October 24, 2025

Abbott Ireland
Cherie Lipowsky
Regulatory Affairs Manager
Diagnostics Division
Lisnamuck
Longford,
Ireland

Re: K252357
Trade/Device Name: Glucose2
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: CFR
Dated: July 29, 2025
Received: July 29, 2025

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an

established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k252357

Device Name
Glucose2

Indications for Use *(Describe)*
The Glucose2 assay is used for the quantitation of glucose in human serum, plasma, urine, or cerebrospinal fluid (CSF) on the ARCHITECT c System.
Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

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.

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: K252357

I. Applicant Name

Abbott Ireland
Diagnostics Division
Lisnamuck, Longford,
Co. Longford,
Ireland

Primary contact person for all communications:

Cherie Lipowsky, Regulatory Affairs Manager
Abbott Diagnostics Division
Phone: (224) 668-1435
Fax: (224) 667-4836
Email: cherie.lipowsky@abbott.com

Secondary contact person for all communications:

Jacob Richards, Associate Director of Regulatory Affairs
Abbott Diagnostics Division
Phone: (224) 668-8852
Fax: (224) 667-4836
Email: jacob.richards@abbott.com

Date Summary Prepared: September 25, 2025

II. Subject Device

Trade Name: Glucose2

Device Classification: Class II
Classification Name: Glucose Test System
Regulation Number: 21 CFR §862.1345
Product Code: CFR

III. Predicate Device

Glucose; k060383

IV. Description of Device

A. Principles of the Procedure

The Glucose2 assay is an automated clinical chemistry assay.

Glucose is phosphorylated by hexokinase in the presence of adenosine triphosphate (ATP) and magnesium ions to produce glucose-6-phosphate (G-6-P) and adenosine diphosphate (ADP). Glucose-6-phosphate dehydrogenase (G-6-PDH) specifically oxidizes G-6-P to 6-phosphogluconate with the concurrent reduction of nicotinamide adenine dinucleotide phosphate (NADP) to its reduced form (NADPH). One micromole of NADPH is produced for each micromole of glucose consumed. The NADPH produced absorbs light at 340 nm and can be detected spectrophotometrically as an increased absorbance.

Methodology: Hexokinase/G6PDH

B. Reagent

The configurations of the Glucose2 reagent kits are described below.

	List Number (LN)	
	04T0120	**04T0130**
Tests per cartridge set	520	1500
Number of cartridge sets per kit	4	4
Tests per kit	2080	6000
Reagent 1 (R1)	31.2 mL	82.6 mL
Reagent 2 (R2)	34.2 mL	91.4 mL

R1: Active ingredients: b-NADP, disodium salt 6.300 g/L, adenosine triphosphate (ATP) 2.420 g/L. Preservative: sodium azide.

R2 Active ingredients: hexokinase 19.200 KU/L, glucose-6-phosphate dehydrogenase 6.400 KU/L. Preservative: sodium azide.

C. Predetermined Change Control Plan (PCCP)

A PCCP permits the blood collection tube type of potassium fluoride/EDTA to be added for use with the Glucose2 assay following successful verification using a predetermined study design and acceptance criteria.

V. Intended Use of the Device

The Glucose2 assay is used for the quantitation of glucose in human serum, plasma, urine, or cerebrospinal fluid (CSF) on the ARCHITECT c System.

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

VI. Comparison of Technological Characteristics

The Glucose2 assay (subject device) is an automated clinical chemistry assay for the quantitation of glucose in human serum, plasma, urine, or CSF on the ARCHITECT c System.

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

Table VI.1
Assay Similarities

Characteristics	Subject Device Glucose2 (LN 04T01) (k252357)	Predicate Device Glucose (LN 3L82) (k060383)
Platform	ARCHITECT c System	Same
Intended Use and Indications for Use	The Glucose2 assay is used for the quantitation of glucose in human serum, plasma, urine, or cerebrospinal fluid on the ARCHITECT c System. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.	A glucose test system is a device intended to measure glucose quantitatively in blood and other bodily fluids. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.
Methodology	Hexokinase/G6PDH	Same
Specimen Type	Human serum, plasma, urine, or CSF	Same
Assay Principle/ Principle of Procedure	The Glucose2 assay is an automated clinical chemistry assay. Glucose is phosphorylated by hexokinase in the presence of adenosine triphosphate (ATP) and magnesium ions to produce glucose-6-phosphate (G-6-P) and adenosine diphosphate (ADP). Glucose-6-phosphate dehydrogenase (G-6-PDH) specifically oxidizes G-6-P to 6-phosphogluconate with the concurrent reduction of nicotinamide adenine dinucleotide phosphate (NADP) to its reduced form (NADPH). One micromole of NADPH is produced for each micromole of glucose consumed. The NADPH produced absorbs light at 340 nm and can be detected spectrophotometrically as an increased absorbance.	Same

Assay Similarities (Continued)

Characteristics	Subject Device Glucose2 (List Number [LN] 04T01) (k252357)	Predicate Device Glucose (LN 3L82) (k060383)
Use of Calibrators	Yes	Same
Use of Controls	Yes	Same
Standardization	NIST SRM 965	Same

NIST = National Institute of Standards and Technology
SRM = Standard Reference Material

Table VI.2
Assay Differences

Characteristics	Subject Device Glucose2 (LN 04T01) (k252357)	Predicate Device Glucose (LN 3L82) (k060383)
Assay Range	Serum/Plasma: Analytical Measuring Interval (AMI): 5–800 mg/dL (0.28–44.40 mmol/L) Extended Measuring Interval (EMI): 800–4000 mg/dL (44.40–222.00 mmol/L) Urine: Analytical Measuring Interval (AMI): 1–800 mg/dL (0.06–44.40 mmol/L) CSF: Analytical Measuring Interval (AMI): 2–800 mg/dL (0.11–44.40 mmol/L)	Serum: 5–800 mg/dL (0.28–44.40 mmol/L) Urine/CSF: 1–800 mg/dL (0.06–44.40 mmol/L)
Lower Limits of Measurement	Serum/Plasma: Limit of Blank (LoB): 0.17 mg/dL (0.01 mmol/L) Limit of Detection (LoD): 0.30 mg/dL (0.02 mmol/L) Limit of Quantitation (LoQ): 1.16 mg/dL (0.06 mmol/L) Urine: LoB: 0.15 mg/dL (0.01 mmol/L) LoD: 0.29 mg/dL (0.02 mmol/L) LoQ: 0.47 mg/dL (0.03 mmol/L)	Serum: LoD: 2.5 mg/dL (0.139 mmol/L) LoQ: 5.0 mg/dL (0.278 mmol/L) Urine/CSF: LoD: 1.0 mg/dL (0.056 mmol/L) LoQ: 1.0 mg/dL (0.056 mmol/L)

Characteristics	Subject Device Glucose2 (LN 04T01) (k252357)	Predicate Device Glucose (LN 3L82) (k060383)
	CSF: LoB: 0.23 mg/dL (0.01 mmol/L) LoD: 0.35 mg/dL (0.02 mmol/L) LoQ: 1.25 mg/dL (0.07 mmol/L)	

VII. Summary of Nonclinical Performance

A. Measuring Interval – Serum/Plasma

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.

	mg/dL
Analytical Measuring Interval (AMI)[a]	5–800
Extended Measuring Interval (EMI)[b]	800–4000

[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 EMI extends from the upper limit of quantitation (ULoQ) to the ULoQ x sample dilution.

B. Measuring Interval – Urine

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.

	mg/dL
Analytical Measuring Interval (AMI)[a]	1–800

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

C. Measuring Interval – CSF

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.

	mg/dL
Analytical Measuring Interval (AMI)[a]	2–800

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

D. 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 Glucose2 reagents, 3 lots of the Consolidated Chemistry Calibrator (ConCC), 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 are 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	43	0.5	1.2	0.5 (0.4–0.5)	1.3 (1.0–1.3)
Control Level 2	80	132	1.0	0.8	1.3 (1.2–1.6)	1.0 (0.9–1.2)
Panel A	80	10	0.1	1.1	0.1 (0.0–0.4)	1.1 (0.0–3.8)
Panel B	80	20	0.2	1.3	0.4 (0.2–0.5)	1.9 (0.8–2.4)
Panel C	80	740	4.1	0.5	5.9 (5.9–6.9)	0.8 (0.8–0.9)

[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 Glucose2 reagents, 1 lot of the ConCC, 1 lot of the commercially available controls, and 3 instruments. Each instrument was operated by a different technician, and each individual sample set was prepared independently. Two controls and 3 human serum 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	42	0.4	1.0	0.5	1.2	0.8	1.8
Control Level 2	90	132	1.0	0.7	1.7	1.3	1.7	1.3
Panel A	90	10	0.3	2.6	0.3	2.8	0.3	2.9
Panel B	90	20	0.1	0.7	0.2	0.9	0.2	0.9
Panel C	90	745	6.9	0.9	7.9	1.1	8.0	1.1

[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. 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 Glucose2 reagents, 3 lots of the ConCC, 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 are 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	41	0.4	1.0	0.5 (0.4–0.6)	1.2 (1.0–1.6)
Control Level 2	80	338	2.5	0.7	2.8 (2.8–4.0)	0.8 (0.8–1.2)
Panel A	80	3	0.0	0.0	0.0 (0.0–0.0)	0.0 (0.0–0.0)
Panel B	80	100	0.8	0.8	1.1 (0.8–1.1)	1.1 (0.8–1.1)
Panel C	80	732	6.0	0.8	8.2 (6.1–8.2)	1.1 (0.8–1.1)

[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 Glucose2 reagents, 1 lot of the ConCC, 1 lot of the commercially available controls, and 3 instruments. Each instrument was operated by a different technician, and each individual sample set was prepared independently. 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	40	0.6	1.4	0.6	1.5	0.8	1.9
Control Level 2	90	338	2.8	0.8	3.4	1.0	3.4	1.0
Panel A	90	3	0.1	4.4	0.2	6.9	0.2	6.9
Panel B	90	99	0.8	0.8	1.1	1.1	1.5	1.5
Panel C	90	733	5.6	0.8	6.5	0.9	7.3	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.

F. Within-Laboratory Precision - CSF

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 Glucose2 reagents, 1 lot of the Consolidated Chemistry Calibrator, 1 lot of commercially available controls, and 1 instrument. Two controls and 3 human CSF panels were tested in 2 replicates twice per day on 20 days on 3 reagent lots. 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	64	0.6	1.0	0.7 (0.6–0.7)	1.1 (1.0–1.1)
Control Level 2	80	32	0.4	1.2	0.5 (0.5–0.5)	1.5 (1.5–1.5)
Panel A	80	10	0.1	1.1	0.1 (0.1–0.4)	1.1 (1.1–3.5)
Panel B	80	253	1.9	0.8	2.4 (2.2–2.4)	1.0 (0.9–1.0)
Panel C	80	744	5.3	0.7	7.0 (7.0–7.5)	0.9 (0.9–1.0)

[a] Includes within-run, between-run, and between-day variability.
[b] Minimum and maximum SD or %CV across reagent lots.

[*] 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 Glucose2 reagents, 1 lot of the ConCC, 1 lot of the commercially available controls, and 3 instruments. Each instrument was operated by a different technician, and each individual sample set was prepared independently. Two controls and 3 human CSF 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	63	0.9	1.4	1.1	1.7	1.3	2.0
Control Level 2	90	32	0.4	1.4	0.6	1.8	0.6	1.9
Panel A	90	10	0.1	1.1	0.1	1.1	0.1	1.1
Panel B	90	244	2.3	0.9	2.9	1.2	2.9	1.2
Panel C	90	751	5.9	0.8	7.5	1.0	7.6	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.

G. Accuracy

A study was performed to estimate the bias of the Glucose2 assay relative to standard reference material (NIST SRM 965b Levels 1 through 4). Testing was conducted using 4 concentrations of the standard, 3 lots of the Glucose2 reagents, 2 lots of the ConCC, and 1 instrument. The bias ranged from -0.3% to 5.4% for serum.

H. Lower Limits of Measurement - Serum

A study was performed based on guidance from CLSI EP17-A2.* Testing was conducted using 3 lots of the Glucose2 reagents on each of 2 instruments over a minimum of 3 days. The maximum observed LoB, LoD, and LoQ values are summarized below.

	mg/dL
LoB[a]	0.17
LoD[b]	0.30
LoQ[c]	1.16

[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.

I. Lower Limits of Measurement - Urine

A study was performed based on guidance from CLSI EP17-A2.* Testing was conducted using 3 lots of the Glucose2 reagents on each of 2 instruments over a minimum of 3 days. The maximum observed LoB, LoD, and LoQ values are summarized below.

	mg/dL
LoB[a]	0.15
LoD[b]	0.29
LoQ[c]	0.47

[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.

J. Lower Limits of Measurement - CSF

A study was performed based on guidance from CLSI EP17-A2.* Testing was conducted using 3 lots of the Glucose2 reagents on one instrument over a minimum of 3 days. The maximum observed LoB, LoD, and LoQ values are summarized below.

	mg/dL
LoB[a]	0.23
LoD[b]	0.35
LoQ[c]	1.25

[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.

K. Linearity - Serum

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

The assay was demonstrated to be linear across the AMI of 5 mg/dL to 800 mg/dL.

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

L. Linearity - Urine

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

The assay was demonstrated to be linear across the AMI of 1 mg/dL to 800 mg/dL.

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

M. Linearity - CSF

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

The assay was demonstrated to be linear across the AMI of 2 mg/dL to 800 mg/dL.

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

N. Potentially Interfering Endogenous and Exogenous Substances - Serum

Potentially Interfering Endogenous Substances

A study was performed based on guidance from CLSI EP07 3rd ed.* Each substance was tested at 2 levels of the glucose analyte (approximately 40 mg/dL and 220 mg/dL).

No significant interference (interference within ± 6%) was observed at the following concentrations.

No Significant Interference (Interference within ± 6%)	
Potentially Interfering Substance	**Interferent Level**
Bilirubin (conjugated)	40 mg/dL
Bilirubin (unconjugated)	40 mg/dL
Hemoglobin	1,000 mg/dL
Total protein	12 g/dL
Triglycerides	1,070 mg/dL

Interference beyond ± 6% (based on 95% Confidence Interval [CI]) was observed at the concentrations shown below for the following substances.

Interference beyond ± 6% (based on 95% Confidence Interval [CI])			
Potentially Interfering Substance	**Interferent Level**	**Analyte Level**	**% Interference (95% CI)**
Total protein	15 g/dL	220 mg/dL	-6% (-7%, -6%)
Triglycerides	1574 mg/dL	40 mg/dL	-8% (-8%, -7%)

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

Potentially Interfering Exogenous Substances

A study was performed based on guidance from CLSI EP07 3rd ed.* Each substance was tested at 2 levels of the glucose analyte (approximately 40 mg/dL and 220 mg/dL).

No significant interference (interference within ± 6%) was observed at the following concentrations.

No Significant Interference (Interference within ± 6%)	
Potentially Interfering Substance	**Interferent Level**
Acetaminophen	160 mg/L
Acetylcysteine	150 mg/L
Acetylsalicylic acid	30 mg/L
5-amino-4-imidazole-carboxamide (AIC)	3 mg/L
Ampicillin-Na	80 mg/L
Ascorbic acid	60 mg/L
Biotin	3510 ng/mL
Ca-dobesilate	60 mg/L
Cefoxitin	6,600 mg/L
Cyclosporine	2 mg/L
Doxycycline	20 mg/L
Eltrombopag	300 mg/L
Ibuprofen	220 mg/L
Levodopa	8 mg/L
Methyldopa	25 mg/L
3-methyl-(triazen-1-yl) imidazole-4-carboxamide (MTIC)	0.6 mg/L
Metronidazole	130 mg/L

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

No Significant Interference (Interference within ± 6%)	
Potentially Interfering Substance	**Interferent Level**
Phenylbutazone	330 mg/L
Rifampicin	50 mg/L
Sodium heparin	4 U/mL
Sulfapyridine	300 mg/L
Sulfasalazine	300 mg/L
Temozolomide	20 mg/L
Tetracycline	3 mg/dL
Theophylline (1,3-dimethylxanthine)	60 mg/L

O. Potentially Interfering Endogenous and Exogenous Substances - Urine

Potentially Interfering Endogenous Substances

A study was performed based on guidance from CLSI EP07 3rd ed.[*]. Each substance was tested at 2 levels of the glucose analyte (approximately 15 mg/dL and 90 mg/dL).

No significant interference (interference within ± 10%) was observed at the following concentrations.

No Significant Interference (Interference within ± 10%)	
Potentially Interfering Substance	**Interferent Level**
Ascorbate	200 mg/dL
Protein	50 mg/dL
Sodium oxalate	60 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

A study was performed based on guidance from CLSI EP07 3rd ed.* Each substance was tested at 2 levels of the glucose analyte (approximately 15 mg/dL and 90 mg/dL).

No significant interference (interference within ± 10%) was observed at the following concentrations.

No Significant Interference (Interference within ± 10%)	
Potentially Interfering Substance	**Interferent Level**
Acetic acid (8.5N)	6.25 mL/dL
Boric acid	250 mg/dL
Hydrochloric acid (6N)	2.5 mL/dL
Nitric acid (6N)	5.0 mL/dL
Sodium carbonate	1.25 g/dL
Sodium fluoride	400 mg/dL

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

P. 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 Glucose2 assay to the comparator Glucose assay.

Glucose2 vs Glucose on the ARCHITECT c8000 System

	n	Units	Correlation Coefficient	Intercept	Slope	Concentration Range
Serum	130	mg/dL	1.00	6	0.97	6–797

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

Q. 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 Glucose2 assay to the comparator Glucose assay.

Glucose2 vs Glucose on the ARCHITECT c8000 System

	n	Units	Correlation Coefficient	Intercept	Slope	Concentration Range
Urine	148	mg/dL	1.00	4	0.98	1–800

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

R. Method Comparison - CSF

A study was performed based on guidance from CLSI EP09c 3rd ed.* using the Passing-Bablok regression method. The study compared the Glucose2 assay to the comparator Glucose assay.

Glucose2 vs Glucose on the ARCHITECT c8000 System

	n	Units	Correlation Coefficient	Intercept	Slope	Concentration Range
CSF	135	mg/dL	1.00	3	1.00	3–772

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

S. Tube Type Equivalence - Serum

A study was performed to evaluate the suitability of specific blood collection tube types for use with the Glucose2 assay. Samples were collected from 69 donors and evaluated across tube types. The following blood collection tubes were determined to be acceptable for use with the Glucose2 assay:

Serum

- Serum
- Serum separator

Plasma

- Dipotassium EDTA
- Tripotassium EDTA
- Lithium heparin
- Lithium heparin separator
- Potassium fluoride/citrate/EDTA
- Sodium fluoride/EDTA
- Sodium fluoride/potassium oxalate
- Sodium heparin

T. Dilution Verification

A study was performed based on guidance from CLSI EP34 1st ed.[*] to evaluate the recovery of the Glucose2 automated and manual dilution, relative to the assigned concentration, on the ARCHITECT c System.

Five samples were prepared to have glucose concentrations within the EMI of the Glucose2 assay by spiking normal human serum with glucose stock (D-(+)-Glucose - ACS reagent[*]) to the assigned concentration values of 926 mg/dL, 1,628 mg/dL, 2,250 mg/dL, 2,785 mg/dL, and 3,651 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.

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

[*] 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.

[*] Sigma-Aldrich

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 Glucose2 (LN 04T01), is substantially equivalent to the predicate device, ARCHITECT Glucose (k060383).

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