

# ANA BIO ISP CALCIUM ARS (III)

(Arsenazo III Method)

## For Miura Instruments

### Intended Use

Calcium Arsenazo (III) is used for the quantitative determination of calcium concentration in serum based on the colorimetric method using Arsenazo III.

### Principle

Calcium with Arsenazo III at neutral pH yields a blue coloured complex. The intensity of the colour formed is directly proportional to calcium concentration.

### Components & Concentration of Reagents

Reagent	Component	Concentration
Reagent	Imidazole buffer, pH 7.0	100 mmol/L
	Arsenazo III	90 µmol/L
	Stabilizers, excipients & surface active agents	

### Reagent storage and stability

The kit should be stored at 15° - 25°C and is stable till the expiry date indicated on the label.

### Reagent Preparation

Liquid reagent ready for use. After opening the reagent is stable for 30 days if closed, stored at 2° - 8°C, and protect from direct light and contamination. Do not mix different batches.

### Specimen collection and preservation

Blood should be collected in a clean dry container. Avoid the use of plastic or siliconized container which may prolong clotting time. Serum is preferred but heparinized plasma (200 IU/ml of blood) can also be used. EDTA, Citrate, Oxalate and calcium salt of heparin interfere in the assay and should not be used as anticoagulant. Calcium is stable in serum or plasma for 5 days when stored at 2 - 8°C and 20 days when stored at - 10°C.

### Automation

This kit, though developed and manufactured to be used as manual assay and with I.S.E. Miura Analyzer, can be used also with other analyzers able to meet the specifications indicated in section "Reaction conditions – Test procedure" Application sheets are available for automatic instruments.

All applications not explicitly approved by KDPL. Cannot be guaranteed in terms of performance, and must there be established by the operator.

### Calibration

For Calibration use the "Multicalibrator"

### Calibration Stability

For the instrumentation series Miura, the calibration is recommended to be done every 10 days.

### Materials required but not supplied in the kit

Calibrators and controls

### Assay guidelines for Analyzer I.S.E. Miura

Analyte Name	Calcium ARS	
Method Code	Ca	
Type	End-Point	
Unit	mg/dl	
Filter F1	630 nm	
Blank in	Used	
Step	Reaction Volume	U.M.
Volume reagent R1	200	µl
Sample Volume	4	µl
Final Incubation	60	Sec.

### Normal range

Guidance Value - 8.5 – 11 mg / dl

**Note:** Expected range varies from population to population and each laboratory should establish its own normal range.

### Limitation

The reagent is linear up to 18 mg / dl. For higher value, dilute sample with normal saline and perform the assay. Multiply the final result by dilution factor to get the real value.

### Quality Control

To ensure adequate quality control, it is recommended that each batch should include a normal and an abnormal commercial reference control serum. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glassware, Wavelength setting, Expiration date of reagents and accuracy of prob aspiration.

### Accuracy-Recovery

Calcium added to a serum matrix containing known amounts of calcium gave an average recovery of 97%.

### Interference

The high dilution of the sample with the reagent reduces to a minimum the interference by lipids. Bilirubin below 58 mg/dl does not interfere in the reaction. Haemoglobin interferes at concentrations above 10 g/L.

### Precision of the Method

Within-run					
Range	U.M	Mean	S.D.	C.V.(%)	No. run
Low	mg/dl	9.92	0.14	1.40	20
High	mg/dl	12.50	0.33	2.61	20
Between run					
Range	U.M	Mean	S.D.	C.V.(%)	No. run
Low	mg/dl	9.72	0.14	1.43	60
High	mg/dl	12.42	0.23	1.80	60














### Sensitivity

At 630 nm, a concentration of about 0.1 mg/dl of calcium can estimate.


### References

1. Smith, H. G.Jr.and Bauer, P.J.(1979) *Biochemistry*, 18, 5067-5073.
2. Budesinsky, b. (1969) in chlantes in *Analytical chemistry*.
3. Cadwell P.C. (1970) in calcium An. Cellular function.
4. Cuthbert,A.W.Ed., PP-10-16 macmillan, London.

### Symbols

 IVD	In Vitro Diagnostics		Caution
 LOT	Batch No.		Product Expiry Date
 CONT	Content		Manufactured By
	Read Instructions		Date of Manufacture
	Storage Temperature		Keep Dry
 REF	Catalogue No.		Fragile
			Keep away from sun light



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