



CALCIUM KIT

(Arsenazo III Method)

(For veterinary invitro diagnostic use only)

INTENDED USE

QUADRAPED™ Calcium kit used for the determination of Calcium in serum or plasma.

SUMMARY

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.

PRINCIPLE

Calcium combines specifically with Arsenazo III at a neutral pH to form a blue purple coloured complex. Intensity of the colour formed is directly proportional to the amount of calcium present in the sample.

Calcium + Arsenazo III \longrightarrow Blue Purple Coloured Complex

EXPECTED VALUES

Species	Calcium (mg/dl)
Dog	9.1 - 11.7
Cat	8.7 - 11.7
Cow	8.0 - 11.4
Horse	10.2 - 13.4
Pig	7.1 - 11.6
Sheep	11.5 - 12.8
Goat	8.9 - 11.7
Rabbit	9.0 - 12.0
Buffalo	8.5 - 12.5

It is recommended that each laboratory establish its own range as reference ranges may vary between laboratories.

PRESENTATION

REF	1126050025
Pack Size	25 tests
L1 Calcium Reagent	25 x 1 ml
S Calcium Standard (10 mg/dl)	5 ml

COMPOSITION

Goods Buffer 50mM; pH 6.5; Arsenazo III 0.12mM; Detergent and Preservatives.

STORAGE / STABILITY

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

REAGENT PREPARATION

Reagents are ready to use. Protect from bright light.

SAMPLE MATERIAL

Serum / Heparinized plasma. Calcium is reported to be stable in serum for 5 days when stored 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.

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

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

MATERIAL REQUIRED BUT NOT PROVIDED

Photometer analyzer with standard thermostatic cuvette holder, micropipette and appropriate laboratory equipment.

PROCEDURE

Wavelength / filter : 630 nm (Hg 623 nm) / Red
 Temperature : R.T.
 Light path : 1 cm

Sample to be added directly into the vial.

Addition Sequence	B (ml)	S (ml)	T (ml)
Calcium Reagent (L1)	1.0	1.0	1.0
Distilled Water	0.01	--	--
Calcium Standard (S)	--	0.01	--
Sample	--	--	0.01

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

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.

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

SPECIFIC PERFORMANCE CHARACTERISTICS

LOD: 0.05 mg/dl at 630nm

LOQ: 0.625 mg/dl at 630nm

Lower Limit: 0.05 mg/dl

Higher Limit: 15 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.

Interferences:

Sample when spiked with interferent such as upto 20 mg/dl Bilirubin, 1000 mg/dl intralipid and 200 mg/dl heamoglobin does not affect the ability of the kit to determine the Calcium concentration.

Precision:

Within run

Within run	n	Mean	SD	% CV
Sample 1	10	9.42	0.11	1.13
Sample 2	10	12.51	0.11	0.86
Sample 3	10	10.37	0.13	1.29

Between run

Between run	n	Mean	SD	% CV
Sample 1	10	9.40	0.11	1.22
Sample 2	10	12.50	0.11	0.89
Sample 3	10	10.33	0.16	1.57

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.

NOTE

In vitro diagnostic reagent for laboratory and professional use only Not for medicinal use. The reagent contain sodium azide 0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water. Only clean and dry glassware must be used. 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.

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.

Do not use turbid, deteriorated or leaking reagents.

REFERENCES

- Smith, H.G. Jr. et al. (1979), Biochem. 18: 5067.
- Clinical Chemistry, Principles, Procedures, Correlations, Michael L. Bishop et.al., 5th Edition.
- Duncan and Prasse's Veterinary Laboratory Medicine: Clinical Pathology, Kenneth S. Latimer, ISBN Jane Wardrop - 6th Edition - 2010.
- Clinical Biochemistry of Domestic Animals, Sixth Edition, 2008 by Kaneko J.J., Harvey J.W. & Bruss M.L.

System Parameters

Reaction	: End Point	Interval	: ---
Wavelength	: 630 nm	Sample Vol.	: 0.01 ml
Zero Setting	: Reagent Blank	Reagent Vol.	: 1.00 ml
Incub. Temp.	: R. T.	Standard	: 10 mg/dl
Incub. Time	: 5 min.	Factor	: ---
Delay Time	: ---	React. Slope	: Increasing
Read Time	: ---	Linearity	: 15 mg/dl
No. of read.	: ---	Units	: mg/dl

SYMBOL KEYS

Store at 2-8°C	Manufacturer	In vitro Diagnostic Medical Device	Calcium Reagent	Arsenazo III Method
Use by (Last day of stated month)	Consult Instructions for use	Batch Number	Calcium Standard (10 mg/dl)	This way up
Date of Manufacture	Catalogue Number	Contains sufficient for <n> tests		



Manufactured by:

Coral Clinical Systems

A Division of Tulip Diagnostics (P) Ltd.

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