TECO DIAGNOSTICS
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CALCIUM (ARSENAZO III)
TC MATRIX-240/480

INTENDED USE
The test is applied for the quantitative determination of calcium in serum and urine.

SUMMARY AND EXPLANATION OF THE TEST[1,2,3,4,5,6]
Extraskeletal functions of calcium include playing a role in blood coagulation, neuromuscular transmission, skeletal and cardiac muscle excitability, enzyme activation, and maintenance of cell membrane integrity and permeability. Increased serum calcium levels can also be observed in multiple myeloma and other neoplastic diseases. Hypocalcemia can be seen in diseases such as hypoparathyroidism, nephrosis and pancreatitis.
Arsenazo (III) combines with calcium at slight acidic pH to form a blue complex, the absorbance of which is measured at 660 nm. The reaction has high specificity and interference from magnesium must be avoided due to pH.

TEST PARAMETERS
Method : Colorimetric, Endpoint, Increasing Reaction
Wavelength : 670 nm (650 - 670 nm)
Linearity : 20 mg/dL

REAGENT COMPONENTS
Arsenazo (III) : ≤ 0.2 mmol
Good's buffer : ≤ 50 mmol
pH 6.8
Stabilizers

REAGENT PREPARATION
No preparation is required.

REAGENT STORAGE AND STABILITY[7]
Reagents are stable at 2-8˚C until the expiration date stated on the label which is only for closed vials.
Once opened vials are stable for 30 days at 2-8˚C in optimum conditions. On board stability is strongly related to auto analyzers' cooling specification and carry-over values.
Reference interval has been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol

SAMPLE
Serum is collected according to the standard procedure. Do not use citrate, oxalate and EDTA as anticoagulant. Total calcium is stable for:
7 days at 20-25ºC,
3 weeks at 2-8˚C,
8 months at -20°C.
Urine specimens must be collected in a 20-30 mL bottles containing 6 mol/L HCl (for 1-2 mL urine) for 24 hour sampling in order to prevent calcium salt precipitation. Urine is stable for:
2 days at 20-25ºC,
4 days at 2-8˚C,
3 weeks at -20ºC.

Unit Conversion:
mg/dL x 0.2495 = mmol/L

REFERENCE INTERVAL (NORMAL VALUES) [8]
Serum/Plasma : 8.5 - 10.5 mg/dL
Urine : 100 - 250 mg/24 hour
It is recommended that each laboratory establish its own normal range.
Reference interval has been verified by using CLSI EP28-A3c protocol.

QUALITY CONTROL AND CALIBRATION
Commercially available control material with established values determined by this method may be used:
The assay requires the use of an Auto Calibrator.

Calibration Study:
It strongly depends on the application characteristics of in-use auto analyzer and capacity of cooling. Calibration stability is 15 days.
Serum traceability is provided by SRM 956 material. Each laboratory should establish its own internal Quality Control scheme and procedures for corrective and preventive action if controls do not recover within the acceptable tolerances.
Daily Quality control testing is recommended. Calibration is not recommended if quality control values are acceptable. Reagent should be calibrated after lot changes.

PROCEDURES
Settings for TC-Matrix 240/480

Test Name:	Ca	R1:	200
Full Name:	Calcium	R2:	0
Pri. Wave:	670 nm	Sample Volume:	2.0
Sec. Wave:	700 nm	Calibration Type:	2 point linear
Assay/ Point:	1 Point end	K Value:	/
Start - End:	1 - 18	Point:	2
Decimal place:	2	Blank Type:	Reagent
Unit:	mg/dL	Point 0 (Blank) Con.:	0.0
Linearity Range:	2.0000 - 20.0000	Point 1 (STD) Con.:	Calibrator/
Correlation Factor:	1.0000 - 0.0000		standard

PERFORMANCE CHARACTERISTICS
Limit of Detection (LoD): The limit of detection for serum and urine is 0.5 mg/dL.

Limit of Quantitation (LoQ) [LoQ values are based on Coefficient of Variation Percentage (CV)%][9] **:** ≤20% It is 1.5 mg/dL for serum and urine.

LoD and LoQ values have been verified by using CLSI EP17-A protocol.

High Linearity: The assay is linear up to 20 mg/dL for serum and urine. For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilutionfactor.
Linearity may vary considerably depending on the instrument used.

Precision Studies : [10]
Repeatability (Within Run)

Mean Concentration	SD*	CV%	n
9.14 mg/dL	0.35	3.86	40
12.40 mg/dL	0.11	0.90	40

Reproducibility (Day-to-Day Run)

Mean Concentration	SD*	CV%	n
8.62 mg/dL	0.35	4.05	84
12.61 mg/dL	0.47	3.73	84

**SD: Standard Deviation*
**CV: Coefficient of Variation*

Deviations of ±10% CV% between devices may be observed.
Precision Studies data have been verified by using CLSI EP05-A3 protocol.

Method Comparison:[11, 12]
Correlation with a comparative method is: r= 0.993
According to Passing-Bablok Fit:
Slope: 1.17
Intercept: -2.08

INTERFERNCE: [4,5,6,13]
No significant interference was observed for hemoglobin,conjugated bilirubin, lipemia up to the interferent concentration given.

Interferant and Concentration	Calcium Target (mg/dL)	N	%Observed Recovery
Hemoglobin 1260 mg/dL	8.48	3	101
Bilirubin 48.3 mg/dL	7.97	3	105
Lipemi 1650.6 mg/dL	8.72	3	108

The acceptable interference limit is set 10% below the highest interference concentration within ± 10% recovery of the target.

Interferences may affect the results due to medication or endogenous substances.
These performance characteristics have been obtained by using an analyzer. Results may vary if a different instrument or a manual procedure is used.

WARNINGS AND PRECAUTIONS
IVD: For in Vitro Diagnostic use only.Do not use expired reagents.
Reagents with two different lot numbers should not beinterchanged. For professional use.
Follow Good Laboratory Practice (GLP) guidelines. CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled inaccordance with OSHA standards.

REFERENCES

1. Endres DB, Rude RK. Mineral and Bone Metabolism. In: Burtis CA, Ashwood ER, Bruns ED, eds. TietzTextbook of Clinical Chemistry and Molecular Diagnostics, 4th ed. St. Louis (MO): Saunders Elsevier 2006:1891-1965.
2. Tietz, N.W., Fundamentals of Clinical Chemistry, p. 940, W.B. Saunders Co., Philadelphia, 1987
3. Tietz NW. Clinical Guide to Laboratory Test. 2nd ed. Philadelphia, PA: WB Saunders Company; 1995,52.
4. Tietz NW. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia, PA: WB Saunders Company; 1995:88- 91.
5. Tietz NW, ed. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia: WB Saunders 1995:919.
6. Tietz Fundamentals of Clinical Chemistry. 5th ed. Burtis CA, Ashwood ER, eds. Philadelphia, PA: WB Saunders Company; 2001:605.
7. Clinical and Laboratory Standards Institute (CLSI). Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline. CLSI Document EP25-A. Wayne,PA: CLSI; 2009.
8. Clinical and Laboratory Standards Institute (CLSI). Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition. CLSI Document EP28-A3c. Wayne, PA: CLSI; 2010.
9. Clinical and Laboratory Standards Institute (CLSI). Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline.CLSI Document EP17-A. Wayne, PA: CLSI; Vol. 24 No. 34
10. Clinical and Laboratory Standards Institute (CLSI). Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014
11. Passing-Bablok W et al. A General Regression Procedure for Method Transformation. J Clin Chem Clin Biochem 1988;26.783-79.
12. Clinical and Laboratory Standards Institute (CLSI). Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition; Approved Guideline.CLSI Document EP09-A2. Wayne, PA: CLSI; Vol. 22 No. 19.
13. Clinical and Laboratory Standards Institute (CLSI). Interference Testing in Clinical Chemistry; Approved Guideline.CLSI Document EP07. Wayne, PA: CLSI; 3rd Edition.CHERIAN G., SOLDIN ST. Clin. Chem. 27/5:748-752 (1981)
14. Young DS. Effects of Drugs on Clinical Laboratory Tests, AACC Press, Third Edition, Washington (1990).
15. Tietz NW. Clinical Guide to Laboratory Standards. 3rd ed. Philadelphia, PA: WB Saunders Company; 1995:102-105.
16. Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).
17. Endres DB, Rude RK. Mineral and bone metabolism. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B SaundersCompany; 1999. p. 1395-1457
18. Gitelman HJ. An improved procedure for the determination of calcium in biochemical specimens. Ana Biochem. 1967;18:521-531.
19. Clinical Chemistry vol. 38 N. 6 - 904-908 - (1992).
20. Clinical and Laboratory Standards Institute [formerly NCCLS (*National Committee for Clinical Laboratory Standards*)]. Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Second Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2004. NCCLS Document EP05-A2.
21. Zak B., Epstein E., Babinski E.S., Review Calcium Methodologies, Annals of Clinical and Laboratory Science 5, 195-212 (1975).

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