

FOR USE WITH

ARCHITECT

REF 3L79-22
REF 3L79-32
REF 3L79-42



Calcium 3L79 G95986R04 B3LS90

Revised April 2022.

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

NAME

Calcium

INTENDED USE

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

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. Longterm lithium therapy has been reported to cause hyperparathyroidism in some individuals, with resulting hypercalcemia.

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 ARCHITECT System Operations Manual, Section 3.

REAGENTS

Kit Contents

Calcium 3L79.

Supplied as a liquid, ready-to use single-reagent kit.

REF	3L79-22	3L79-32	3L79-42
Σ	1500*	11440*	24370*
R1	5 x 13 mL	10 x 41 mL	10 x 84 mL

*Calculation is based on the minimum reagent fill volume per kit.

Reactive Ingredients	Concentration
R1	
Arsenazo-III dye	0.94 mmol/L
Sodium acetate	271 mmol/L

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.³⁻⁶

The following warnings and precautions apply to: R1

<u>(!)</u>	
WARNING:	Contains methylisothiazolone.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H316*	Causes mild skin 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.

* Not applicable where regulation EC 1272/2008 (CLP) or OSHA Hazard Communication 29 CFR 1910.1200 (HCS) 2012 have been implemented.

Follow local chemical disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.

For the most current hazard information, see the product Safety Data Sheet.

Safety Data Sheets are available at www.corelaboratory.abbott or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

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Reagent Handling

- Do not use reagents beyond the expiration date.
- · Do not pool reagents within a kit or between kits.
- Do not use components from one lot with components from another lot.
- Do not invert reagent cartridges prior to use. Reagents are susceptible to the formation of foam and bubbles.
- Remove any air bubbles present in the reagents with a new applicator stick, or allow the reagents to sit at the appropriate storage temperature to allow the bubbles to dissipate. To minimize volume depletion, do not use a transfer pipette to remove bubbles.

CAUTION: Bubbles may interfere with proper detection of reagent level in the cartridge and cause insufficient reagent aspiration which could impact results.

For a detailed discussion of handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Reagent Storage

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	15-30°C	Until expiration date	
Onboard	System temperature	30 days	After 30 days, the reagent kit must be discarded.
			For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5.

For information on unloading reagents, refer to the ARCHITECT System Operations Manual, Section 5.

Indications of Reagent Deterioration

Instability or deterioration should be suspected if there are precipitates, visible signs of leakage or contamination, turbidity, or if calibration or controls do not meet the appropriate package insert and/or ARCHITECT System Operations Manual criteria.

For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The Calcium assay file must be installed on the ARCHITECT cSystem prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.

For information on printing assay parameters or for a detailed description of system procedures, refer to the ARCHITECT System Operations Manual, Section 5.

Alternate Result Units

The Conventional result unit for the Calcium assay is mg/dL. The corresponding SI result unit is mmol/L. To convert mg/dL to mmol/L, multiply mg/dL by 0.25. To convert mmol/L to mg/dL, divide mmol/L by 0.25.

When converting to units other than those listed, refer to the ARCHITECT System Operations Manual, Section 2.

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

24 hour excretion = $[(V \times c) \div 100]$ 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 hour excretion = [(V × c) ÷ 1000] 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 covert mmol/day to mg/day divide mmol/day by 0.025.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

Verified specimen types to be used with this assay.

Specimen Type	Collection Vessel
Serum	Glass or plastic tubes with or without gel barrier
Plasma	Glass or plastic 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)	Collect random specimens in a bottle containing 1 to 2 mL of 6 mol/L HCL in order to prevent calcium salt precipitation. ⁷
Urine (24 hour)	Collect 24 hour specimens in a bottle containing 20 to 30 mL of 6 mol/L HCl in order to prevent calcium salt precipitation. ⁷

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

The instrument does not provide the capability to verify specimen type. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.

Specimen Conditions

Liquid anticoagulants may have a dilution effect resulting in lower concentrations for individual patient specimens.

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 and this may cause erroneous results.

For accurate results, plasma specimens should be free of platelets and other particulate matter. Ensure centrifugation is adequate to remove platelets.

For additional information on specimen conditions, refer to the Interference section of this package insert.

Preparation for Analysis

Serum: Ensure complete clot formation has taken place prior to centrifugation. Centrifuge according to tube manufacturer's specifications to ensure proper separation of serum from blood cells. Plasma: Centrifuge according to tube manufacturer's specifications to remove platelets and ensure proper separation of plasma from blood cells.

Frozen specimens must be completely thawed before mixing. Mix thawed specimens thoroughly.

Visually inspect thawed specimens. If layering or stratification is observed, mix until specimens are visibly homogeneous. If specimens are not mixed thoroughly, inconsistent results may be obtained. NOTE: Stored specimens must be inspected for particulates. If present, mix and centrifuge the specimen to remove particulates prior to testing.

For total sample volume requirements, refer to the ARCHITECT System Operations Manual, Section 5.

Specimen Storage

Analyze fresh specimens if possible. Avoid repeated freeze/thaw cycles.

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

^{*}A tolerance of \pm 10% (\pm 2°C) is assumed not to change the stability of the specimen. (W. Guder, personal communication, August 6, 2001).

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.

Specimen Shipping

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

Do not exceed the storage limitations listed above.

PROCEDURE

Materials Provided

3L79 Calcium Reagent Kit

Materials Required but not Provided

- 1E65 Multiconstituent Calibrator
- Control material
- Saline (0.85% to 0.90% NaCl) for specimen dilution

For information on materials required for operation of the instrument, refer to the ARCHITECT System Operations Manual, Section 1. For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

Assay Procedure

For a detailed description of how to run an assay, refer to the ARCHITECT System Operations Manual, Section 5.

For sample volume requirements, refer to the ASSAY PARAMETERS section of this package insert. Minimum sample volume is calculated by the system and printed on the Order List Report. Ensure adequate sample volume is present prior to running the test.

Specimen Dilution Procedures

The ARCHITECT cSystems have an automatic dilution feature; for additional information, refer to the ARCHITECT System Operations Manual, Section 2.

Serum and plasma specimens with calcium values exceeding the 24.0 mg/dL (6.00 mmol/L) are flagged and may be diluted by following the Manual Dilution Procedure, or the Automatic Dilution Protocol provided in the assay parameters. If an Automatic Dilution Protocol is not provided, refer to the ARCHITECT System Operations Manual, Section 2 for configuration information, and verify results according to your laboratory's standard operating procedures. Urine specimens with calcium values exceeding 24.0 mg/dL (6.00 mmol/L) are flagged and may be diluted by following the Manual Dilution Procedure, or the Automatic Dilution Protocol

Automated Dilution Protocol

provided in the assay parameters.

When using the Automated Dilution Protocol, the system performs a dilution of the specimen and automatically corrects the concentration by multiplying the result by the appropriate dilution factor.

Manual Dilution Procedure

- 1. Dilute the specimen with saline (0.85% to 0.90% NaCl).
- Enter the dilution factor in the Patient or Control order screen.
 The system uses this dilution factor to automatically correct the concentration by multiplying the result by the entered factor. If the operator does not enter the dilution factor, the result must be manually multiplied by the appropriate dilution factor before reporting the result.

$$\mbox{Manual Dilution Factor} = \frac{\mbox{(Volume of Specimen + Volume of Dilution Reagent)}}{\mbox{Volume of Specimen}}$$

If a diluted specimen result is flagged indicating it is less than the linear low limit, do not report the result. Rerun using an appropriate dilution.

For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.

Calibration

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

The urine application uses the serum calibration.

For information on calibrator standardization, refer to the Multiconstituent Calibrator package insert.

For detailed information on how to perform an assay calibration, refer to the ARCHITECT System Operations Manual, Section 6.

Quality Control Procedures

As appropriate, refer to your laboratory standard operating procedure(s) and/or quality assurance plan for additional quality control requirements and potential corrective actions.

- Two levels of controls (normal and abnormal) are to be run every 24 hours
- If more frequent control monitoring is required, follow the established quality control procedures for your laboratory.
- If quality control results do not meet the acceptance criteria defined by your laboratory, patient values may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

RESULTS

Representative performance data are given in the EXPECTED VALUES and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert. Results obtained in individual laboratories may be different from the data presented.

Calculation

For additional information on results calculations, refer to the ARCHITECT System Operations Manual, Appendix C.

Interpretation of Results

As with all analyte determinations, the calcium value should be used in conjunction with information available from clinical evaluation and other diagnostic procedures.

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 ARCHITECT System Operations Manual, Section 5.

LIMITATIONS OF THE PROCEDURE

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

EXPECTED VALUES

Reference Range Serum/Plasma¹⁰

	Range	Range
	(mg/dL)	(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

Urine¹⁰

	Range	Range
Calcium in diet	(mg/day)	(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

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

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity

The linearity of Calcium serum and urine is 2.0 to 24.0 mg/dL (0.50 to 6.00 mmol/L). Calcium is linear within \pm 5% or \pm 0.2 mg/dL, whichever is greater from 2.0 to 18.0 mg/dL (0.50 to 4.50 mmol/L) and within \pm 10% from > 18.0 to 24.0 mg/dL (> 4.50 to 6.00 mmol/L) with 95% confidence.

Limit of Detection (LOD)

The LOD for Calcium serum and urine is 0.5 mg/dL (0.125 mmol/L). The LOD is the mean concentration of an analyte-free sample + 2 SD, where SD = the pooled, within-run standard deviation of the analyte-free sample.

Limit of Quantitation (LOQ)

The LOQ for Calcium serum and urine is 1.0 mg/dL (0.25 mmol/L). The LOQ is the analyte concentration at which the CV = 20%.

Interference

Interference effects were assessed by Dose Response and Paired Difference methods, at the medical decision levels of the analyte. Medical Decision Level 1

Interfering				Та	rget	Observed
Substance	Interferent	Concentration	N	(mg/dL)	(mmol/L)	(% of Target)
Bilirubin	30 mg/dL	(513 µmol/L)	4	8.0	2.00	99.4
DIIIIUDIII	60 mg/dL	(1,026 µmol/L)	4	8.0	2.00	98.2
Hamaglahin	1,000 mg/dL	(10.0 g/L)	4	7.6	1.90	100.3
Hemoglobin	2,000 mg/dL	(20.0 g/L)	4	7.6	1.90	101.4
Introlinid	500 mg/dL	(5.0 g/L)	4	7.2	1.80	103.6
Intralipid	750 mg/dL	(7.5 g/L)	4	7.2	1.80	105.7

Medical Decision Level 2

Interfering				Та	rget	Observed
Substance	Interferent	Concentration	N	(mg/dL)	(mmol/L)	(% of Target)
Bilirubin	30 mg/dL	(513 μmol/L)	4	12.7	3.18	98.8
DIIIIUUIII	60 mg/dL	(1,026 µmol/L)	4	12.7	3.18	97.4
Hamaalahin	1,000 mg/dL	(10.0 g/L)	4	11.3	2.83	99.9
Hemoglobin	2,000 mg/dL	(20.0 g/L)	4	11.3	2.83	99.9
Introlinid	500 mg/dL	(5.0 g/L)	4	10.9	2.73	102.9
Intralipid	750 mg/dL	(7.5 g/L)	4	10.9	2.73	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 \pm 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. 11

Precision

The imprecision of the Calcium assay is $\leq 3\%$ Total CV. For serum, representative data from studies using Clinical and Laboratory Standards Institute (CLSI) protocol NCCLS EP5-A2¹² are summarized below.

Serum				
Control		Level 1	Level 2	
N		80	80	
Mean (mg/dL)		8.81	11.77	
Mean (mmol/L)		2.20	2.94	
	SD (mg/dL)	0.05	0.07	
Within Run	SD (mmol/L)	0.01	0.02	
	%CV	0.5	0.6	
	SD (mg/dL)	0.05	0.03	
Between Run	SD (mmol/L)	0.01	0.008	
	%CV	0.5	0.3	
	SD (mg/dL)	0.09	0.08	
Between Day	SD (mmol/L)	0.02	0.02	
	%CV	1.0	0.7	
	SD (mg/dL)	0.11	0.11	
Total	SD (mmol/L)	0.028	0.028	
•	%CV	1.2	1.0	

For urine, representative data from studies using CLSI protocol NCCLS EP10-A2¹³ are summarized below.

	Urin	е	
Control		Level 1	Level 2
N		50	50
Mean (mg/dL)		7.59	11.00
Mean (mmol/L)		1.90	2.75
	SD (mg/dL)	0.05	0.05
Within Run	SD (mmol/L)	0.01	0.01
	%CV	0.6	0.5
	SD (mg/dL)	0.01	0.03
Between Run	SD (mmol/L)	0.003	0.008
	%CV	0.2	0.3
	SD (mg/dL)	0.02	0.04
Between Day	SD (mmol/L)	0.005	0.01
	%CV	0.3	0.3
	SD (mg/dL)	0.05	0.07
Total	SD (mmol/L)	0.01	0.02
	%CV	0.7	0.7

Method Comparison

Correlation studies were performed using CLSI protocol NCCLS EP9-A2.¹⁴

Serum and urine results from the Calcium assay on the AEROSET System and an ARCHITECT cSystem were compared with those from a commercially available Arsenazo Dye methodology (Abbott Calcium 7D61).

Serum and urine results from the Calcium assay on an ARCHITECT cSystem were compared with those from the Calcium assay on the AEROSET System.

Serum	AEROSET vs.	ARCHITECT vs.	
	Comparative	Comparative	ARCHITECT vs.
	Method	Method	AEROSET
N	102	96	121
Y-Intercept (mg/dL)	0.31	0.31	0.04
Y-Intercept	0.078	0.078	0.010
(mmol/L)			
Correlation	0.999	0.999	0.998
Coefficient			
Slope	0.96	0.96	1.00
Range (mg/dL)	2.4 to 24.6	2.4 to 24.6	2.3 to 23.4
Range (mmol/L)	0.60 to 6.15	0.60 to 6.15	0.58 to 5.85
			·

Urine	AEROSET vs.	ARCHITECT vs.	ADQUITEOT
	Comparative Method	Comparative Method	ARCHITECT vs. Aeroset
N	47	47	47
Y-Intercept (mg/dL)	0.17	0.17	0.00
Y-Intercept (mmol/L)	0.043	0.043	0.00
Correlation Coefficient	0.999	0.999	0.999
Slope	0.95	0.94	0.99
Range (mg/dL)	2.2 to 25.2	2.2 to 25.2	2.2 to 23.9
Range (mmol/L)	0.55 to 6.30	0.55 to 6.30	0.55 to 5.98

BIBLIOGRAPHY

- Jacobs DS, DeMott WR, Oxley DK, et al. Laboratory Test Handbook. Hudson, OH: Lexi-Comp; 2001:131–133.
- Bendz H, Sjödin I, Toss G, et al. Hyperparathyroidism and long-term lithium therapy—a cross-sectional study and the effect of lithium withdrawal. J Intern Med 1996;240:357–365.
- US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
- US Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories. 5th ed. Washington, DC: US Government Printing Office; December 2009.
- World Health Organization. Laboratory Biosafety Manual. 3rd ed. Geneva: World Health Organization; 2004.
- Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition. CLSI Document M29-A4. Wayne, PA: CLSI; 2014.
- Burtis CA, Ashwood ER, editors. Tietz Fundamentals of Clinical Chemistry, 5th ed. Philadelphia, PA: WB Saunders; 2001:800.
- Guder WG, Narayanan S, Wisser H, et al. List of Analytes— Preanalytical Variables. Annex In: Samples: From the Patient to the Laboratory. Darmstadt, Germany: GIT Verlag; 1996:Annex 10–1, 36–7
- US Pharmacopeial Convention, Inc. General notices. In: US Pharmacopeia National Formulary, 1995 ed (USP 23/NF 18). Rockville, MD: The US Pharmacopeial Convention, Inc; 1994:11.
- Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry, 2nd ed. Philadelphia, PA: WB Saunders; 1994:2180.
- Young DS. Effects of Drugs on Clinical Laboratory Tests, 4th ed. Washington, DC: AACC Press; 1995:3-115–3-124.
- National Committee for Clinical Laboratory Standards (NCCLS). *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition.* NCCLS Document EP5-A2. Wayne, PA: NCCLS; 2004.
- Krouwer JS, Tholen DW, Garber CC, et al. Preliminary Evaluation of Quantitative Clinical Laboratory Methods; Approved Guideline— Second Edition (EP10-A2). Wayne, PA: The National Committee for Clinical Laboratory Standards, 2002.
- National Committee for Clinical Laboratory Standards (NCCLS). Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition. NCCLS Document EP9-A2. Wayne, PA: NCCLS; 2002.

Key to Symbols

ISO 1	5223 Symbols
Ţ <u>i</u>	Consult instructions for use
	Manufacturer
Σ	Sufficient for
1	Temperature limitation
Σ	Use by/Expiration date
IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
REF	List Number
SN	Serial number
Oth	er Symbols
DISTRIBUTED IN THE USA BY	Distributed in the USA by
DO NOT SHAKE	Do not shake/agitate
FOR USE WITH	Identifies products to be used together
INFORMATION FOR USA ONLY	Information needed for United States of America only
MANUFACTURED FOR	Manufactured for
PRODUCT OF UK	Product of United Kingdom
R1	Reagent 1
Rx ONLY	For use by or on the order of a physician only (applicable to USA classification only).

The ARCHITECT cSystem family of instruments consists of c4000, c8000, and c16000 instruments.

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ASSAY PARAMETERS

Calcium Serum/Plasma—Conventional and SI Units

Configure assay paran	neters — (General		
● General ○ Calibrat	ion OS	martWash	O Results	O Interpretation
Assay: CaC	T	ype: Pho	tometric	Version: †
Number: 1066				
Run controls for onl	ooard reage	nts by: Lot		
 Reaction definition 	O Rea	agent / Sam	ple O	Validity checks
Reaction mode: End up				-
	Primary	Secondary		Read times
Wavelength:	660 /	700	M	lain: 10 - 14
Last required read:	14			
Absorbance range:			Color correct	tion:
Sample blank type:	None			

	Reagent / S	Sample	O Val	idity chec	ks
				R1	
		Reager	nt volume:	32	
		Wate	r volume:	126	
уре 0		Dispen	se mode:	Type 0	
Diluted sample	Diluent ——	Water = = = = = =			Defaul dilution O
	Reagent / S	Sample	● Va	lidity ched	cks
None					
	sample —— ——	iype 0 Diluted sample Diluent —— —— —— —— —— —— —— —— —— —— O Reagent / S	Reager Wate Type 0 Dispen Diluted sample Diluent Water	Reagent volume: Water volume: Water volume: Objective of the volume of the volume: Water volume: Water volume: Water Dispense mode: Diluted of the volume of the volume: Water Dilution for the volume of the volume: Objective of the volume: Water volume: Water volume: Water volume: Water volume: Water Dispense mode: Objective of the volume: Water Dispense mode: Objective of the volume: Water Dispense mode: Wate	R1 Reagent volume: 32 Water volume: 126 Type 0 Dispense mode: Type 0

Configure assa	y parameters	— Calibra	tion		
O General	Calibration	O SmartWa	ash	O Results	O Interpretation
Assay: CaC	Calibrat	ion method:	Linea	ar	
 Calibrators 	O Volum	nes	O In	tervals	O Validity checks
Calibrator set:			Calib	rator level:	Concentration:
MCC		Blank:	Wate	r	0 [‡]
		Cal 1:	MCC	1	††
Replicates: 3	[Range 1 - 3]	Cal 2:	MCC	2	††

O Calibrators	Volumes	01	ntervals	O Valid	lity checks
Calibrator: MCC	Calibrator level	Sample	Diluted sample	Diluent	Water
Blank:	Water	2.6			
Cal 1:	MCC1	2.6			
Cal 2:	MCC2	2.6			

O Calibrators	O Volum	es	Intervals	O Validity checks
Calibrat	ion intervals:			
	Full interval:	720	(hours)	
Calibrat	ion type:			
	Adjust type:	None		

O Calibrators	O Volumes	0	In	tervals	Valid	lity checks
Blank	absorbance range:		-			
	Span:	Blank	-	Blank		
Span	absorbance range:		-			
E:	spected cal factor:	0.00				
Expected cal f	actor tolerance %:	0				

Configure ass	ay parameters — S	SmartWash		
O General	O Calibration	SmartWash O Res	ults C	Interpretation
Assay: CaC				
COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates
R1	PHNO9	0.5% Acid Wash	345	2

Calcium Serum/Plasma—Conventional Units

Configure ass	ay parameter	s — Results				
O General	O Calibration	O SmartWash	•	Results	O Int	erpretation
	Assay:	CaC		Assay nu	umber:	1066
Dilution	default range:			Result	t units:	mg/dL
		Low-Linearity:	2.0			
		High-Linearity:	24.0			
Gender and age	specific ranges:					
GENDER	AGE (UNITS)	NORMAL		EX1	TREME	
Either	0 - 130 (Y)	8.4 – 10.2				

Configure result units	
Assay:	CaC
Version:	†
Result units:	mg/dL
Decimal places:	1 [Range 0 – 4]
Correlation factor:	1.0000
Intercept:	0.0000

Calcium Serum/Plasma—SI Units

Configure ass	ay parameter	s — Results				
O General	O Calibration	O SmartWash	•	Results	O Int	erpretation
	Assay:	CaC		Assay n	umber:	1066
Dilution	n default range:			Resul	t units:	mmol/L
		Low-Linearity:	0.50			
		High-Linearity:	6.00			
Gender and age	specific ranges:					
GENDER	AGE (UNITS)	NORMAL		EX	TREME	
Either	0 - 130 (Y)	2.10 - 2.55				

Configure result units	
Assay:	CaC
Version:	†
Result units:	mmol/L
Decimal places:	2 [Range 0 – 4]
Correlation factor:	1.0000
Intercept:	0.0000
·	

Due to differences in instrument systems and unit configurations, version numbers may vary.

Displays the number of decimal places defined in the decimal places parameter field.
†† Refer to the concentration specified on calibrator labeling or value sheet. These values are defined on the Configure calibrator set screen.

ASSAY PARAMETERS

Calcium Urine—Conventional and SI Units

● General O Calibrati	ion OS	martWa	sh O Resu	ults	O Interpretation
Assay: CaCU	1	уре:	Photometric	Ve	ersion: †
Number: 1097					
Run controls for ont	oard reage	nts by:	Lot		
 Reaction definition 	O Re	agent /	Sample	O Vali	dity checks
Reaction mode: End up					•
	Primary	Secor	ndary		Read times
Wavelength:	660 /	700		Main:	10 – 14
Last required read:	14				
Absorbance range:			Color co	rrection:	
Sample blank type:	None				

O Reaction definition	•	Reagent / S	Sample	O Val	idity chec	ks
					R1	
Reagent: CAC99			Reager	t volume:	32	
Diluent: Saline			Wate	r volume:	126	
Diluent dispense mode: 1	Гуре 0		Dispen	se mode:	Type 0	
Dilution name Sample	Diluted sample	Diluent	Water	Dilution fa	actor	Defaul dilution
STANDARD: 2.6			=	1:1.00		•
:			=			0
:			=			Ο
O Reaction definition		Reagent /	Sample	● Va	idity ched	rke
Reaction check:	None	ricugent /	oumpic	- 10	idity office	JNO.

O Gener	al 🗨	Calibration	O SmartWash	O Results	O Interpretation
Assay:	CaCU		tion method: Us	,	ank

Maximum absorbance variation:

Configure as:	say parameters — \$	SmartWash			
O General	O Calibration	SmartWash	O Resu	lts C	Interpretation
Assay: CaC	U				
COMPONENT	REAGENT / ASSAY	WASH		Volume	Replicates
R1	PHNO9	0.5% Aci	d Wash	345	2

Calcium Urine—Conventional Units

Configure as	say parameter	s — Results				
O General	O Calibration	O SmartWash	•	Results	O Int	erpretation
	Assay:	CaCU		Assay no	umber:	1097
Dilutio	n default range:			Resul	t units:	mg/dL
		Low-Linearity:	2.0			
		High-Linearity:	24.0			
Gender and age	specific ranges:					
GENDER	AGE (UNITS)	NORMAL		EXT	TREME	

Configure result units	
Assay:	CaCU
Version:	†
Result units:	mg/dL
Decimal places:	1 [Range 0 – 4]
Correlation factor:	1.0000
Intercept:	0.0000

Calcium Urine—SI Units

Configure assay parameters — Results						
O General	O Calibration	O SmartWash	•	Results	O Int	erpretation
	Assay:	CaCU		Assay no	umber:	1097
Dilution	default range:			Resul	t units:	mmol/L
		Low-Linearity:	0.50			
		High-Linearity:	6.00			
Gender and age s	specific ranges:					
GENDER	AGE (UNITS)	NORMAL		EXT	TREME	

Configure result units	
Assay:	CaCU
Version:	†
Result units:	mmol/L
Decimal places:	2 [Range 0 – 4]
Correlation factor:	1.0000
Intercept:	0.0000
•	

[†] Due to differences in instrument systems and unit configurations, version numbers may vary.