-8°C and 8 months at -20°C.

TEST PROCEDURE

- The single reagent is ready for use and no preparation is required.
- Test conditions: (System parameters of the applicable instruments are available upon request from our company.)

Primary/Secondary Wavelength	660nm/700 nm	Calibration Type	Linearity
Sample: Reagent Ratio	3/300 μ L	Time of Mixture of Serum+R1	5 min
Method	One-point end assay	Total Reaction Time	5 min
Calibration Method	Two-point calibration	Direction	Upward

(Absorbance (A) read by the instrument = $A_{\text{Primary Wavelength}} - A_{\text{Secondary Wavelength}}$)

Operating procedures:

Single reagent

Substances Added	Test Tube	Standard Tube	Blank Tube
Reagent	300 μ L	300 μ L	300 μ L
Sample	3 μ L	-	-
Standard Solution	-	3 μ L	-
Distilled Water	-	-	3 μ L

Mix well, incubate at 37°C for 5 min, and read the absorbance (A) of the standard and test tubes against the blank tube.

- Calibration procedure: A calibrator from Getein is recommended, and a calibration serum from Randox can also be used.
- Quality control procedure: Select quality control serum from Randox, and its measured value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:
 - 4.1 Check whether the parameter settings and light source are correct.
 - 4.2 Check whether the cuvettes and sample probes are clean.
 - 4.3 Check whether water is contaminated, and bacterial growth will cause incorrect results.
 - 4.4 Check reaction temperature.
 - 4.5 Check the expiration date of the kit.

5.Result calculation

Calcium Concentration (mmol/L) = Concentration of Calcium Standard Reference Material (SRM) $\times \Delta A_{\text{test sample}} / \Delta A_{\text{SRM}}$

REFERENCE RANGE

2.0 - 2.5 mmol/L (8.0 - 10 mg/dL)

The above reference range is only a guideline. Each laboratory should establish its own reference range.

RESULT INTERPRETATION

Since hemolysis interferes with determination, it should be avoided as much as possible during operation. The time period between sample collection and tests may also affect the measurement results.

LIMITATIONS

There is no interference with measurement when hemoglobin is ≤ 500 mg/dL, ascorbic acid ≤ 60 mg/dL, bilirubin ≤ 80 mg/dL, and triglycerides ≤ 450 mg/dL.

PERFORMANCE CHARACTERISTICS

- Appearance
Reagent in the kit is a clear dark purple liquid, which may contain a small number of insoluble particles that do not affect determination.
- Reagent blank absorbance
Reagent blank absorbance $A_{660nm} \leq 0.500$.
- Accuracy
The relative deviation should not fall outside the range of $\pm 5.0\%$.
- Linear range
For serum sample testing within the reagent linear range of [0.50, 4.00] mmol/L:
a) The linear correlation coefficient (r) should not be less than 0.990;
b) The deviation from linearity should not fall outside the range of $\pm 10\%$ for testing within the linear range.
- Analytical sensitivity
When a sample has a concentration of 2.5 mmol/L, its absorbance difference should be ≤ 0.630 .
- Precision
 - Repeatability
Repeatability (coefficient of variation, CV) should be $\leq 3.0\%$.
 - Between-run precision
Between-run precision should be $\leq 5.0\%$.

PRECAUTIONS

- General precautions
 - This product is for *in vitro* diagnostic use only.
 - For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
 - Please use this product according to the IFU.
- Precautions for operation
 - Treat the specimens as dangerous materials that may cause infection with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
 - If the reagents get into the eyes or mouth, or touch the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
- Precautions for use
 - Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
 - Please do not use expired reagents whose test results may be inaccurate.
 - Please avoid adding reagents halfway during a test.
 - Please avoid direct sunlight during operation.
 - Do not use the reagents with visible signs of turbidity.
- Precautions for waste disposal
Samples, waste liquids, etc. are potentially biologically hazardous. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
- Other precautions
 - On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
 - The amounts of the reagent and sample can be changed proportionally according to the requirements

of different instruments.

5.3 Please do not use the reagent bottles for other purposes.

5.4 Glassware should be thoroughly washed to avoid contamination caused by traces of calcium.

5.5 A result calculated with the k value is not as reliable as that obtained using the SRM (calibrator).
















5.6 Please do not mix reagents in different batches.

REFERENCE

Shang Hong, et al. National Standard Operating Procedure for Clinical Testing (4th Edition). People's Medical Publishing House, 2015: 255-257.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Ca Reagent Kit (Arsenazo III Colorimetric Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date		Catalogue number
	Date of manufacture		Batch code		Temperature limit
	<i>In vitro</i> diagnostic medical device		Keep away from sunlight		Biological risks
	Consult <i>instructions for use</i> or consult <i>electronic instructions for use</i>		Do not use if package is damaged and consult <i>instructions for use</i>		Authorized representative
	CE mark		This way up		Do not re-use



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