BioMed-Calcium

Colorimetric, Endpoint

REF: CAL103100 (2 × 50 ml)
CAL103120 (2 × 60 ml)

INTENDE FOR USE:

For the quantitative determination of calcium in serum , plasma and urine .

Principle :

The O-Cresolphthalein complexone (O-CPC) , reacts in alkaline medium with calcium to yield a colour complex .
The intensity of the colour is directly proportional to the amount of calcium present in the sample.
The 8-hydroxylquinoline eliminates magnesium interference.

SPECIMEN COLLECTION :

Non hemolized fresh serum, plasma (heparin).
Urine 24/h diluted 1:2 with distilled water and acidified with 2-3 drops of HCl 23%.

Notes:
Anticoagulants other than heparin shall not be used.
Serum should be separated from the clot as soon as possible.
Old serums presenting evident precipitates shall not be analyzed.
Calcium in serum is reported stable for 24 hours at room temperature, 7 days at +2-8°C and up to 5 months when stored in the refrigerator at -20°Can protected against evaporation.
Shake and bring the samples at room temperature (+15-25°C) before use.

REAGENT COMPOSITION:

R1	Calcium Standard	10 mg/dL (2.5 mmol/L)
R2	DEA Buffer	100 mmol/L
R3	OCPC 8-hydroxyquinoline	1mmol/L < 0.1%

PACKAGE : Collection and Storage .

Store at room temperature **(+15-25°C).**
Stable until the expiration date reported upon the package.
After the unsealing and the taking of the reagent , it is advised to close up the bottle immediately in order to avoid evaporation , direct light exposure and bacterial contamination .

PRECAUTION & WARNING

Do not pipette by mouth .
The preparation , according to current regulation . Pipette is classified as not dangerous.
The total concentration of non active components (preservatives , detergents ,stabilizers) is below the minimum required for citation .
Anyway handle with care , avoid ingestion , avoid contact with eyes , skin and mucous membranes.
The samples must be handle as potentially infected from HIV or Hepatitis .

REAGENT PREPARATION AND STABILITY :

The Reagent (R2) is limpid /colorless; Reagent (R3) is limpid/pale yellow
Mix in the ratio 1:1 Reagents (R2) and (R3).
Reagent mixture is stable at least 3 days at room temperature (+15-25°C) and in dark bottle.

REQUIRED MATERIALS NOT PROVIDED :

General Laboratory Equipment and instrumentations.

PROCEDURE :

Wavelength	578 nm (550-580)
Optical path :	1 cm light path
Temperature :	20-25°C
Reading :	Against blank reagent
Assay type :	End Point

	BLANK	STANDARD	SAMPLE
Reagent (R2+R3)	1000 µL	1000 µL	1000 µL
Distilled Water	10 µL		
Standard		10 µL	
Sample			10 µL

Mix, incubate for 5 min at 20-25°C.
Read sample and standard absorbance, against blank reagent.
Color is stable at least 60 min at room temperature.
Volumes can be proportionally modified.
This methodology describes the manual procedure to use the kit.
For automated procedure, ask for specific application.

CALCULATION:

$$\text{Serum Calcium (mg/dl)} = \frac{A_{specimen}}{A_{standard}} \times 10$$

$$\text{Urine Calcium mg/24 hrs} = \frac{A_{specimen}}{A_{standard}} \times 10 \times 10^{*} \times 2^{*} \times V^{*}$$

* The factor "10" converts mg/dl to mg/liter
* The factor "2" represents the dilution factor
* "V" represents the 24-hour urine volume in liters

EXPECTED VALUES :

Serum children up to 12 y :	8.8-12.0 mg/dL	2.2-3.0 mmol/L
Serum adults :	8.8-10.5 mg/dL	2.2-2.6 mmol/L
Urine:	100-300 m/24h	25-75 mmol/L

The above mentioned values are to be considered as a reference.
It is strongly recommended that each laboratory establish its own normal range .

WASTE DISPOSAL :

The disposal of the product must be in accordance with local regulation concerning waste disposal.

QUALITY CONTROL :

It is recommended to execute the quality control at every kit utilization to verify that values are within the reference range indicated by the methodology.

PERFORMANCE :

MEASURE INTERVAL / LINEARITY :	0.61-20 mg/dL
DETECTION LIMIT (2DS)	0.61 mg/dL
SENSITIVITY :	0.1 mg/dL = 0.00198A-578 nm

INTRA-ASSAY PRECISION : n=20

LOW LEVEL	M = 4.35 mg/dL	C.V = 4.35%
MEDIUM LEVEL	M = 9.18 g/dL	C.V = 2.75%
HIGH LEVEL	M = 20.41 mg/dL	C.V = 1.52%

INTER-ASSAY PRECISION : n=20

LOW LEVEL	M = 4.51 mg/dL	C.V = 3.61%
MEDIUM LEVEL	M = 8.98 mg/dL	C.V = 2.20%
HIGH LEVEL	M = 19.66 mg/dL	C.V = 3.74%
CORELATION	r = 0.996	n=40
LIN. REGRESSION	y = 0.95 × +0.47	n = 40

INTERFERENCE:

Interferences are negligible up to :	
Hemoglobin	10 g/L
Triglycerides	1250 mg/dL
Biliru bin	20 mg/dL

METHOD LIMITATIONS:

For concentration higher than 20 mg/dl, repeat the measure on a sample diluted 1:2 with saline solution and multiply the result x 2 .
Highly hemolyzed serums may cause falsely high calcium level .
Prepare a blank sample with distilled water.
Care must be taken to avoid calcium contamination of glassware .The use of disposable plastic tubes is strongly recommended. If glassware is used ,it should be soak in diluted HCl and thoroughly rinsed with deionized water.
for a thorough evaluation of the interning substances , consult: Young , D . S , et al , Clin , Chem , 21:1D (1975) .

REFERENCES :

1. Connerty H.V.& Briggs A.R., Clin.Chem11(716), 1965.
2. Connerty H.V.& Briggs A.R., Am J Clin Path45(290)1966
3. Moorehead W.R.&Briggs A.R., Clin. Chem 20(1458)1977
4. Young D.S. et al., Clin Chem 21(272), 1975.
5. Friedman R.B. et al., Clin Chem 26(61), 1980

	Consult Instructions for Use
	Caution, Consult accompanying
IVD	In Vitro Diagnostic Medical Device
2°C 8°C	Temperature Limitation
	Manufacturer
EC REP	Authorized Representative in the European Community
REF	Catalogue Number
LOT	Batch Code
	Use by

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