SBio CALCIUM KIT

(OCPC Method)

(For invitro diagnostic use only)

REF	90252275
Pack Size	2 x 75 ml

CE

8°C / 2°C Store at 2-8°C	Manufacturer	IVD *In vitro* Diagnostic Medical Device	L2 Colour Reagent	This way up
Use by (Last day of stated month)	Consult Instructions for use	LOT Batch Number	S Calcium Standard (10 mg/dl)	EC REP Authorised Representative in the European Community
Date of Manufacture	REF Catalogue Number	L1 Buffer Reagent	OCPC OCPC Method	

INTENDED USE

Calcium Kit is used for the determination of Calcium in serum or plasma.

PRINCIPLE OF THE TEST

Calcium in an alkaline medium combines with o-Cresolphthalein Complexone to form a purple coloured complex. Intensity of the colour formed is directly proportional to the amount of calcium present in the sample.

Calcium + OCPC ⟶ Purple Coloured Complex

CLINICAL SIGNIFICANCE

Calcium, in the body, is found mainly in the bones (approximately 99%). In serum calcium exists equally in a free ionised form and in a bound form (with albumin). Hence a decrease in Albumin causes lower Calcium levels and vice versa. The levels of Calcium in serum depend on the parathyroid hormone.

Increased Calcium levels are found in bone tumours, hyperparathyroidism. Decreased levels are found in hypoparathyroidism, renal failure, rickets, Vitamin D deficiency and pancreatitis.

PRESENTATION	**2 x 75 ml**
L1 : Buffer Reagent	75 ml
L2 : Colour Reagent	75 ml
S : Calcium Standard (10 mg/dl)	5 ml

COMPOSITION

DEA Buffer 500 mM; OCPC 0.6 mM; 8 Hydroxyquinilone, Detergent.

STORAGE / STABILITY

Contents are stable at 2-8°C till the expiry mentioned on the labels.

SAMPLE REQUIRED

Serum / Heparinized plasma.

REAGENT PREPARATION

Reagents are ready to use. Protect from bright light.

Working Reagent: For convenience a single working reagent may be prepared by mixing equal parts of the Buffer Reagent (L1) and Colour Reagent (L2). This combined reagent is stable for 7 days at 2-8°C.

SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.

This product requires the handling of human specimen. It is recommended that all human sourced material are considered potentially hazardous and are handled in accordance with the OSHA standard on blood borne pathogens.

Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

Handle specimen, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

PROCEDURE

Wavelength/filter	:	570 nm (Hg 578 nm) / Yellow
Temperature	:	R.T.
Light path	:	1 cm

MATERIALS REQUIRED BUT NOT PROVIDED

General laboratory instrumentation like Spectrophotometer/Analyzer, Thermostatic Cuvette holder, Cuvettes, Micropipettes, Test tubes, Waterbath, Stopwatch/Timer.

Pipette into clean dry test tubes labeled as Blank (B), Standard (S) and Test (T):

Addition Sequence	B (ml)	S (ml)	T (ml)
Buffer Reagent (L1)	0.5	0.5	0.5
Colour Reagent (L2)	0.5	0.5	0.5
Distilled Water	0.02	--	--
Calcium Standard (S)	--	0.02	--
Sample	--	--	0.02

Mix well and incubate at R. T. (25°C) for 5 minutes. Measure the absorbance of the Standard (Abs. S), and Test Sample (Abs. T) against Blank, within 60 minutes.

CALCULATIONS

$$\text{Calcium in mg/dl} = \frac{\text{Abs. T}}{\text{Abs. S}} \times 10$$

QUALITY CONTROL

The following process is recommended for QC during the assay of Calcium. *Define and establish acceptable range for your laboratory.

1. Two levels of control (Normal and Abnormal) are to be run on a daily basis.
2. If QC results fall outside acceptance criteria, recalibration may be necessary.
3. Review QC results and run acceptance criteria following a change of reagent lot.

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity:

This procedure is linear upto 18 mg/dl. If values exceed this limit, dilute the sample with distilled water and repeat the assay. Calculate the value using the proper dilution factor.

Limit of detection:

The limit of detection for Calcium is 0.05 mg/dl.

Interferences:

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Precision:

Precision studies were performed with two controls using NCCLS protocol EP5-A. The results of the precision studies are shown below:

Sample	Within-run		Between-run		Total	
	Mean	CV%	Mean	CV%	Mean	CV%
Control 1	8.25	3.40	8.20	2.24	16.45	5.64
Control 2	12.20	3.52	8.22	1.96	20.42	5.48

Method comparison:

Comparative studies were done to compare our reagent with another commercial Calcium Assay. No significant differences were observed. Details of the comparative studies are available on request.

REFERENCE RANGE

Serum / Plasma : 8.7 - 11.0 mg/dl

It is recommended that each laboratory establish its own normal range representing its patient population*.

NOTE

Calcium is reported to be stable in serum for 7 days when stored at 2-8°C. As calcium is a very widely distributed ion, care should be taken to avoid any contamination. All glassware being used for the test should first be rinsed with 1% or 0.1 N HCl and then with good quality deionised water before use.

It is suggested that after the rinsing of the tubes with HCl the reagent be pipetted in their respective tubes and the tubes be rinsed with the reagent. The reagent then should be pooled together in the 'blank' tube and repipetted out into the 'standard' and 'test' test tubes. This will ensure that any remaining contamination will be carried over equally in all the tubes. For flow cell cuvettes it is suggested that some reagent be aspirated before the blank to take away any contamination in the flow through tubing or cuvette which may cause a higher than the actual blank of the reagent.

Chelating agents such as EDTA, present even in traces, prevent the formation of the colour complex, hence necessary care should be taken during the assay.

The reagent may be used in several automated analyzers. Instructions are available on request.

Standard is traceable to standard reference material (SRM) 909b. Do not use turbid, deteriorated or leaking reagents.

REFERENCES

1. Gitelman, H.J., (1967), Anal. Biochem. 18: 521.
2. Bagainski, E.S., (1973), Clin. Chem. Acta. 46:46.
3. Clinical Chemistry, Principles, Procedures, Correlations, Michael L. Bishop et.al., 5th Edition.

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EC REP

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