

Alinity c Calcium-07**Prepared by:** Yusra Othman /Director/Supervisor-Chem **Date:** May/20/2024**Reviewed by:** Jordan Dillard /Instructor **Date:** July 10 2024**Approved by:** Sanford N. Bailey, M.D. /Chairman **Date:** July 12 2024**BIENNIAL REVIEW:****REVIEWED**

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SUPERSEDES: Procedure titled _____**INTENDED USE**

The Alinity c Calcium assay is used for the quantitation of calcium in human serum, plasma, or urine on the Alinity c analyzer.

SUMMARY AND EXPLANATION OF THE TEST

The majority of calcium in the body is present in bones. The remainder of the calcium is in serum and has various functions. For example, calcium ions decrease neuromuscular excitability, participate in blood coagulation, and activate some enzymes.

Hypercalcemia can result from hyperparathyroidism, hypervitaminosis D, multiple myeloma, and some neoplastic diseases of bone.[1](#) Long-term lithium therapy has been reported to cause hyperparathyroidism in some individuals, with resulting hypercalcemia.[2](#)

Hypocalcemia can result from hypoparathyroidism, hypoalbuminemia, renal insufficiency, and pancreatitis.[1](#)

Calcium has traditionally been difficult to measure accurately and precisely, and a large variety of methods have been developed. Among these are flame photometry, oxalate precipitation with titration, atomic absorption spectrophotometry, EDTA chelation, and more recently calcium dye complexes which are measured spectrophotometrically. Examples of calcium dyes are o-cresolphthalein complexone and Arsenazo III, the latter being the dye used for calcium determination in this method.

PRINCIPLES OF THE PROCEDURE

Arsenazo-III dye reacts with calcium in an acid solution to form a blue-purple complex. The color developed is measured at 660 nm and is proportional to the calcium concentration in the sample.

Methodology: Arsenazo III

For additional information on system and assay technology, **refer to the Alinity ci-series Operations Manual, Section 3.**

REAGENTS

Kit Contents

Alinity c Calcium Reagent Kit 07P57

Volumes (mL) listed in the table below indicate the volume per cartridge.

REF	07P5720	07P5730
Tests per cartridge	400	1500
Number of cartridges per kit	10	10
Tests per kit	4000	15 000
R1	16.5 mL	51.7 mL
R1 Active ingredients: arsenazo-III dye (0.94 mmol/L), sodium acetate (271 mmol/L). Preservative: methylisothiazolone hydrochloride (0.04 %).		

Warnings and Precautions


. IVD

- For *In Vitro* Diagnostic Use

- **Rx ONLY**

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.[3](#), [4](#), [5](#), [6](#)

The following warnings and precautions apply to: R1	
	
WARNING	Contains methylisothiazolone.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
Prevention	
P261	Avoid breathing mist / vapors / spray.
P264	Wash hands thoroughly after handling.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice / attention.
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.

P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

Safety Data Sheets are available at www.abbottdiagnostics.com or/and SDS folder.

For a detailed discussion of safety precautions during system operation, **refer to the Alinity ci-series Operations Manual, Section 8.**

Reagent Handling

- Upon receipt, place reagent cartridges in an upright position for 8 hours before use to allow bubbles that may have formed to dissipate.
- If a reagent cartridge is dropped, place in an upright position for 8 hours before use to allow bubbles that may have formed to dissipate.
- Do not invert reagent cartridges prior to use.
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.

For a detailed discussion of reagent handling precautions during system operation, refer to the Alinity ci-series Operations Manual, Section 7.

Reagent Storage

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	15 to 30°C	Until expiration date	Store in upright position.
Onboard	System Temperature	30 days	
Opened	15 to 30°C	Until expiration date	Store in upright position. Do not reuse containers, original reagent caps, or replacement caps due to the risk of contamination and the potential to compromise reagent performance.

Reagents may be stored on or off the system. If removed from the system, store reagents with new replacement caps in an upright position at 15 to 30°C. For reagents stored off the system, it is recommended that they be stored in their original trays or boxes to ensure they remain upright.

For information on unloading reagents, **refer to the Alinity ci-series Operations Manual, Section 5.**

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when:

- a calibration error occurs
- a control value is out of the specified range

Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary.

For troubleshooting information, **refer to the Alinity ci-series Operations Manual, Section 10.**

INSTRUMENT PROCEDURE

The Alinity c Calcium assay file must be installed on the Alinity c analyzer prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, **refer to the Alinity ci-series Operations Manual, Section 2.**

For information on printing assay parameters, **refer to the Alinity ci-series Operations Manual, Section 5.**

For a detailed description of system procedures, **refer to the Alinity ci-series Operations Manual.**

Alternate Result Units

Edit assay parameter "Result Units" to select an alternate unit.

Conversion formula:

(Concentration in Default result unit) x (Conversion factor) = (Concentration in Alternate result unit)

Default Result Unit	Conversion Factor	Alternate Result Unit
mg/dL	0.25	mmol/L

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

The specimen types listed below were verified for use with this assay.

Other specimen types, collection tube types, and anticoagulants have not been verified with this assay.

Specimen Type	Collection Vessel
Serum	Serum tubes (with or without gel barriers)
Plasma	Collection tubes Acceptable anticoagulants are: Lithium heparin (with or without gel barrier) Sodium heparin
Urine (random specimens or timed specimens collected over intervals shorter than 24 hours)	Bottle containing 1 to 2 mL of 6 mol/L HCL in order to prevent calcium salt precipitation. 7
Urine (24 hour)	Bottle containing 20 to 30 mL of 6 mol/L HCl in order to prevent calcium salt precipitation. 7

- Liquid anticoagulants may have a dilution effect resulting in lower concentration values for individual specimens.
- The instrument does not provide the capability to verify specimen types. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.

Specimen Conditions

- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- For accurate results, plasma specimens should be free of platelets and other particulate matter. Ensure centrifugation is adequate to remove platelets.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.

- Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross-contamination.

To ensure consistency in results, recentrifuge specimens prior to testing if

- they contain fibrin, red blood cells, or other particulate matter.

NOTE: If fibrin, red blood cells, or other particulate matter are observed, mix by low speed vortex or by inverting 10 times prior to recentrifugation.

Prepare frozen specimens as follows:

- Frozen specimens must be completely thawed before mixing.
- Mix thawed specimens thoroughly
- Visually inspect the specimens. If layering or stratification is observed, mix until specimens are visibly homogeneous.
- If specimens are not mixed thoroughly, inconsistent results may be obtained.

Specimen Storage

Specimen Type	Temperature	Maximum Storage Time	Special Instructions
Serum/Plasma	20 to 25°C	7 days ⁸	
	2 to 8°C	3 weeks ^{8, 9}	
	-20°C	8 months ⁸	
Urine	20 to 25°C	2 days ⁸	Acidify to pH < 2
	2 to 8°C	4 days ^{8, 9}	Acidify to pH < 2
	-20°C	3 weeks ⁸	Acidify to pH < 2

Analyze fresh specimens if possible.

Avoid multiple freeze/thaw cycles.

Guder et al. suggest storage of frozen specimens at -20°C for no longer than the time intervals cited above.¹⁰

Each laboratory may establish a range around -20°C from either the freezer manufacturer's specifications or your laboratory standard operating procedure(s) for specimen storage.

Stored specimens must be inspected for particulates. If present, mix with a low speed vortex or by inversion and centrifuge the specimen to remove particulates prior to testing.

Specimen Shipping

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

PROCEDURE

Materials Provided

07P57 Alinity c Calcium Reagent Kit

Materials Required but not Provided

- Alinity c Calcium assay file
- 08P6001 Alinity c Multiconstituent Calibrator Kit
- Commercially available controls containing calcium
- Saline (0.85% to 0.90% NaCl) for specimen dilution

For information on materials required for operation of the instrument, refer to the Alinity ci-series Operations Manual, Section 1.

For information on materials required for maintenance procedures, refer to the Alinity ci-series Operations Manual, Section 9.

Assay Procedure

For a detailed description of how to run an assay, refer to the Alinity ci-series Operations Manual, Section 5.

- If using primary or aliquot tubes, **refer to the Alinity ci-series Operations Manual, Section 4 to ensure sufficient specimen is present.**
- To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.
- Minimum sample volume requirements:
 - Sample volume for single test: 2.6 µL.

NOTE: This amount does not include the dead volume plus the additional over-aspiration volume. For total sample volume requirements, refer to the Alinity ci-series Operations Manual, Section 4.
- Refer to the Alinity c Multiconstituent Calibrator Kit package insert and commercially

available control material package insert for preparation and usage.

- For general operating procedures, refer to the Alinity ci-series Operations Manual, Section 5.
- For optimal performance, it is important to perform routine maintenance as described in the Alinity ci-series Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Sample Dilution Procedures

Serum/ Plasma

Samples with calcium values exceeding 24.0 mg/dL (6.00 mmol/L) are flagged with the code "> 24.0 mg/dL" (6.00 mmol/L) and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

Urine

Samples with calcium values exceeding 24.0 mg/dL (6.00 mmol/L) are flagged with the code "> 24.0 mg/dL" (6.00 mmol/L) and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

Automated Dilution Protocol

Serum/ Plasma

If using an automated dilution protocol, the system performs a dilution of the sample and automatically calculates the concentration by multiplying the result by the dilution factor. For details on configuring automated dilutions, refer to the Alinity ci-series Operations Manual, Section 2.

Urine

If using an automated dilution protocol, the system performs a dilution of the sample and automatically calculates the concentration by multiplying the result by the dilution factor. For details on configuring automated dilutions, refer to the Alinity ci-series Operations Manual, Section 2.

Manual Dilution Procedure

Dilute the sample with saline (0.85% to 0.90% NaCl).

The operator must enter the dilution factor in the Specimen or Control tab of the Create Order screen. The system will use this dilution factor to automatically calculate the concentration of the sample and report the result.

If the operator does not enter the dilution factor, the result must be manually multiplied by the appropriate dilution factor before reporting the result. If a diluted sample result is less than the lower value of the measuring interval of 2.0 mg/dL (0.50 mmol/L), do not report the result. Rerun using an appropriate dilution.

For detailed information on ordering dilutions, refer to the Alinity ci-series Operations Manual, Section 5.

Calibration

For instructions on performing a calibration, **refer to the Alinity ci-series Operations Manual, Section 5.**

Calibration is stable for approximately **30 days (720 hours)**, but is required with each change in reagent lot. Verify calibration with at least 2 levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary.

This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

Quality Control Procedures

- At least two levels of controls (normal and abnormal) are to be run every day testing performed.
- If quality control results do not meet the acceptance criteria defined by laboratory quality control procedure, sample results may be suspect. Follow the established quality control procedures to troubleshoot. Recalibration may be necessary. For troubleshooting information, **refer to the Alinity ci-series Operations Manual, Section 10.**
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Commercial controls should be used according to the guidelines and recommendations of the control manufacturer. Concentration ranges provided in the control package insert should be used only for guidance.

For any control material in use, the laboratory should ensure that the matrix of the control material is suitable for use in the assay per the assay package insert.

Quality Control Guidance

Refer to “Basic QC Practices” by James O Westgard, Ph.D. for guidance on laboratory quality control practices.[11](#)

Verification of Assay Claims

For protocols to verify package insert claims, refer to Verification of Assay Claims in the Alinity ci-series Operations Manual.

RESULTS

Calculation

The Alinity c Calcium assay utilizes the Linear data reduction method to generate a calibration and results.

For information on alternate result units, refer to the INSTRUMENT PROCEDURE, Alternate Result Units section of this package insert.

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the Alinity ci-series Operations Manual, Section 5.

Measuring Interval

Measuring interval is defined as the range of values in mg/dL (mmol/L) which meets the limits of acceptable performance for linearity, imprecision, and bias.

The **measuring interval** of the Alinity c Calcium assay is **2.0 to 24.0 mg/dL** (0.50 to 6.00 mmol/L).

LIMITATIONS OF THE PROCEDURE

Refer to the SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert.

EXPECTED VALUES

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

Reference Range

Serum/Plasma¹²

	Range (mg/dL)	Range (mmol/L)
Cord	8.2 to 11.2	2.05 to 2.80
Newborn		
Premature	6.2 to 11.0	1.55 to 2.75
0 to 10 days	7.6 to 10.4	1.90 to 2.60
10 days to 24 months	9.0 to 11.0	2.25 to 2.75
Child, 2 to 12 years	8.8 to 10.8	2.20 to 2.70
Adult	8.4 to 10.2	2.10 to 2.55
Male > 60 years	8.8 to 10.0	2.20 to 2.50

Urine¹²

Calcium in diet	Range (mg/day)	Range (mmol/day)
Calcium-free	5 to 40	0.13 to 1.00
Low to average	50 to 150	1.25 to 3.75
Average (800 mg/day or 20 mmol/day)	100 to 300	2.50 to 7.50

24-Hour Urinary Excretion

To convert results from mg/dL to mg/day (24-hour urinary excretion):

$$24\text{-hour excretion} = [(V \times c) \div 100] \text{ mg/day}$$

Where:

V = 24-hour urine volume (mL)

c = analyte concentration mg/dL

To convert results from mmol/L to mmol/day (24-hour urinary excretion):

$$24\text{-hour excretion} = [(V \times c) \div 1000] \text{ mmol/day}$$

Where:

V = 24-hour urine volume (mL)

c = analyte concentration mmol/L

To convert results from mg/day to mmol/day, multiply mg/day by 0.025. To convert mmol/day to mg/day divide mmol/day by 0.025.

SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

The Alinity c analyzer, and the ARCHITECT c System and AEROSET System utilize the same reagents and sample/reagent ratios.

Unless otherwise specified, all studies were performed on the Alinity c analyzer.

Precision

Within-Laboratory Precision

A study was performed based on guidance from CLSI EP05-A2. Testing was conducted using 1 lot of the Alinity c Calcium Reagent Kit, 1 lot of the Alinity c Multiconstituent Calibrator Kit, and 1 lot of commercially available controls and 1 instrument. Three controls were assayed in a minimum of 2 replicates at 2 separate times per day on 20 different days

for the serum assay. Two controls were assayed in a minimum of 2 replicates at 2 separate times per day on 20 different days for the urine assay.[13](#)

Serum

Sample	n	Mean (mg/dL)	Within-Run (Repeatability)		Within-Laboratory (Total) ^a	
			SD	%CV	SD	%CV
Control Level 1	120	6.9	0.05	0.8	0.07	1.0
Control Level 2	120	10.3	0.07	0.7	0.10	1.0
Control Level 3	120	13.6	0.10	0.7	0.12	0.8

^aIncludes within-run, between-run, and between-day variability.

Serum

Sample	n	Mean (mmol/L)	Within-Run (Repeatability)		Within-Laboratory (Total) ^a	
			SD	%CV	SD	%CV
Control Level 1	120	1.73	0.014	0.8	0.018	1.1
Control Level 2	120	2.58	0.017	0.7	0.026	1.0
Control Level 3	120	3.41	0.026	0.8	0.030	0.9

^aIncludes within-run, between-run, and between-day variability.

Urine

Sample	n	Mean (mg/dL)	Within-Run (Repeatability)		Within-Laboratory (Total) ^a	
			SD	%CV	SD	%CV
Control Level 1	120	7.3	0.06	0.9	0.07	1.0
Control Level 2	119	14.0	0.12	0.9	0.16	1.1

^aIncludes within-run, between-run, and between-day variability.

Urine

Sample	n	Mean (mmol/L)	Within-Run (Repeatability)		Within-Laboratory (Total) ^a	
			SD	%CV	SD	%CV
Control Level 1	120	1.83	0.015	0.8	0.017	0.9
Control Level 2	119	3.50	0.030	0.9	0.040	1.1

^aIncludes within-run, between-run, and between-day variability.

Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2. Testing was conducted using 3 lots of the Alinity c Calcium Reagent Kit on each of 2 instruments over a minimum of 3 days. The Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) values are summarized below. These representative data support the lower limit of the measuring interval.[14](#)

	mg/dL	mmol/L
LoB ^a	0.2	0.05
LoD ^b	0.3	0.08
LoQ ^{c, d}	1.0	0.25

^aThe LoB represents the 95th percentile from $n \geq 60$ replicates of zero-analyte samples.

^bThe LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on $n \geq 60$ replicates of low-analyte level samples.

^c The LoQ is defined as the lowest concentration at which a maximum allowable precision of 20 %CV was met.

^dThis value represents the observed LoQ on the ARCHITECT System. The LoQ observed on the Alinity c analyzer supports this LoQ.

Linearity

A study was performed based on guidance from CLSI EP06-A.[15](#)

This assay is linear across the measuring interval of **2.0 to 24.0 mg/dL** (0.50 to 6.00 mmol/L).

Interference

This study was performed on the AEROSET System.

Potentially Interfering Endogenous Substances

Interference effects were assessed by Dose Response and Paired Difference methods, at the medical decision levels of the analyte.

Medical Decision Level 1

Potentially Interfering Substance	Interferent Level		Target Level (mg/dL)	Recovery (% of Target)
	Default Units	Alternate Units		
Bilirubin	30 mg/dL	513 µmol/L	8.0	99.4
	60 mg/dL	1026 µmol/L	8.0	98.2
Hemoglobin	1000 mg/dL	10.0 g/L	7.6	100.3
	2000 mg/dL	20.0 g/L	7.6	101.4
Intralipid	500 mg/dL	5.0 g/L	7.2	103.6
	750 mg/dL	7.5 g/L	7.2	105.7

Medical Decision Level 2

Potentially Interfering Substance	Interferent Level		Target Level (mg/dL)	Recovery (% of Target)
	Default Units	Alternate Units		
Bilirubin	30 mg/dL	513 µmol/L	12.7	98.8
	60 mg/dL	1026 µmol/L	12.7	97.4
Hemoglobin	1000 mg/dL	10.0 g/L	11.3	99.9
	2000 mg/dL	20.0 g/L	11.3	99.9
Intralipid	500 mg/dL	5.0 g/L	10.9	102.9

Potentially Interfering Substance	Interferent Level		Target Level (mg/dL)	Recovery (% of Target)
	Default Units	Alternate Units		
	750 mg/dL	7.5 g/L	10.9	104.8

Bilirubin solutions at the above concentrations were prepared by addition of a bilirubin stock to human serum pools. Hemoglobin solutions at the above concentrations were prepared by addition of hemolysate to human serum pools. Intralipid solutions at the above concentrations were prepared by addition of intralipid to human serum pools.

For the urine application, glucose up to 500 mg/dL (27.8 mmol/L), ascorbate up to 100 mg/dL (5.7 mmol/L), protein up to 30 mg/dL (0.3 g/L), hydrochloric acid (6 N) up to 2.5 mL/dL (150 mmol/L), and boric acid up to 250 mg/dL (40 mmol/L) demonstrated $\leq 5\%$ or ± 0.2 mg/dL (0.05 mmol/L) interference, whichever is greater. Acetic acid (8.5 N) up to 6.25 mL/dL (531 mmol/L) and nitric acid (6 N) up to 5.0 mL/dL (300 mmol/L) demonstrated $> 10\%$ interference.

Interferences from medications or endogenous substances may affect results.[16](#)

Method Comparison

A study was performed based on guidance from CLSI EP09-A3 using the Passing-Bablok regression method.[17](#)

		Units	n	Correlation Coefficient	Intercept	Slope	Concentration Range
Alinity c Calcium vs ARCHITECT Calcium	Serum	mg/dL	132	1.00	0.13	1.00	4.4 - 23.9
		mmol/L	132	1.00	0.03	1.00	1.09 - 5.98
Alinity c Calcium vs ARCHITECT Calcium	Urine	mg/dL	130	1.00	0.05	1.00	2.3 - 21.0
		mmol/L	130	1.00	0.01	1.00	0.58 - 5.25

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