Calcium

CYPRESS DIAGNOSTICS

CE

IVD

Arsenazo III. Colorimetric.
Monoreagent
Liquid

Store at 2-8 °C

Configuration

REF	HB0030	HB0030A	HB0030M
VOL	2 x 125 mL	8 x 125 mL	8 x 30 mL
Reagent	2 x 125 mL	8 x 125 mL	8 x 30 mL
Standard	1 x 5 mL	4 x 5 mL	-
Instrument	Universal	Universal	Mindray BS-120, BS-200, BS-200E, BS-230, BS-240, BS-240 Pro

Intended use

The Cypress Diagnostics Calcium kit is an in vitro diagnostic medical device intended to be used by healthcare professionals for the quantitative measurement of calcium in human serum or plasma.
The measurement of calcium is intended to be used for the screening for, aid in diagnosis and monitoring of a range of medical conditions causing hypocalcemia or hypercalcemia.
For *in vitro* diagnostic use only. For professional use only.

Clinical significance

More than 99% of body calcium exists in bones and teeth. The remaining 1% is present in blood and soft tissues and serves as a cofactor in blood coagulation, metabolism and neuromuscular physiology. Many factors influence serum calcium levels: hypercalcemia (increased serum calcium) is observed in hyperparathyroidism, hypervitaminosis, sarcoidosis, myeloma and certain cancers of the bone. Hypocalcemia (decreased serum calcium) is encountered in hypoparathyroidism, rickets, nephrosis, nephritis, steatorrhea and pancreatitis. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Principle

Calcium with Arsenazo III [1,8-Dihydroxy-3,6-disulpho-2,7-naphtalenebis (azo)-dibenzenearsonic acid], at neutral pH, yields a blue colored complex, whose intensity is proportional to the calcium concentration.

Reagent composition

Reagent	Arsenazo III Imidazole buffer pH 6,75 (100 mmol/L) Arsenazo III (0,120 mmol/L)
Standard	Calcium aqueous (value: see vial)

Precautions

Reagent: Danger. H360: May damage fertility or the unborn child. P280: Wear eye protection, face protection, protective clothing, protective gloves. P501: Dispose of contents in an appropriate container observing applicable local regulations.
- All body fluid samples should be considered potentially infectious materials and the appropriate precautions should be taken. Wear personal protective equipment such as gloves, safety glasses, lab coats or aprons when working with possible biohazard contaminants.
- Use Good Laboratory Practices (GLP) when handling this product.
- Please refer to the MSDS, available on our website, for further information.

Preparation

The reagent and standard are ready for use.

Storage, stability and disposal

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2-8 °C.
Handle standard very carefully to prevent contamination. The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 620 nm ≥ 0,80 the reagent should be discarded.
Do not use the product if deterioration or contamination is suspected or beyond the expiration date or open container stability period. Dispose unused or deteriorated product and waste in compliance with local regulations.

Additional material required but not provided

- Spectrophotometer or colorimeter measuring at 620 nm
- Matched cuvettes 1,0 cm light path
- General laboratory equipment [Note 4,5]

Samples

Serum or plasma: separated from cells as rapidly as possible. Blood anticoagulants with oxalate, citrate or EDTA are not acceptable since these chemicals will strongly chelate calcium.
Urine: collect 24 hours urine specimen in calcium free containers. The collected bottles should contain 10 mL of diluted Nitric acid (50% v/v). Record the volume. Dilute a sample 1:2 in distilled water. Mix. Multiply results by 2 (dilution factor).
Stability of the samples: Calcium is stable 10 days at 2-8 °C.

Procedure

Make sure the reagents and samples are at room temperature.
1. Wavelength 620 nm (610 - 660); Temperature 15 - 25 °C; Cuvette (1 cm light path).
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

For Blank	1,0 mL Reagent
For Standard	20 µL Standard + 1,0 mL Reagent
For Sample	20 µL Sample + 1,0 mL Reagent
Mix and incubate for 2 min at 15 - 25 °C. Read the absorbance (A) of standard and sample against the blank. The color is stable for at least 1 hour.	

Calculation

Serum and plasma:

$$Calcium\ (mg/dL) = \frac{A_{Sample} - A_{Blank}}{A_{Standard} - A_{Blank}}\ x\ standard\ conc.\ (\frac{mg}{dL})$$

Urine (24h):

$$Calcium\ (\frac{mg}{24h}) = \frac{A_{Sample} - A_{Blank}}{A_{Standard} - A_{Blank}}\ x\ stand.\ conc.\ (\frac{mg}{24h})\ x\ vol\ (dL) urine/24h\ x\ f$$

f = dilution factor.
Conversion Factor: mmol/L = 0,25 x mg/dL

Quality control

Control sera are recommended to monitor the performance of assay procedures. Use Biochemistry Normal and Pathological Controls (HBC01, HBC02).
Prepare and measure these controls the same as samples. If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

Reference values [8]

Serum or plasma - Adults	8,6 - 10,2 mg/dL (2,15 - 2,55 mmol/L)
Serum or plasma - Children	8,4 - 11,0 mg/dL (2,10 - 2,75 mmol/L)
Serum or plasma - Newborns	7,6 - 10,4 mg/dL (1,90 - 2,60 mmol/L)
Urine - Adults	100 - 300 mg/24h (2,50 - 7,50 mmol/24h)
Urine - Children	≤ 6,0 mg/kg/24h (≤ 0,15 mmol/kg/24h)

These values are for orientation purpose. Each laboratory should establish its own reference range.

Performance characteristics

Measuring range: from 0,163 mg/dL (detection limit) to 20 mg/dL (linearity limit). If the obtained results are greater than 20 mg/dL, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

Precision:

	intra-assay (n=20)		inter-assay (n=20)	
Mean (mg/dL)	8,74	13,96	8,70	13,52
SD	0,19	0,2	0,08	0,12
CV (%)	2,16	1,43	0,97	0,87

Sensitivity: 1 mg/dL = 0,03323 AU

Accuracy: Results obtained using CYPRESS DIAGNOSTICS reagents did not show systematic differences when compared with other commercial reagents.
The results of the performance characteristics depend on the analyzer used.

Interferences

No interferences were observed with ascorbic acid up to 20 mg/dL and bilirubin up to 15 mg/dL. A list of drugs and other interfering substances with calcium determination has been reported by Young et al.

Notes

1. For best use of this kit on a Cypress Diagnostics analyzer, we kindly advise to follow the application sheets of the respective analyzer. Please log in to our website (www.diagnostics.be) as a registered user to download the latest application sheets, which are located under the section of the corresponding analyzer. Compatible Cypress analyzers: CYANSmart, CYANStart, CYANExpert 130, CYANVision
2. For this kit, application sheets for the following Mindray analyzers are available (see website): Mindray BS-120, BS-200, BS-200E
3. Calibration with the aqueous standard may cause a systematic error in automatic procedures. In this case, it is recommended to use a serum based Biochemistry calibrator (HBC03).
4. It is recommended to use disposable material. If glassware is used, the material should be scrupulously cleaned with 1:1 HNO_3 in water and then thoroughly rinsed with distilled water.

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5. Most of the detergents and water softening products used in the laboratories contain chelating agents. A defective rinsing will invalidate the procedure.

Bibliography

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Notice: Any serious incident that has occurred in relation to the device shall be reported to Cypress Diagnostics and the competent authority of the Member State in which the user and/or patient is established.

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