May 19, 2023

Abbott Laboratories
Melissa Vaughan
Director, Regulatory Affairs
1915 Hurd Drive
Irving, Texas 75038

Re: K230790
Trade/Device Name: Alinity i Total β-hCG Reagent Kit, Alinity c Glucose Reagent Kit, Alinity c ICT Sample Diluent, Alinity ci-series
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: DHA, CFR, JGS, CEM, CGZ, JJE
Dated: March 21, 2023
Received: March 22, 2023

Dear Melissa Vaughan:

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. 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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Marianela Perez-torres -S

Marianela Perez-Torres, Ph.D.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230790

Device Name
Alinity ci-series, Alinity c ICT Sample Diluent, Alinity c Glucose Reagent Kit, Alinity i Total β-hCG Reagent Kit

Indications for Use *(Describe)*

The Alinity ci-series is intended for in vitro diagnostic use only.

The Alinity ci-series is a System comprised of individual Alinity i or Alinity c analyzers/processing modules that may be arranged into individual or multimodule configurations including up to four Alinity i processing modules, up to four Alinity c processing modules, or a combination of up to four of Alinity i and Alinity c processing modules with a shared system control module to form a single workstation.

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.

The Alinity i System is a fully automated analyzer allowing random and continuous access, as well as priority and automated retest processing using chemiluminescent microparticle immunoassay (CMIA) technology. CMIA technology is used to determine the presence of antigens, antibodies, and analytes in samples.

The Alinity c ICT (Integrated Chip Technology) is used for the quantitation of sodium, potassium, and chloride in human serum, plasma, or urine on the Alinity c analyzer.

> Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.
>
> Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.
>
> Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

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 i Total β-hCG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative and qualitative determination of beta-human chorionic gonadotropin (β-hCG) in human serum and plasma for the early detection of pregnancy on the Alinity i analyzer.

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.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary

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. 510(k) Number

K230790

II. Applicant Name

Abbott Laboratories
1915 Hurd Drive
Irving, TX 75038

Primary contact person for all communications:

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Date Summary Prepared: May 19, 2023

III. Device Name

- Alinity ci-series

  Device Classification: Class I
  Classification Name: Discrete photometric chemistry analyzer for clinical use
  Governing Regulation: 21 CFR § 862.2160
  Code: JJE

  Alinity i Total ß-hCG Reagent Kit

  Device Classification: Class II

Classification Name: Human chorionic gonadotropin (HCG) test system
Governing Regulation: 862.1155
Code: DHA

Alinity c Glucose Reagent Kit

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

Alinity c ICT Sample Diluent

Device Classification: Class II
Classification Name: Electrode, ion-specific, chloride/potassium/sodium
Governing Regulation: 862.1170/862.1600/862.1665
Code: CGZ/CEM/JGS

IV. Predicate Device

Alinity i System (k170317)

Alinity i Total β-hCG (k170317)

Alinity c System (k170316)

Alinity c Glucose (k170316)

Alinity c ICT Sample Diluent (k170320)

V. Description of Device

A. Introduction

The Alinity i System (k170317) and the Alinity c System (k170316) were designed to be combined into multimodule configurations. The Alinity ci-series is comprised of individual processing modules that may be arranged into individual or multimodule configurations which include either multiple Alinity i processing modules, multiple Alinity c processing modules, or a combination of up to four of both Alinity i and Alinity c processing modules with a shared system control module (SCM). The SCM includes the reagent and sample manager (RSM). The multimodule configurations do not have a separate device label or list number. In a multimodule configuration, each processing module retains its original unique identification label.

B. Multimodule System (Device Design and Components)

1. Multimodule Overview

The Alinity ci-series multimodule configuration includes a combination of up to 4 Alinity i and Alinity c processing modules which perform all sample processing activities independently and can be physically joined to form a single multimodule configuration with the multimodule integration kit. The selection of processing module(s) determines the configuration of the system. Each multimodule configuration includes a single shared SCM with a single shared RSM.

a. System Control Module

The SCM contains the following items:

- A user interface computer provides the software interface to the Alinity ci-series and provides an interface to a host or middleware computer.
- The power supply operates the user interface computer and the RSM.

b. Reagent and Sample Manager

The RSM is a transport system used to load calibrators, controls, specimens, reagents, and onboard solutions. The design of the RSM provides random and continuous access to load and unload sample racks, calibration and control racks, and reagent cartridges.

One primary RSM transports samples and reagents through an Alinity ci-series regardless of the type and number of processing modules.

The RSM performs the following functions:

- Lifts racks and cartridges from the loading area and moves them past the barcode reader
- Positions racks and cartridges for the barcode reader to identify samples, reagents, and solutions
- Moves racks and cartridges to the appropriate processing module or returns them to the loading area

c. Alinity i Processing Module

The Alinity i processing module uses chemiluminescent microparticle immunoassay (CMIA) detection technology to measure the concentration of analytes in samples. The Alinity i processing module is an immunoassay analyzer that performs sample processing. The processing module processes a maximum of 200 CMIA tests per hour and has 47 positions in the reagent carousel to hold assay reagent cartridges and calibrator/control racks at a controlled temperature.

Assay processing occurs within a single processing module, and there is no difference in the execution of an assay when run on a single module or a multimodule configuration.

d. Alinity c Processing Module

The Alinity c processing module uses photometric detection technology to measure sample absorbance for the quantification of analyte concentration and uses potentiometric detection technology to measure the electrical potential in a sample. An integrated chip technology (ICT) module is used to measure potentiometric assays (electrolytes). The ICT module contains Na+, K+, Cl-, and reference electrodes to potentiometrically measure the concentration of analytes in samples.

The Alinity c System is a chemistry analyzer that performs sample processing. The Alinity c processing module is capable of processing a maximum of 1350 photometric and potentiometric tests per hour and has a reagent carousel with 70 positions to hold assay reagent cartridges and calibrator/control racks at a controlled temperature.

Assay processing occurs within a single processing module, and there is no difference in the execution of an assay when run on a single module or a multimodule configuration.

e. Multimodule Integration Kit

The multimodule integration kit provides the components necessary to physically connect different processing modules, which extends the RSM, to create a shared load platform for multimodule configurations.

C. Alinity i Total β-hCG Reagent Kit

The Alinity i Total β-hCG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative and qualitative determination of beta-human chorionic gonadotropin (β-hCG) in human serum and plasma for the early detection of pregnancy on the Alinity i analyzer.

D. Alinity c Glucose Reagent Kit

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.

E. Alinity c ICT Sample Diluent

Alinity c ICT (Integrated Chip Technology) (Na+, K+, and Cl is used for the quantitation of sodium, potassium, and chloride in human serum, plasma, or urine on the Alinity c analyzer.

VI. Intended Use of the Device

The Alinity ci-series is intended for in vitro diagnostic use only.

The Alinity ci-series is a System comprised of individual Alinity i or Alinity c analyzers/processing modules that may be arranged into individual or multimodule configurations including up to four Alinity i processing modules, up to four Alinity c processing modules, or a combination of up to four of Alinity i and Alinity c processing modules with a shared system control module to form a single workstation.

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.

The Alinity i System is a fully automated analyzer allowing random and continuous access, as well as priority and automated retest processing using chemiluminescent microparticle immunoassay (CMIA) technology. CMIA technology is used to determine the presence of antigens, antibodies, and analytes in samples.

The Alinity c ICT (Integrated Chip Technology) is used for the quantitation of sodium, potassium, and chloride in human serum, plasma, or urine on the Alinity c analyzer.

Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

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 i Total β-hCG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative and qualitative determination of beta-human chorionic gonadotropin (β-hCG) in human serum and plasma for the early detection of pregnancy on the Alinity i analyzer.

VII. Comparison of Technological Characteristics

The similarities and differences between the subject device Alinity ci-series and the predicate device(s) Alinity i System (k170317) and Alinity c System (k170316) are presented in the comparison table below. There is no difference between the subject and predicate devices' indications for use. The minor technological differences between the subject device and the predicate device do not affect the safety and effectiveness of the subject device. The results presented in this 510(k) demonstrate that the Alinity ci-series multimodule system is safe and effective for the stated intended use.

Comparison of Subject & Predicate Device				
	Subject Device: Alinity ci-series (Multimodule System)	**Predicate Device: Alinity i System (k170317)**	**Predicate Device: Alinity c System (k170316)**	**Comparison**
General Device Characteristics Similarities				
Methodology	- Alinity i processing module: chemiluminescent microparticle immunoassay (CMIA) - Alinity c processing module: Spectrophotometry (monochromatic and bichromatic modes of measurement)	CMIA	Spectrophotometry (monochromatic and bichromatic modes of measurement)	Same
Intended Use and Indications for Use	The Alinity ci-series is intended for *in vitro* diagnostic use only. The Alinity ci-series is a System comprised of individual Alinity i or Alinity c analyzers/processing modules that may be arranged into individual or multimodule configurations including up to four Alinity i processing modules, up to four Alinity c processing modules, or a combination of up to four of Alinity i and Alinity c processing modules with a shared system control module to form a single workstation. 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.	The Alinity i System is a fully automated analyzer allowing random and continuous access, as well as priority and automated retest processing using chemiluminescent microparticle immunoassay (CMIA) technology. CMIA technology is used to determine the presence of antigens, antibodies, and analytes in samples.	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

Comparison of Subject & Predicate Device				
	Subject Device: Alinity ci-series (Multimodule System)	**Predicate Device: Alinity i System (k170317)**	**Predicate Device: Alinity c System (k170316)**	**Comparison**
General Device Characteristics Similarities				
	The Alinity i System is a fully automated analyzer allowing random and continuous access, as well as priority and automated retest processing using chemiluminescent microparticle immunoassay (CMIA) technology. CMIA technology is used to determine the presence of antigens, antibodies, and analytes in samples.			
Principle of Analyte Detection	- Alinity i processing module: utilize chemiluminescent labels with magnetic microparticle solid phase for analyte detection. - Alinity c processing module: utilize photometric and potentiometric technology for analyte detection.	Alinity i systems utilize chemiluminescent labels with magnetic microparticle solid phase for analyte detection.	Alinity c systems utilize photometric and potentiometric technology for analyte detection.	Same
Sample Aspiration	Directly from sample tubes, control bottles within each independent Alinity i and/or Alinity c processing modules	Directly from sample tubes, control bottles	Directly from sample tubes, control bottles	Same
Physical Laboratory Automation System (LAS)	Pipettor probe samples from the back of the individual processing module	Pipettor probe samples from the back of the individual processing module	Pipettor probe samples from the back of the individual processing module	Same
Sample Transport	- Shared robotic sample handler customized to system configuration. Shared transport system provides random and continuous access to samples for each Alinity i or Alinity c processing module from a shared load platform. - Moves samples requiring multiple tests to multiple independent processing modules as ordered. - Autoretest capability - Priority and batch sample loading	- Robotic sample handler. Transport system that has random and continuous access to samples. - Autoretest capability - Priority and batch sample loading	- Robotic sample handler. Transport system that has random and continuous access to samples. - Autoretest capability - Priority and batch sample loading	Same

Comparison of Subject & Predicate Device				
	Subject Device: Alinity ci-series (Multimodule System)	**Predicate Device: Alinity i System (k170317)**	**Predicate Device: Alinity c System (k170316)**	**Comparison**
General Device Characteristics Similarities				
Sample Identification	The RSM performs the following functions: - Lifts racks and cartridges from the loading area and moves them past the barcode reader. - Positions racks and cartridges for the barcode reader to identify samples, reagents, and solutions.	The RSM performs the following functions: - Lifts racks and cartridges from the loading area and moves them past the barcode reader. - Positions racks and cartridges for the barcode reader to identify samples, reagents, and solutions.	The RSM performs the following functions: - Lifts racks and cartridges from the loading area and moves them past the barcode reader. - Positions racks and cartridges for the barcode reader to identify samples, reagents, and solutions.	Same

A comparison of the representative immunoassay is presented below.

Comparison of Subject & Predicate Device		
	Subject Device: **Alinity ci-series (Multimodule System)** **Alinity i Total β-hCG**	**Predicate Device:** **Alinity i Total β-hCG** **(k170317)**
General Device Characteristics Similarities		
Assay Protocol	2-step	Same
Methodology	Chemiluminescent Microparticle Immunoassay (CMIA)	Same
Calibration Curve Type	6-point 4 Parameter Logistic Curve fit data reduction method (4PLC, Y-weighted)	Same
Intended Use/Indications for Use	The Alinity i Total β-hCG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative and qualitative determination of beta-human chorionic gonadotropin (β-hCG) in human serum and plasma for the early detection of pregnancy on the Alinity i analyzer.	Same
Specimen Type	Serum and plasma	Same
Specific Analyte Detected	Total β-hCG	Same
Formulation	Microparticles – Anti-β-hCG (mouse, monoclonal) coated microparticles in TRIS buffer with protein (bovine) stabilizers. Minimum concentration: 0.06% solids. Preservatives: antimicrobial agents. Conjugate – Anti-β-hCG (mouse, monoclonal) acridinium-labeled conjugate in MES buffer with protein (bovine) stabilizers. Minimum concentration: 2.9 µg/mL. Preservative: antimicrobial agent.	Same

A comparison of the representative clinical chemistry assays are presented in the following tables below.

Comparison of Subject & Predicate Device		
	Subject Device: **Alinity ci-series (Multimodule System)** **Alinity c Glucose**	**Predicate Device:** **Alinity c Glucose** **(k170316)**
General Device Characteristics Similarities		
Assay Protocol	1-step	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
Methodology	Spectrophotometry (monochromatic and bichromatic modes of measurement)	Same
Calibration Curve Type	Linear (End up)	Same
Intended Use	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.	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
Specimen Type	Human serum, plasma, urine, or CSF	Same
Specific Analyte Detected	Glucose	Same
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

Comparison of Subject & Predicate Device		
	Subject Device: **Alinity ci-series (Multimodule System)** **Alinity c ICT Sample Diluent**	**Predicate Device:** **Alinity c ICT Sample Diluent (k170320)**
General Device Characteristics Similarities		
Assay Protocol	1-step	Same
Assay Principle	Ion-selective electrode diluted (Indirect)	Same
Methodology	Potentiometric	Same
Calibration Curve Type	Linear (End up)	Same
Intended Use/ Indications for Use	The Alinity c ICT (Integrated Chip Technology) is used for the quantitation of sodium, potassium, and chloride in human serum, plasma, or urine on the Alinity c analyzer. Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance. Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.	Same
Specimen Type	Human serum, plasma or urine	Same
Specific Analyte Detected	Sodium, potassium, and chloride	Same
Formulation	Active Ingredient: Buffer	Same

VIII. Summary of Nonclinical Performance

Nonclinical testing included 5-day precision and method comparison studies which were completed using assays that were cleared with the Alinity i System (k170317) and Alinity c System (k170316, k170320) to demonstrate the equivalent performance between the single module configuration and multimodule configurations. Additionally, electromagnetic compatibility (EMC) and electrical safety testing was completed.

EMC testing was completed according to IEC 61326 2 6:2020, *Electrical equipment for measurement, control and laboratory use EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment*. Where applicable, modules were immunity tested beyond the requirements per IEC 61326 2-6:2020 to more closely align with the levels required per IEC 60601 1 2:2014 + A1:2020, *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance Collateral Standard: Electromagnetic disturbances - Requirements and tests.*

A. Within-Laboratory Precision (5-Day)

The Alinity i Total β-hCG assay demonstrated equivalent assay performance for within-laboratory precision between the investigational method (Alinity ci-series system in a 4-module configuration) and the comparator method (Alinity i system in a single module configuration). For samples from 5.25 to 12,850 mIU/mL, the %CV ranged from 1.2 to 5.0%.

The Alinity c Glucose assay demonstrated equivalent assay performance for within-laboratory precision between the investigational method (Alinity ci-series system in a 4-module configuration) and the comparator method (Alinity c system in a single module configuration) using the serum and urine application. For serum samples from 7 to 688 mg/dL, the %CV ranged from 0.4 to 1.8%. For urine samples from 36 to 737 mg/dL, the %CV ranged from 0.6 to 1.3%.

The Alinity c ICT Sodium assay, Alinity c ICT Potassium assay, and Alinity c ICT Chloride assay demonstrated equivalent assay performance for within-laboratory precision between the investigational method (Alinity ci-series system in a 4-module configuration) and the comparator method (Alinity c system in a single module configuration). For sodium samples from 110 to 193 mmol/L, the %CV ranged from 0.3 to 0.5%. For potassium samples from 1.9 to 9.0 mmol/L, the %CV ranged from 0.5 to 2.7%. For chloride samples from 55 to 140 mmol/L, the %CV ranged from 0.4 to 1.2%.

B. Method Comparison

The method comparison results were determined to be acceptable when comparing the investigational method (Alinity ci-series system in a 4-module configuration) and the comparator method (Alinity i system in a single module configuration) when using the Alinity i Total β-hCG assay. The slope was 0.98 and the correlation coefficient was 1.00 for samples ranging from 2.74 to 14,998.60 mIU/mL using the Alinity i Total β- hCG assay.

The method comparison results were determined to be acceptable when comparing the investigational method (Alinity ci-series system in a 4-module configuration) and the comparator method (Alinity c system in a single module configuration) when using the Alinity c Glucose assay serum and urine application. The slope was 1.00 and the correlation coefficient was 1.00 for samples ranging from 14 to 659 mg/dL using the Alinity c Glucose serum assay.The slope was 0.99 and the correlation coefficient was 1.00 for samples ranging from 1 to 705 mg/dL using the Alinity c Glucose urine assay.

The method comparison results were determined to be acceptable when comparing the investigational method (Alinity ci-series system in a 4-module configuration) and the comparator method (Alinity c system in a single module configuration) when using the Alinity c ICT Sodium assay, Alinity c ICT Potassium assay and Alinity c ICT Chloride assay. The slope was 1.00 and the correlation coefficient was 1.00 for samples ranging from 120 to 198 mmol/L using the sodium assay. The slope was 1.00 and the correlation coefficient was 1.00 for samples ranging from 2.3 to 9.6 mmol/L using the

potassium assay. The slope was 1.00 and the correlation coefficient was 1.00 for samples ranging from 89 to 144 mmol/L using the chloride assay.

IX. Conclusion Drawn from Nonclinical Laboratory Studies and Clinical Performance

The information submitted in this premarket notification is complete and supports a substantial equivalence determination.