TECO DIAGNOSTICS
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CALCIUM (ARSENAZO III), ENDPOINT

INTENDED USE
For the quantitative determination of calcium concentration in serum or plasma.

SUMMARY AND EXPLANATION OF THE TEST
In plasma, calcium consists of three forms: free, conglutinated with proteins or complex with anions such as phosphate, bicarbonate and citrate. Calcium is an absolutely necessary cation for cell functions. For example: muscle contraction, bone mineralization, glycogen metabolism, blood concretion and nerve impulses conduction.
Renal diseases, liver diseases, intestinal malabsorption, acute pancreas inflammation, vitamin D deficiency, adrenal cortical hormone therapy, diuretic treatment and hypoparathyroidism all may result in low levels of total calcium.
Hyperparathyroidism, hyperthyroidism, Addison's disease, intussuscept vitamin D or vitamin A excessively, malignant diseases with metastases and sarcoidosis will lead to high levels of total calcium.
The ratio is one part sample to 100 parts reagent. The change in absorbance at 650 nanometers is directly proportional to the concentration of calcium in the sample.

2 ArsenazoIII + Ca++ ⟶ Ca++--ArsenazoIII complex
(Bluish-purple)

REAGENT CONTENTS:
Calcium Reagent contents:
Arsenazo III ≥ 0.17 mM,
8-Hydroxyquinoline Sulfonate 5.0 mM,
Buffer, Surfactant.

REAGENT PREPARATION
No preparation is required.

REAGENT STORAGE AND STABILITY
Calcium Reagent stored unopened at room temperature stable until the expiration date showed on the bottle label.
DO NOT FREEZE.

REAGENT DETERIORATION
The reagent should be discarded if the turbidity has occurred; turbidity may be a sign of contamination.

SPECIMEN COLLECTION AND HANDLING
1. Serum, heparin plasma is suitable for sample. Do not use oxalate, EDTA, or citrate plasma. Whole blood and hemolytic are not recommended for use as a sample. Freshly drawn serum is the preferred specimen.
2. Use the suitable tubes or collection containers and follow the instruction of the manufacturer; avoid effect of the materials of the tubes or other collection containers.
3. Centrifuge samples containing precipitate before performing the assay.
4. Stability:
   Plasma must be assayed fresh.

Serum: 7 days at 20-25^{O}C
3 weeks at 4-8 ^{O}C
8 months at -20 ^{O}C

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT
At least two levels of control material.

MANUAL PROCEDURE
1. Label tubes Blank, Standard, Controls, Patients, etc.
2. Transfer 1.0 ml of reagent into each tube.
3. Add 0.01 ml (10 µl) of sample to the respective tubes and mix*.
4. Let stand for at least sixty seconds (60) at room temperature.
5. Zero spectrophotometer with blank at 650~670 nm.
6. Read and record absorbance of all tubes. Final color is stable for sixty minutes (60).

* *TC MULTI-PURPOSE CALIBRATOR MAY BE USED TO REPLACE STANDARD.*

CALCULATIONS
$\frac{\text{Abs. of Unknown}}{\text{Abs. of Standard}}$ x Conc. of std. = Calcium (mg/dl).

Example: If the absorbance of unknown = 0.74. absorbance of standard = 0.84, concentration of standard = 10 mg/dl, then,

$\frac{0.74}{0.84}$ x 10 = 8.8 mg/dl

NOTE: To convert mg/dl to meq/L, divide mg/dl by two (2).

PROCEDURE (for TC MATRIX)

TEST NAME:	CA	R1:	300
TEST NO.		R2:	0
FULL NAME:	Calcium	SAMPLE VOLUME:	3
REFERENCE NO.:		R1 BLANK:	/
ANALY.TYPE:	Endpoint	MIX REAG. BLANK:	/
PRI. WAVE :	670 nm	CONCENTRATION:	/
SECON. WAVE:	/	LINEARITY LIMIT:	0.0 – 15.0
TREND:	Ascending	SUBSTRATE LIMIT:	/
REACT. TIME:	0 - 8	FACTOR:	/
INCUBATE TIME:	/	PROZONE CHECK:	/
UNIT:	mg/dl	Q1: / Q2: / Q3: /	Q4: /
PRECISION:	0.1	PC: /	ABS.: /
Calibration Type:	Calibrate + Rgt..Blk	Calibration Rule: Two-point linear	

INTERFERENCE

1. Hemoglobin levels up to 500 mg/dl, Lipemia levels up to 500mg/dl, Ascorbic acid levels up to 30 mg/dl and Bilirubin levels up to 50 mg/dl were found to exhibit negligible interference.
2. On this method, refer to the work of Young for a review of drug and comprehensive list of substances effect on calcium level.

EXPECTED VALUE
8.4 to 10.2 mg/dL or 2.1 to2.6 mmol/L

PRECAUTIONS:
1. For in vitro diagnostic use only.
2. Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.
3. Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.

PERFORMANCE CHARACTERISTICS
Linearity: 15.0 mg/dL

Comparison: Studies performed using the present method with a similar method yielded a cosfficient of correlation of 0.9950 with a regression equation of y=0.9980X - 0.0359. Sample values from 1.8 to 16.1mg/dl (N=81).

Precision: Within Run precision for Calcium Reagent Set was determined following a modification of NCCLS EP5-A.Two commercial human serum were assayed for 25 times.

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	9.0	12.0
Standard Deviation (mg/dl)	0.2	0.2
Coefficient of Variation (%)	1.7	1.8

Run-Day precision for Calcium Reagent was determined following a modification of NCCLS EP5-A.Two commercial human serum were assayed five times per day for five days for the total of 25 values.

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	9.6	12.5
Standard Deviation (mg/dl)	0.35	0.33
Coefficient of Variation (%)	3.8	2.7

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