DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 19, 2017

ABBOTT LABORATORIES
NOAH LERMER, PH.D.
REGULATORY AFFAIRS DIRECTOR
DEPT. 9AA, BLDG CP01-3,
100 ABBOTT PARK ROAD
ABBOTT PARK, IL 60064

Re: K170316
Trade/Device Name: Alinity c Glucose Reagent Kit
Alinity c System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: CFR, JJE
Dated: September 06, 2017
Received: September 07, 2017

Dear Dr. Noah Lermer:

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 (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. 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.

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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Stayce Beck -A

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k170316

Device Name
Alinity c Glucose Reagent Kit

Indications for Use *(Describe)*
The Alinity c Glucose Reagent Kit is used for the quantitation of glucose in human serum, plasma, urine, or cerebrospinal fluid (CSF) on the Alinity c analyzer. 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k170316

Device Name
Alinity c System

Indications for Use *(Describe)*
The Alinity c System is a fully automated, random/continuous access, clinical chemistry analyzer intended for the in vitro determination of analytes in body fluids.

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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k170613
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 SMDA 1990 and 21 CFR 807.92.

I. Applicant Name

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Date Summary Prepared: January 31, 2017.

Date Summary Revised: October 19, 2017

II. Device Name

Alinity c Glucose Reagent Kit
Alinity c System

Alinity c Glucose Reagent Kit

Device Classification: Class II
Classification Name: Hexokinase, glucose
Governing Regulation: CFR 862.1345
Product Code: CFR

Alinity c System

Device Classification: Class I
Classification Name: Discrete photometric chemistry analyzer for clinical use
Governing Regulation: CFR 862.2160
Product Code: JJE

III. Predicate Device

Reagent
Glucose (k060383)

Instrument

AEROSET/ARCHITECT *c* System family members (k980367)

IV. Description of Device

A. Alinity c Glucose Reagent Kit

Kit Contents

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

Ref	**07P5520**	**07P5530**
Tests per cartridge	400	1100
Number of cartridges per kit	10	10
Tests per kit	4000	11,000
Reagent 1 (R1)	26.5 mL	66.4 mL

Reagent	**Reactive Ingredients**	**Concentration**
Reagent 1	ATP •2Na	9.0 mg/mL
	NAD	5.0 mg/mL
	G-6-PDH	3000 U/L
	Hexokinase	15,000 U/L

B. Alinity c Multiconstituent Calibrator Kit

The Alinity c Multiconstituent Calibrator contains:

	Number of Bottles × Volume
Component	**08P6001**
Cal 1	3 × 2.9 mL
Cal 2	3 × 2.9 mL

The Alinity c Multiconstituent calibrators are prepared from a human-based matrix containing multiple analytes, including glucose. Sodium azide is present as a preservative.

The Alinity c Multiconstituent calibrators are prepared and standardized, for glucose, as described in the table below:

Analyte	Reference Material	Reference Method
Glucose	NIST SRM 965	ID-GC/MS

NIST- National Institute of Standards and Technology
SRM- Standard Reference Materials
ID-GC/MS- Isotope Dilution- Gas Chromatography Mass Spectrophotometry

C. Alinity c System

The Alinity c System is a fully automated chemistry analyzer allowing random and continuous access, as well as priority and automated retest processing using photometric and potentiometric detection technology. The Alinity c System uses photometric detection technology to measure sample absorbance for the quantification of analyte concentration.

D. Principles of the Procedure

Glucose is phosphorylated by hexokinase (HK) 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 (NAD) to nicotinamide adenine dinucleotide reduced (NADH). One micromole of NADH is produced for each micromole of glucose consumed. The NADH produced absorbs light at 340 nm and can be detected spectrophotometrically as an increased absorbance.

Methodology: Enzymatic (Hexokinase/ G-6-PDH)

V. Intended Use of the Device

The Alinity c Glucose Reagent Kit is used for the quantitation of glucose in human serum, plasma, urine, or cerebrospinal fluid (CSF) on the Alinity c analyzer. 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.

The Alinity c System is a fully automated, random/continuous access, clinical chemistry analyzer intended for the *in vitro* determination of analytes in body fluids.

VI. Comparison of Technological Characteristics

The Alinity c Glucose Reagent Kit is used for the quantitative analysis of glucose in human serum/plasma, urine or cerebrospinal fluid on the Alinity c analyzer.

The similarities and differences of the candidate assay (Alinity c Glucose Reagent Kit, LN 07P55) to the predicate assay (Glucose assay, LN 3L82) are presented in Table 1 starting on page 7 and Table 2 starting on page 8, respectively.

The similarities and differences between the Alinity c System and the AEROSET/ARCHITECT c System (k980367) are presented in Table 3 on page 9 and Table 4 on page 10, respectively.

Table 1: Reagent Similarities

Characteristics	Candidate Assay Alinity c Glucose Reagent Kit (LN 07P55)	Predicate Assay (k060383) Glucose (LN 3L82)
Technical Characteristics		
Reagent Formulation	R1: Active ingredients: ATP• 2Na (9.0 mg/mL), NAD (5.0 mg/mL), G-6-PDH (3000 U/L), Hexokinase (15 000 U/L), Preservative: sodium azide (0.05%).	Same
Analyte Measured	Glucose	Same
Intended Use	The Alinity c Glucose assay is used for the quantitation of glucose in human serum, plasma, urine, or cerebrospinal fluid (CSF).	Same
Indications for Use	A glucose test system is a device intended to measure glucose quantitatively in blood and other body 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.	Same
Assay Principle	Glucose is phosphorylated by hexokinase (HK) 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 (NAD) to nicotinamide adenine dinucleotide reduced (NADH). One micromole of NADH is produced for each micromole of glucose consumed. The NADH produced absorbs light at 340 nm and can be detected spectrophotometrically as an increased absorbance.	Same
Detection of Analyte	End-point colorimetric.	Same
Specimen Type	Human serum, plasma, urine, or CSF.	Same

Characteristics	Candidate Assay Alinity c Glucose Reagent Kit (LN 07P55)	Predicate Assay (k060383) Glucose (LN 3L82)
Performance Characteristics		
Assay Range	**Serum/Plasma** 5 to 800 mg/dL (0.28 to 44.40 mmol/L). **Urine/ CSF** 1 to 800 mg/dL (0.06 to 44.40 mmol/L).	Same
Measuring Interval	**Serum/ Plasma** The measuring interval of the serum/plasma application is 5 to 800 mg/dL (0.28 to 44.40 mmol/L). **Urine/ CSF** The measuring interval of the urine/CSF application is 1 to 800 mg/dL (0.06 to 44.40 mmol/L).	Same
Tube Types	**Serum** Serum tubes (with or without gel barrier). **Plasma** Collection tubes Acceptable anticoagulants are: Lithium heparin (with or without gel barrier), Sodium heparin, Sodium fluoride/ potassium oxalate, EDTA.	Same
Use of Calibrators	Yes	Same
Use of Controls	Yes; Commercially available controls	Same

Table 2: Reagent Differences

Characteristics	Alinity c Glucose Reagent Kit (LN 07P55)	Predicate Assay (k060383) Glucose (LN 3L82)
Reagent Container	Polypropylene Black color	High Density Polyethylene White colorant
Closure Material	High Density Polyethylene Black color	F217 cap liner Polyethylene Foam between Low-Density Polyethylene liners Green color

Table 3: Instrument Similarities

Characteristics	Candidate Device Alinity c System	Predicate Device AEROSET/ARCHITECT *c* System (k980367)
Intended Use/Indication for Use	The Alinity c System is a fully automated, random/continuous access, clinical chemistry analyzer intended for the *in vitro* determination of analytes in body fluids.	Same
Detection Technology	Potentiometric/Photometric	Same
Sample Handling	Robotic sample handler (RSH). Transport system that has random and continuous access to samples. Autoretest Capability Priority and batch sample loading	Same
Reagent Handling	The on-board storage area cooler provides evaporation control. Continuous Reagent Access.	Same

Table 4: Instrument Differences

Characteristics	Alinity c System	AEROSET / ARCHITECT c System
Calibrator / Control Automation	Direct aspiration from the calibrator/control bottles	No.
Reagent Access	Continuous Reagent Access.	Scheduled Reagent Access.
Bulk Solutions Replenishment	Continuous Bulk Solution Access.	Scheduled Bulk Solution Access.
Priority Sample Loading	All carrier positions are available to have a priority sample loading designation.	Select positions available for priority loading.

VII. Summary of Nonclinical Performance

Within-Laboratory Precision (20-Day)

Alinity Glucose Reagent Kit- Serum Samples

Precision was performed based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP05-A2.

A summary of results is presented below:

				Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	**Control Lot**	**n**	**Mean (mg/dL)**	**SD**	**%CV**	**SD (Range[b])**	**%CV (Range[b])**
Control Level 1	1	264	55	0.6	1.1	0.7 (0.5-0.8)	1.2 (1.0-1.4)
	2	264	55	0.5	0.9	0.6 (0.5-0.7)	1.1 (0.9-1.2)
Control Level 2	1	264	128	1.1	0.8	1.3 (1.1-1.4)	1.0 (0.9-1.1)
	2	263	128	0.9	0.7	1.3 (1.1-1.4)	1.0 (0.9-1.1)
Control Level 3	1	264	315	2.2	0.7	2.8 (2.5-3.1)	0.9 (0.8-1.0)
	2	260	311	2.1	0.7	2.5 (2.1-2.9)	0.8 (0.7-0.9)
Panel A	N/A	527	7	0.1	1.9	0.1 (0.0-0.2)	1.9 (0.0-2.8)
Panel B	N/A	528	106	0.8	0.8	1.0 (0.8-1.2)	0.9 (0.7-1.2)
Panel C	N/A	523	728	5.6	0.8	5.9 (4.4-7.6)	0.8 (0.6-1.1)

[a] Includes within-run, between-run, and between-day variability.
[b] Minimum and maximum SD or %CV for each reagent lot and instrument combination.

The precision of the Alinity c Glucose assay was considered acceptable if the within-laboratory imprecision (within-run, between-run, and between-day) was ≤ 5 %CV for serum samples targeted between 80 to 281 mg/dL.

The Alinity c Glucose assay demonstrated acceptable precision.

Alinity Glucose Reagent Kit- Urine Samples

Precision was performed based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP05-A2.

A summary of results is presented below:

				Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	**Control Lot**	**n**	**Mean (mg/dL)**	**SD**	**%CV**	**SD (Range[b])**	**%CV (Range[b])**
Control Level 1	1	264	38	0.4	1.0	0.5 (0.5-0.5)	1.3 (1.3-1.3)
	2	263	38	0.3	0.9	0.6 (0.5-0.6)	1.4 (1.4-1.5)
Control Level 2	1	260	359	2.9	0.8	3.4 (2.9-4.0)	1.0 (0.8-1.1)
	2	264	353	2.4	0.7	3.0 (2.5-3.3)	0.8 (0.7-0.9)
Panel A	N/A	527	3	0.1	3.8	0.1 (0.0-0.2)	3.8 (0.0-6.4)
Panel B	N/A	526	60	1.0	1.6	1.2 (1.1-1.5)	2.1 (1.8-2.5)
Panel C	N/A	528	110	2.4	2.2	3.1 (2.5-4.2)	2.8 (2.3-3.8)
Panel D	N/A	525	712	6.2	0.9	8.1 (7.4-8.7)	1.1 (1.0-1.2)

[a] Includes within-run, between-run, and between-day variability.
[b] Minimum and maximum SD or %CV for each reagent lot and instrument combination.

The precision of the Alinity c Glucose assay was considered acceptable if the within-laboratory imprecision (within-run, between-run, and between-day) was ≤ 6 %CV for urine samples targeted between 30 to 306 mg/dL.

The Alinity c Glucose assay demonstrated acceptable precision.

Alinity Glucose Reagent Kit- Cerebrospinal Fluid (CSF) Samples

Precision was performed based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP05-A2.

A summary of results is presented below:

				Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	**Control Lot**	**n**	**Mean (mg/dL)**	**SD**	**%CV**	**SD (Range[b])**	**%CV (Range[b])**
Control Level 1	1	264	60	0.5	0.9	0.6 (0.6-0.7)	1.1 (1.0-1.1)
	2	264	61	0.5	0.7	0.6 (0.6-0.6)	1.0 (1.0-1.0)
Control Level 2	1	264	30	0.3	0.9	0.3 (0.3-0.4)	1.1 (0.9-1.2)
	2	263	31	0.4	1.1	0.4 (0.2-0.5)	1.3 (0.8-1.6)
Panel A	N/A	527	3	0.1	4.8	0.1 (0.1-0.2)	4.8 (2.9 -7.5)
Panel B	N/A	528	57	0.4	0.8	0.5 (0.4-0.6)	0.9 (0.8-1.0)
Panel C	N/A	527	107	0.7	0.7	0.8 (0.7-1.0)	0.8 (0.6-1.0)
Panel D	N/A	526	700	3.8	0.5	4.8 (4.3-5.3)	0.7 (0.6-0.8)

[a] Includes within-run, between-run, and between-day variability.
[b] Minimum and maximum SD or %CV for each reagent lot and instrument combination.

The precision of the Alinity c Glucose assay was considered acceptable if the within-laboratory imprecision (within-run, between-run, and between-day) was ≤ 5 %CV for CSF samples targeted between 29 to 60 mg/dL.

The Alinity c Glucose assay demonstrated acceptable precision.

Accuracy

Alinity c Glucose Reagent Kit-Serum

A minimum of 1 level of a NIST standard (SRM 965b, Glucose in Human Serum) at or near the medical decision point of the Alinity c Glucose serum assay was tested.

The results are summarized in the table below.

Sample Set	Target (mg/dL)	N	Mean (mg/dL)	SD	%CV	Bias	%Bias	Total Error (mg/dL)	% Total Error
NIST level 1	33.08	22	33	0.4	1.1	0	0.2	0.8	2.3
NIST level 2	75.56	22	76	0.5	0.7	1	1.2	1.9	2.5
NIST level 3	118.5	22	120	0.6	0.5	1	1.1	2.5	2.1
NIST level 4	294.5	22	306	1.4	0.5	11	3.8	14.0	4.7

Limit of Blank, Limit of Detection, and Limit of Quantitation

Alinity c Glucose Reagent Kit-Serum/Plasma, Urine/CSF Samples

The LoB, LoD, and LoQ study was performed based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP17-A2.

The results are summarized in the table below:

	Serum/Plasma (mg/dL)	Urine/CSF (mg/dL)
LoB[a]	0.33	0.23
LoD[b]	0.55	0.40
LoQ[c]	2.25	0.86

[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 was determined from n ≥ 60 replicates of low-analyte level samples and is defined as the lowest concentration at which a maximum allowable precision of 20 %CV was met.

Linearity

Alinity c Glucose Reagent Kit- Serum/Plasma, Urine/CSF Samples

Linearity was determined based on guidance from Clinical and Laboratory Standards Institute (CLSI) document EP06-A.

Serum/Plasma: The mean observed linear range concentrations ranged from 0 to 828 mg/dL for the sample set.

Urine: The mean observed linear range concentrations ranged from 0 to 843 mg/dL for the sample set.

CSF: The mean observed linear range concentrations ranged from 0 to 887 mg/dL for the sample set.

Measuring Interval

The measuring interval of the Alinity c Glucose Serum/ Plasma application is 5 mg/dL to 800 mg/dL. The measuring interval of the Alinity c Glucose Urine/Cerebrospinal (CSF) application is 1 mg/dL to 800 mg/dL.

The measuring interval is defined as the range of values which meets the limits of acceptable performance for linearity, imprecision, and bias. The inputs to the measuring interval include imprecision, limit of quantification and linearity.

Interference

Alinity c Glucose Reagent Kit– Serum Samples

Potential interference was evaluated based on guidance from the Clinical Laboratory and Standards Institute (CLSI) document EP07-A2.

For serum/plasma, a bias of >6% or >1 mg/dL was considered significant interference.

The Alinity c Glucose assay using the serum application is not susceptible to interference effects from the following interferents at the interferent levels listed in the table below:

Interferent	**Interferent Level**
Unconjugated Bilirubin	≤ 30 mg/dL
Conjugated Bilirubin	≤ 60 mg/dL
Hemoglobin	≤ 2,000 mg/dL
Triglycerides	≤ 2,000 mg/dL
Ascorbic Acid	≤ 6 mg/dL
Acetaminophen	≤ 20 mg/dL
Ibuprofen	≤ 50 mg/dL
Acetylcysteine	≤ 167 mg/dL
Acetylsalicylic Acid	≤ 66 mg/dL
Sodium Salicylate	≤70 mg/dL

Alinity c Glucose Reagent Kit– Urine Samples

Potential interference was evaluated based on guidance from the Clinical Laboratory and Standards Institute (CLSI) document EP07-A2.

For urine, a bias of >10% or >1 mg/dL was considered significant interference.

The Alinity c Glucose assay using the urine application is not susceptible to interference effects from the following interferents at the interferent levels listed in the table below:

Interferent	**Interferent Level**
Protein	≤ 50 mg/dL
Ascorbate	≤ 200 mg/dL
8.5 N Acetic Acid	≤ 6.25 mL/dL
Boric Acid	≤ 250 mg/dL
6 N Hydrochloric Acid	≤ 2.5 mL/dL
6 N Nitric Acid	≤ 5.0 mL/dL
Sodium Oxalate	≤ 60 mg/dL
Sodium Carbonate	≤ 1.25 g/dL
Sodium Fluoride	≤ 400 mg/dL
Acetaminophen	≤ 20 mg/dL
Ibuprofen	≤ 50 mg/dL
Acetylcysteine	≤ 167 mg/dL

Method Comparison

Alinity c Glucose Reagent Kit- Serum, Urine and CSF Samples

The method comparison study was performed based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP09-A3.

Human serum, urine, and CSF specimens that spanned the measuring interval of the assay were evaluated for serum, urine and CSF testing, respectively.

Representative results analyzed using the Passing-Bablok regression method are summarized in the table below:

	Sample Type	**Units**	**N**	**Correlation Coefficient**	**Intercept**	**Slope**	**Concentration Range**
Alinity c Glucose vs. ARCHITECT Glucose	Serum	mg/dL	98	1.00	-1.78	1.00	8 – 791
		mmol/L	98	1.00	-0.09	1.00	0.44 – 43.87
	Urine	mg/dL	118	1.00	0.24	0.99	4 – 785
		mmol/L	118	1.00	0.01	0.99	0.22 – 43.57
	CSF	mg/dL	90	1.00	0.50	1.00	4 – 740
		mmol/L	90	1.00	0.03	1.00	0.22 – 41.07

The method comparison study results of the investigational method, Alinity c Glucose, versus the comparator method, Glucose assay on the ARCHITECT c System, are acceptable for serum, urine and CSF samples.

Auto Dilution

Glucose serum specimens were tested using the 1:5 auto dilution protocol on the ARCHITECT *c*8000 instrument and the Alinity c analyzer

The performance of the Alinity c Glucose auto dilution protocol was considered acceptable if the difference in measured concentration was within ± 10% when comparing auto-diluted samples on the Alinity c analyzer to auto-diluted samples on the ARCHITECT *c* 8000 System.

The Alinity c Glucose assay auto dilution protocol demonstrated acceptable performance. The mean % difference was -0.4% (range: - 5.1% to 2.6%).

Tube Type Equivalency

Tube type equivalency was performed to evaluate whether specific blood collection tube types are suitable for use with the Alinity c Glucose assay using the serum application.

Samples were collected from a minimum of 40 donors and evaluated across tube types.

The following blood collection tube types were determined to be acceptable for use with the Alinity c Glucose assay:

- Serum
- Serum separator
- dipotassium EDTA
- lithium heparin
- sodium heparin
- sodium fluoride/potassium oxalate

VIII. Conclusion Drawn from Nonclinical Laboratory Studies

The results presented in this 510(k) premarket notification demonstrate that the Alinity c Glucose test system that includes the Alinity c System and the Alinity c Glucose Reagent Kit is substantially equivalent to each respective predicate device (Glucose Assay, k060383; AEROSET/ARCHITECT family k980367).

The similarities and differences between the candidate assay (Alinity c Glucose Reagent Kit, List No. 07P55) and the predicate assay (Glucose Assay, k060383), and the candidate instrument and predicate instrument are presented in the tables starting on page 7. Any differences between the candidate assay and the predicate assay, and the candidate instrument and the predicate instrument shown in the tables do not affect the safety and effectiveness of the candidate assay and instrument.