February 10, 2025

Abbott Ireland
Cherie Lipowsky
Regulatory Affairs Manager
Diagnostic Divison
Lisnamuck, Longford
Ireland

Re: K244042
Trade/Device Name: Calcium2
Regulation Number: 21 CFR 862.1145
Regulation Name: Calcium test system
Regulatory Class: Class II
Product Code: CJY
Dated: December 30, 2024
Received: December 30, 2024

Dear Cherie Lipowsky:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Deputy Division Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K244042

Device Name

Calcium2

Indications for Use *(Describe)*

The Calcium2 assay is used for the quantitation of calcium in human serum, plasma, or urine on the ARCHITECT c System.
Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Administrative Documentation - 510(k) Summary (Summary of Safety and Effectiveness)

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, and 21 CFR §807.92.

510(k) Number: K244042

I. Applicant Name

Abbott Ireland
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Ireland

Primary contact person for all communications:

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Date Summary Prepared: February 07, 2025

II. Subject Device

Trade Name: Calcium2

Device Classification: Class II
Classification Name: Calcium Test System
Regulation Number: 21 CFR §862.1145
Product Code: CJY

III. Predicate Device

Abbott Clinical Chemistry Architect/Aeroset Calcium; k062855

IV. Description of Device

A. Principles of the Procedure

The Calcium2 assay is an automated clinical chemistry assay. 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

B. Reagent

The configurations of the Calcium2 reagent kits are described below.

	List Number	
	04S9120	**04S9130**
Tests per cartridge	300	1,350
Number of cartridges per kit	4	4
Tests per kit	1,200	5,400
Reagent 1 (R1)	22.9 mL	91.8 mL

R1: Active ingredient: Arsenazo III 0.932 g/L.
Preservative: sodium azide.

V. Intended Use of the Device

The Calcium2 assay is used for the quantitation of calcium in human serum, plasma, or urine on the ARCHITECT c System.

Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

VI. Comparison of Technological Characteristics

The Calcium2 assay (subject device) is an automated clinical chemistry assay for the quantitation of calcium in human serum, plasma, or urine on the ARCHITECT c System.

The similarities and differences between the subject device and the predicate device are presented in the Assay Similarities (Table VI.1) and Assay Differences (Table VI.2), respectively.

Table VI.1
Assay Similarities

Characteristics	Subject Device Calcium2 (List Number [LN] 04S91) (K244042)	Predicate Device Abbott Clinical Chemistry Architect/Aeroset Calcium (LN 3L79) (k062855)
Intended Use and Indications for Use	The Calcium2 assay is used for the quantitation of calcium in human serum, plasma, or urine on the ARCHITECT c System. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).	The Calcium assay is used for the quantitation of calcium in human serum, plasma, or urine. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).
Methodology	Arsenazo III	Same
Specimen Type	Human serum, plasma, or urine	Same
Assay Principle/ Principle of Procedure	The Calcium2 assay is an automated clinical chemistry assay. 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.	Same
Use of Calibrators	Yes	Same
Use of Controls	Yes	Same
Traceability	NIST SRM 956	Same

Table VI.2
Assay Differences

Characteristics	Subject Device Calcium2 (List Number [LN] 04S91) (K244042)	Predicate Device Abbott Clinical Chemistry Architect/Aeroset Calcium (LN 3L79) (k062855)
Platform	ARCHITECT c8000 System	AEROSET and ARCHITECT c8000 System
Assay Range	Serum/Plasma: Analytical Measuring Interval (AMI): 2.0–24.0 mg/dL Reportable Interval: 0.2–24.0 mg/dL Urine: Analytical Measuring Interval (AMI): 2.0–24.0 mg/dL Extended Measuring Interval (EMI): 24.0–96.0 mg/dL Reportable Interval: 0.2–96.0 mg/dL	Serum/Plasma/Urine: 2.0–24.0 mg/dL
Lower Limits of Measurement	Serum/Plasma: Limit of Blank (LoB): 0.1 mg/dL Limit of Detection (LoD): 0.2 mg/dL Limit of Quantitation (LoQ): 0.4 mg/dL Urine: LoB: 0.1 mg/dL LoD: 0.2 mg/dL LoQ: 0.5 mg/dL	Serum/Urine: LoD: 0.5 mg/dL LoQ: 1.0 mg/dL

VII. Summary of Nonclinical Performance

All performance characteristics were obtained using the ARCHITECT c8000 System.

A. Reportable Interval – Serum/Plasma

Based on the limit of quantitation (LoQ) and the limit of detection (LoD), precision, and linearity, the ranges over which results can be reported are provided below.

	mg/dL
Analytical Measuring Interval (AMI)[a]	2.0 – 24.0
Reportable Interval[b]	0.2 – 24.0

[a] AMI: The AMI is determined by the range of values in mg/dL that demonstrated acceptable performance for linearity, imprecision, and bias.

[b] The reportable interval extends from the LoD to the upper limit of the AMI.

B. Reportable Interval – Urine

Based on the limit of quantitation (LoQ) and the limit of detection (LoD), precision, and linearity, the ranges over which results can be reported are provided below.

	mg/dL
Analytical Measuring Interval (AMI)[a]	2.0 – 24.0
Extended Measuring Interval (EMI)[b]	24.0 – 96.0
Reportable Interval[c]	0.2 – 96.0

[a] AMI: The AMI is determined by the range of values in mg/dL that demonstrated acceptable performance for linearity, imprecision, and bias.

[b] EMI: The EMI extends from the upper limit of quantitation (ULoQ) to the ULoQ × dilution factor.

[c] The reportable interval extends from the LoD to the upper limit of the EMI.

C. Within-Laboratory Precision - Serum

1. Within-Laboratory Precision (20-Day)

A study was performed based on guidance from CLSI EP05-A3.* Testing was conducted using 3 lots of the Calcium2 reagent, 3 lots of the Consolidated Chemistry Calibrator (ConCC), and 1 lot of commercially available controls and 3 instruments. Two controls and 3 human serum panels were tested in 2 replicates, twice per day on 20 days on 3 reagent lot/calibrator lot/instrument combinations, where a unique reagent lot and a unique calibrator lot is paired with 1 instrument. The performance from a representative combination is shown in the following table.

			Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	n	Mean (mg/dL)	SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	80	9.5	0.07	0.8	0.07 (0.07 – 0.08)	0.8 (0.8 – 0.9)
Control Level 2	80	12.7	0.08	0.7	0.09 (0.08 – 0.11)	0.7 (0.6 – 0.9)
Panel A	80	3.3	0.05	1.5	0.05 (0.05 – 0.07)	1.5 (1.5 – 2.3)
Panel B	80	6.3	0.05	0.8	0.07 (0.05 – 0.08)	1.1 (0.8 – 1.3)
Panel C	80	22.5	0.14	0.6	0.20 (0.19 – 0.20)	0.9 (0.9 – 0.9)

[a] Includes within-run, between-run, and between-day variability.
[b] Minimum and maximum SD or %CV across the 3 reagent lot/calibrator lot/instrument combinations.

* 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.

2. System Reproducibility

A study was performed based on guidance from the CLSI document EP05-A3.* Testing was conducted using 1 lot of the Calcium2 reagent, 1 lot of the ConCC, 1 lot of commercially available controls, and 3 instruments. Each instrument was operated by a different technician, and each technician prepared an individual sample set. Two controls and 3 human serum panels were tested in 3 replicates at 2 separate times per day on 5 different days.

Sample	n	Mean (mg/dL)	Repeatability		Within-Laboratory[a]		Reproducibility[b]	
			SD	%CV	SD	%CV	SD	%CV
Control Level 1	90	9.4	0.09	0.9	0.10	1.1	0.13	1.4
Control Level 2	90	12.5	0.10	0.8	0.10	0.8	0.12	1.0
Panel A	90	3.3	0.05	1.5	0.05	1.5	0.08	2.6
Panel B	90	6.3	0.08	1.2	0.08	1.2	0.11	1.7
Panel C	90	22.2	0.18	0.8	0.19	0.9	0.19	0.9

[a] Includes repeatability (within-run), between-run, and between-day variability.
[b] Includes repeatability (within-run), between-run, between-day, and between-instrument variability.

* 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.

D. Within-Laboratory Precision - Urine

1. Within-Laboratory Precision (20-Day)

A study was performed based on guidance from CLSI EP05-A3.* Testing was conducted using 3 lots of the Calcium2 reagent, 3 lots of the ConCC, and 1 lot of commercially available controls and 3 instruments. Two controls and 3 human urine panels were tested in 2 replicates, twice per day on 20 days on 3 reagent lot/calibrator lot/instrument combinations, where a unique reagent lot and a unique calibrator lot is paired with 1 instrument. The performance from a representative combination is shown in the following table.

			Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	n	Mean (mg/dL)	SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	80	6.7	0.07	1.0	0.08 (0.05 – 0.08)	1.1 (0.8 – 1.2)
Control Level 2	80	9.6	0.08	0.9	0.10 (0.06 – 0.10)	1.0 (0.7 – 1.0)
Panel A	80	3.2	0.06	1.9	0.08 (0.04 – 0.08)	2.5 (1.4 – 2.5)
Panel B	80	14.2	0.12	0.8	0.12 (0.10 – 0.12)	0.9 (0.7 – 0.9)
Panel C	80	23.1	0.14	0.6	0.17 (0.14 – 0.17)	0.7 (0.6 – 0.8)

[a] Includes within-run, between-run, and between-day variability.
[b] Minimum and maximum SD or %CV across the 3 reagent lot/calibrator lot/instrument combinations.

* 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.

2. System Reproducibility

A study was performed based on guidance from the CLSI document EP05-A3.* Testing was conducted using 1 lot of the Calcium2 reagent, 1 lot of the ConCC, 1 lot of commercially available controls, and 3 instruments. Each instrument was operated by a different technician, and each technician prepared an individual sample set. Two controls and 3 human urine panels were tested in 3 replicates at 2 separate times per day on 5 different days.

			Repeatability		Within-Laboratory[a]		Reproducibility[b]	
Sample	**n**	**Mean (mg/dL)**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Control Level 1	90	6.9	0.06	0.9	0.07	1.0	0.10	1.4
Control Level 2	90	9.9	0.09	0.9	0.09	0.9	0.11	1.1
Panel A	90	3.1	0.06	1.8	0.07	2.2	0.09	2.9
Panel B	90	14.2	0.11	0.8	0.12	0.8	0.15	1.1
Panel C	90	23.1	0.18	0.8	0.18	0.8	0.23	1.0

[a] Includes repeatability (within-run), between-run, and between-day variability.
[b] Includes repeatability (within-run), between-run, between-day, and between-instrument variability.

* 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.

E. Accuracy

A study was performed to estimate the bias of the Calcium2 assay relative to standard reference material (NIST SRM 956d Level 1 and Level 2). Testing was conducted using 2 concentrations of the standard across 3 lots of the Calcium2 reagent, 2 lots of the Consolidated Chemistry Calibrator, and 1 instrument. The bias ranged from -3.7% to -0.6%.

F. Lower Limits of Measurement - Serum

A study was performed based on guidance from CLSI EP17-A2.* Testing was conducted using 3 lots of the Calcium2 reagent on each of 2 instruments over 3 days. The maximum observed limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) values are summarized below.

	mg/dL
LoB[a]	0.1
LoD[b]	0.2
LoQ[c]	0.4

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 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 and was determined from n ≥ 60 replicates of low-analyte level samples.

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition*. CLSI Document EP17-A2. Wayne, PA: CLSI; 2012.

G. Lower Limits of Measurement - Urine

A study was performed based on guidance from CLSI EP17-A2.* Testing was conducted using 3 lots of the Calcium2 reagent on each of 2 instruments over 3 days. The maximum observed limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) values are summarized below.

	mg/dL
LoB[a]	0.1
LoD[b]	0.2
LoQ[c]	0.5

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 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 and was determined from n ≥ 60 replicates of low-analyte level samples.

H. Linearity - Serum

A study was performed based on guidance from CLSI EP06 2nd ed.†

The assay was demonstrated to be linear from 2.0 to 24.0 mg/dL.

I. Linearity - Urine

A study was performed based on guidance from CLSI EP06 2nd ed.†

The assay was demonstrated to be linear from 2.0 to 24.0 mg/dL

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition*. CLSI Document EP17-A2. Wayne, PA: CLSI; 2012.

† Clinical and Laboratory Standards Institute (CLSI). *Evaluation of the Linearity of Quantitative Measurement Procedure.* 2nd ed. CLSI Document EP06. Wayne, PA: CLSI; 2020.

J. Potentially Interfering Endogenous and Exogenous Substances - Serum

Potentially Interfering Endogenous Substances

A study was performed based on guidance from EP07 3rd ed.* Each substance was tested at 2 levels of the analyte (approximately 9 mg/dL and 12 mg/dL).

No significant interference (interference within ± 5%) was observed at the following concentrations.

No Significant Interference (Interference within ± 5%)	
Potentially Interfering Substance	**Interferent Level**
Bilirubin (conjugated)	40 mg/dL
Bilirubin (unconjugated)	40 mg/dL
Hemoglobin	1,000 mg/dL
Total protein	15 g/dL
Triglycerides	1500 mg/dL

* Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry*. 3rd ed. CLSI Guideline EP07. Wayne, PA: CLSI; 2018.

Potentially Interfering Exogenous Substances

No significant interference (interference within ± 5%) was observed at the following concentrations.

No Significant Interference (Interference within ± 5%)	
Potentially Interfering Substance	**Interferent Level**
Acetaminophen	160 mg/L
Acetylcysteine	150 mg/L
Acetylsalicylic acid	30 mg/L
Ampicillin-Na	80 mg/L
Ascorbic acid	60 mg/L
Ca-dobesilate	46 mg/L
Cefoxitin	6600 mg/L
Cyclosporine	2 mg/L
Doxycycline	20 mg/L
Ibuprofen	220 mg/L
Levodopa	8 mg/L
Magnesium sulfate	50 mg/dL
Methyldopa	25 mg/L
Metronidazole	130 mg/L
Phenylbutazone	330 mg/L
Rifampicin	50 mg/L
Sodium heparin	4 U/mL
Theophylline (1,3-dimethylxanthine)	60 mg/L

Interference beyond ± 5% (based on 95% Confidence Intervals [CI]) was observed at the concentrations shown below for the following substance

Interference beyond ± 5% (based on 95% Confidence Interval [CI])			
Potentially Interfering Substance	**Interferent Level**	**Analyte Level**	**% Interference (95% CI)**
Ca-dobesilate	60 mg/L	9 mg/dL	6% (5%, 6%)

K. Potentially Interfering Endogenous and Exogenous Substances - Urine

Potentially Interfering Endogenous Substances

A study was performed based on guidance from EP07 3rd ed.* Each substance was tested at 2 levels of the analyte (approximately 8 mg/dL and 16 mg/dL).

No significant interference (interference within ± 5%) was observed at the following concentrations.

No Significant Interference (Interference within ± 5%)	
Potentially Interfering Substance	**Interferent Level**
Ascorbate	100 mg/dL
Glucose	500 mg/dL
Magnesium sulfate	50 mg/dL
Total protein	30 mg/dL
Sample pH	2.5 to 6.0
Urea	5000 mg/dL
Uric acid	92 mg/dL

* Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry*. 3rd ed. CLSI Guideline EP07. Wayne, PA: CLSI; 2018.

Potentially Interfering Exogenous Substances

No significant interference (interference within ± 5%) was observed at the following concentrations.

No Significant Interference (Interference within ± 5%)	
Potentially Interfering Substance	**Interferent Level**
Acetaminophen	16 mg/dL
Acetic acid (8.5N)	5.16 mL/dL
Boric acid	250 mg/dL
Hydrochloric acid (6N)	2.5 mL/dL
Ibuprofen	22 mg/dL
Nitric acid (6N)	5.0 mL/dL

Interference beyond ± 5% (based on 95% Confidence Intervals [CI]) was observed at the concentrations shown below for the following substance

Interference beyond ± 5% (based on 95% Confidence Interval [CI])			
Potentially Interfering Substance	**Interferent Level**	**Analyte Level**	**% Interference (95% CI)**
Acetic acid (8.5N)	6.25 mL/dL	8 mg/dL	-7% (-8%, -6%)

L. Method Comparison - Serum

A study was performed based on guidance from CLSI EP09c 3rd ed.[*] using the Passing-Bablok regression method. The study compared the Calcium2 assay to the comparator Calcium assay.

Calcium2 vs Calcium on the ARCHITECT c8000 System						
	n	**Units**	**Correlation Coefficient**	**Intercept**	**Slope**	**Concentration Range**
Serum	120	mg/dL	1.00	-0.1	1.02	2.3–21.1

M. Method Comparison - Urine

A study was performed based on guidance from CLSI EP09c 3rd ed.[†] using the Passing-Bablok regression method. The study compared the Calcium2 assay to the comparator Calcium assay.

Calcium2 vs Calcium on the ARCHITECT c8000 System						
	n	**Units**	**Correlation Coefficient**	**Intercept**	**Slope**	**Concentration Range**
Urine	112	mg/dL	1.00	0.1	0.96	2.1–22.7

[*] Clinical and Laboratory Standards Institute (CLSI). *Measurement Procedure Comparison and Bias Estimation Using Patient Samples.*3rd ed. CLSI Document EP09c. Wayne, PA: CLSI; 2018.

[†] Clinical and Laboratory Standards Institute (CLSI). *Measurement Procedure Comparison and Bias Estimation Using Patient Samples.*3rd ed. CLSI Document EP09c. Wayne, PA: CLSI; 2018.

N. Tube Type Equivalence - Serum

A study was performed to evaluate the suitability of specific blood collection tube types for use with the Calcium2 assay. Samples were collected from 78 donors and evaluated across tube types. The following blood collection tube types were determined to be acceptable for use with the Calcium2 assay:

Serum

- Serum tubes
- Serum separator tubes

Plasma

- Lithium heparin tubes
- Lithium heparin separator tubes
- Sodium heparin tubes

O. Dilution Verification - Urine

A study was performed based on guidance from CLSI EP34 1st ed.* to evaluate the recovery of the Calcium2 automated and manual dilution, relative to the assigned concentration, on the ARCHITECT c System.

Five samples were prepared to have calcium concentrations within the EMI of the Calcium2 assay by spiking normal human urine with calcium stock (calcium chloride dihydrate solution) to the target concentration values of 26, 41, 56, 71, and 85 mg/dL.

The performance of the automated dilution protocol and manual dilution procedure was considered acceptable if, for samples within the EMI, the dilution recovery was within or equal to 100% ± 10% when comparing auto-diluted or manually diluted samples to target or assigned concentrations and the imprecision was ≤ 5 %CV for the automated dilution protocol and ≤ 6 %CV for manual dilution procedure.

The %recovery for the automated dilution and the manual dilution demonstrated acceptable performance.

The dilution reproducibility demonstrated imprecision ≤ 5 %CV for the automated dilution protocol and ≤ 6 %CV for manual dilution procedure.

* Clinical and Laboratory Standards Institute (CLSI). *Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking*. 1st ed. CLSI Guideline EP34. Wayne, PA: CLSI; 2018.

VIII. Summary of Clinical Performance

This section does not apply.

IX. Conclusion Drawn from Nonclinical Laboratory Studies

The results presented in this 510(k) premarket notification demonstrate that the performance of the subject device Calcium2 (LN 04S91), is substantially equivalent to the predicate device, ARCHITECT Calcium (k062855).

The similarities and differences between the subject device and the predicate device are presented in Section VI.