510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K230790

B Applicant

Abbott Laboratories

C Proprietary and Established Names

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

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
DHA	Class II	21 CFR 862.1155 - Human chorionic gonadotropin (HCG) test system	CH - Clinical Chemistry
CFR	Class II	21 CFR 862.1345 - Glucose test system	CH - Clinical Chemistry
JGS	Class II	21 CFR 862.1665 - Sodium test system	CH - Clinical Chemistry
CEM	Class II	21 CFR 862.1600 - Potassium test system	CH - Clinical Chemistry
CGZ	Class II	21 CFR 862.1170 - Chloride test system	CH - Clinical Chemistry
JJE	Class I	21 CFR 862.2160 - Discrete Photometric Chemistry Analyzer for Clinical Use	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Addition of previously cleared human chorionic gonadotropin, glucose, sodium, potassium, and chloride assays to the new Alinity ci-series multimodule instrument platform

B Measurand:

Total beta human chorionic gonadotropin (β-hCG), Glucose, Sodium, Potassium, Chloride

C Type of Test:

β-hCG: Quantitative and qualitative chemiluminescent microparticle immunoassay

Glucose: Quantitative, colorimetric, enzymatic (hexokinase)

Sodium, Potassium, Chloride: Quantitative ion selective electrodes

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) 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 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.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only
For in vitro diagnostic use only

D Special Instrument Requirements:
Alinity ci-series

IV Device/System Characteristics:

A Device Description:

Alinity ci-series
The Alinity i System (previously cleared in k170317) and the Alinity c System (previously cleared in 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 and each multimodule configuration includes a single shared SCM with a single shared RSM. The Alinity ci-series is comprised of the following components and functions:

- **System Control Module (SCM)**: contains a user interface computer that provides 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 Reagent and Sample Manager (RSM).
- **Reagent and Sample Manager (RSM)**: Transport system used to load calibrators, controls, specimens, reagents, and onboard solutions (e.g., lifts, positions, and moves racks and cartridges to and from different areas). One primary RSM transports samples and reagents through an Alinity ci-series.
- **Alinity i processing module**: uses chemiluminescent microparticle immunoassay (CMIA) detection technology to measure analyte concentration in samples. It is an immunoassay analyzer that can process up to 200 CMIA tests per hour and has 47 positions in the reagent carousel to hold assay reagent cartridges and calibrators/control racks at a controlled temperature.
- **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. It is a chemistry analyzer that can process up to 1350 photometric and potentiometric tests per hour and has 70 positions in the reagent carousel to hold assay reagent cartridges and calibrators/control racks at a controlled temperature.

- **Multimodule Integration Kit**: provides the necessary components to physically connect the different processing modules, extending them to the RSM and creating a shared load platform for multimodule configurations. The components in this kit include fasteners, waste manifold, different length drive belt and cables including communications, power, ethernet, motor, and ground.

Alinity i Total β-hCG Reagent Kit (Previously cleared in k170317)
The Alinity i Total β-hCG Reagent Kit consists of magnetic microbeads coated with anti-hCG monoclonal antibody in TRIS buffer with protein (bovine) stabilizers and anti-hCG monoclonal antibody labeled with acridinium in MES buffer with protein (bovine) stabilizers. The Reagent Kit is composed of two cartridges, and each cartridge contains two vials (microparticle antibody and conjugate antibody) and a spacer (empty cartridge).

Alinity c Glucose Reagent Kit (Previously cleared in k170316)
The Alinity c Glucose Reagent Kit consists of ATP•2Na (9.0 mg/mL), NAD (5.0 mg/mL), G-6-PDH (3000 U/L), hexokinase (15 000 U/L), and preservative: sodium azide (0.05%).

Alinity c ICT Sample Diluent (Previously cleared in k170320)
The Alinity c ICT Sample Diluent consists of 68.2 mL reagent 1 and buffer for 9350 tests (935 tests per cartridge, x10 cartridges per kit). One test per sample can generate one to three results (Na+, K+, and Cl-).

B Principle of Operation:

The Alinity i System module is a fully automated immunoassay 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 access chemistry analyzer using detection technologies such as quantitative ion selective electrodes (with an integrated chip technology module) or colorimetric, enzymatic methods to determine analyte concentrations in body fluids.

The Alinity i Total β-hCG Reagent Kit is a two-step immunoassay for the quantitative and qualitative determination of β-hCG in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) technology. A specific mouse anti-hCG monoclonal antibody is coated on the magnetic beads; another monoclonal antibody is labeled with an acridinium-labeled conjugate. After addition of sample, calibrator, or controls to the microbead-antibody conjugate, the mixture is incubated in the reaction vessel (RV) allowing β-hCG present in samples, calibrator, or controls to bind to the monoclonal antibody on the bead. A magnet attracts the paramagnetic microparticles (which are bound to β-hCG) to a wall of the RV. The wash zone assembly washes the reaction mixture to remove unbound materials. After a washing

step, the chemiluminescent, acridinium-labeled conjugate is added to the RV, reacting with hCG already bound to the magnetic beads to form sandwich complexes. The wash zone assembly washes the reaction mixture once more to remove unbound materials. Subsequently, the Pre-Trigger Solution (hydrogen peroxide) is added to prepare the mixture for the chemiluminescent reaction. Then the Trigger Solution (sodium hydroxide) is added to initiate a chemiluminescent reaction. The resulting chemiluminescent reaction is measured as Relative Light Units, which is proportional to the concentration of total β-hCG present in samples. For qualitative interpretation of the Alinity I Total β-hCG test results, specimens with β-hCG levels less than or equal to 5.00 mIU/mL will be reported in the INTERPRETATION field on the test results screen or printout as "NEGATIVE." Specimens with β-hCG greater than or equal to 25.00 mIU/mL will be reported as "POSITIVE." Specimens with β-hCG levels greater than 5.00 mIU/mL and less than 25.00 mIU/mL will be reported with concentrations only. No interpretation will be reported for these results.

The concentration of glucose is determined by the glucose hexokinase method. Glucose in the specimen 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) oxidizes G-6-P to 6-phosphogluconate with the concurrent reduction of nicotinamide adenine dinucleotide (NAD) to nicotinamide adenine dinucleotide reduced (NADH). The NADH produced is detected spectrophotometrically at 340 nm.

Ion-selective electrodes (ISE) for sodium, potassium, and chloride utilize membranes selective to each of these ions. An electrical potential (voltage) is developed across the membranes between the reference and measuring electrodes in accordance with the Nernst equation. The voltage is compared to previously determined calibrator voltages and converted into ion concentration.

C Instrument Description Information:

1. Instrument Name:
   Alinity ci-series

2. Specimen Identification:
   The Reagent and Sample Manager 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.

3. Specimen Sampling and Handling:
   - 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.
   - All sample testing and processing takes place in the corresponding Alinity c or i processing module independently.
   - Moves samples requiring multiple tests to multiple independent processing modules as ordered.
   - Autoretest capability
   - Priority and batch sample loading

4. Calibration:

   Provided in:
   k170316 (Alinity c Glucose Reagent Kit; Alinity c System)
   k170317 (Alinity i Total β-hCG Reagent Kit; Alinity i System)
   k170320 (Alinity c ICT Sample Diluent)

5. Quality Control:

   Provided in:
   k170316 (Alinity c Glucose Reagent Kit; Alinity c System)
   k170317 (Alinity i Total β-hCG Reagent Kit; Alinity i System)
   k170320 (Alinity c ICT Sample Diluent)

V Substantial Equivalence Information:

A Predicate Device Name(s):
Alinity c Glucose Reagent Kit and Alinity c ICT Sample Diluent, Alinity c System; Alinity i Total ß-hCG Reagent Kit, Alinity i System

B Predicate 510(k) Number(s):
k170316, k170317, k170320

C Comparison with Predicate(s):

Item	Candidate Device Alinity ci-series (Multimodule System) k230790	Predicate Device Alinity c System k170316
Intended Use/ Indications For Use	Fully automated, random/continuous access analyzer intended for the in vitro determination of analytes in body fluids.	Same
Sample Aspiration	Directly from sample tubes, control bottles within each processing modules	Same
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.	Same
Differences		
Analyzer Configuration	Multimodule configuration including a combination of Alinity i and Alinity c processing modules	Single module

Item	Candidate Device Alinity i Total β-hCG Reagent Kit K230790	Predicate Device Alinity i Total β-hCG Reagent Kit K170317
Similarities		
Intended Use	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
Methodology	Chemiluminescent Microparticle Immunoassay (CMIA)	Same
Calibration Curve Type	6-point 4 Parameter Logistic Curve fit data reduction method (4PLC, Y-weighted)	Same
Specimen Type	Serum and plasma	Same
Differences		
Analyzer	Alinity ci-series	Alinity i System

Item	Candidate Device Alinity c Glucose Reagent Kit K230790	Predicate Device Alinity c Glucose Reagent Kit K170316
Similarities		
Intended Use	For the quantitation of glucose in human serum, plasma, urine, or cerebrospinal fluid (CSF).	Same
Methodology	Spectrophotometry (monochromatic and bichromatic modes of measurement)	Same
Calibration Curve Type	Linear (End Up)	Same
Specimen Type	Human serum, plasma, urine, or CSF	Same
Differences		
Analyzer	Alinity ci-series	Alinity c System

Item	Candidate Device Alinity c ICT Sample Diluent K230790	Predicate Device Alinity c ICT Sample Diluent K170320
Similarities		
Intended Use	For the quantitation of sodium, potassium, and chloride in human serum, plasma, or urine.	Same
Methodology	Potentiometric	Same
Calibration Curve Type	Linear (End Up)	Same
Specimen Type	Human serum, plasma, or urine	Same
Differences		
Analyzer	Alinity ci-series	Alinity c System

VI Standards/Guidance Documents Referenced:

IEC 61326-1: 2021, Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1

IEC 61326-2-6: 2021, Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6

IEC 61010-1:2010 (3rd Edition) Safety Requirements for Electrical Equipment for Measurement Control and Laboratory Use

IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes

CLSI LIS01-A2 Specification for Low-Level Protocol to Transfer Messages

CLSI LIS02-A2 Specification for Transferring Information Between Clinical Instruments and Information Systems

CLSI EP09c Measurement Procedure Comparison and Bias Estimation Using Patient Samples

CLSI EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Alinity i Total β-hCG 5-Day Precision Study on the Alinity ci-series

Precision studies for the Alinity i Total β-hCG Reagent Kit assay were previously reviewed under k170317 on the single module Alinity i system using human serum.

A precision study was performed to evaluate the precision of the Alinity i Total β-hCG Reagent Kit assay on the Alinity ci-series. Precision studies were performed using two panels of pooled human serum specimens prepared by combining β-hCG positive serum (pooled serum specimens from pregnant females) with β-hCG negative serum (pooled serum specimens from pre-menopausal females) and three levels of β-hCG controls tested on one lot and one instrument. The samples were tested in replicates of four, two times per day on five different days for a total of 40 measurements per sample. The precision results on the Alinity ci-series are shown below.

Alinity i Total β-hCG Reagent Kit Assay Precision (5-Day) On the Alinity ci-series

Sample	N	Mean (mIU/mL)	Within-Run		Between-Run		Between-Day		Within-Lab	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Panel PBE1	40	5.3	0.3	4.9	0.1	0.9	0	0	0.3	5.0
Panel PBE3	40	12850.6	150.4	1.2	45.9	0.4	135.9	1.1	207.9	1.6
High Control	40	5048.3	38.2	0.8	18.6	0.4	39.8	0.8	58.2	1.2
Low Control	40	25.1	0.8	3.3	0	0	0.4	1.5	0.9	3.6
Medium Control	40	751.3	7.7	1.0	5.2	0.7	6.3	0.8	11.3	1.5

Alinity c Glucose (Serum) 5-Day Precision Study on the Alinity ci-series

Precision studies for the Alinity c Glucose Reagent Kit assay using serum were previously reviewed in k170316 on the single module Alinity c System using human serum, urine, and cerebrospinal fluid.

A precision study was performed to evaluate the precision of the Alinity c Glucose Reagent Kit assay on the Alinity ci-series. Three panels were prepared by combining glucose serum stock solution with serum stripped of glucose to create panels with target concentrations of 7, 100, and 720 mg/dL. In addition to these three panels, three levels of controls were tested using one reagent lot and one instrument. The samples were tested in replicates of four, two times per day on five different days for a total of 40 measurements per sample. The precision results on the Alinity ci-series are shown below.

Alinity c Glucose Reagent Kit Assay (Serum) Precision (5-Day) on the Alinity ci-series

Sample	N	Mean (mg/dL)	Within-Run		Between-Run		Between-Day		Within-Lab	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Control 1	40	52	0.2	0.3	0.1	0.2	0.0	0.0	0.2	0.4
Control 2	40	147	0.5	0.3	0.5	0.3	0.6	0.4	0.9	0.6
Control 3	40	306	0.9	0.3	0.9	0.3	0.9	0.3	1.6	0.5
Panel 1	40	7	0.1	1.7	0.0	0.0	0.0	0.7	0.1	1.8
Panel 3	40	103	0.3	0.3	0.2	0.2	0.0	0.0	0.4	0.4
Panel 5	40	688	2.2	0.3	0.6	0.1	1.2	0.2	2.6	0.4

Alinity c Glucose (Urine) 5-Day Precision Study on the Alinity ci-series

Precision studies for the Alinity c Glucose Reagent Kit assay using urine were previously reviewed in k170316 on the single module Alinity c System using human serum, urine, and cerebrospinal fluid.

A precision study was performed to evaluate the precision of the Alinity c Glucose Reagent Kit assay on the Alinity ci-series using urine samples. One panel was prepared by combining glucose urine stock solution with synthetic urine to create a panel with target concentration of 750 mg/dL. In addition to these this panel, two levels of controls were tested using one reagent lot and one instrument. The samples were tested in replicates of four, two times per day on five different days for a total of 40 measurements per sample. The precision results on the Alinity ci-series are shown below.

Alinity c Glucose Reagent Kit Assay (Urine) Precision (5-Day) on Alinity ci-series

Sample	N	Mean (mg/dL)	Within-Run		Between-Run		Between-Day		Within-Lab	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Control 1	40	36	0.3	0.9	0.3	0.7	0.2	0.6	0.5	1.3
Control 2	40	355	1.5	0.4	0.1	0.0	1.3	0.4	2.0	0.6
Panel 6	40	737	3.5	0.5	2.5	0.3	2.5	0.3	5.0	0.7

Alinity c ICT Sample Diluent Sodium 5-Day Precision Study on the Alinity ci-series

Precision studies for the Alinity c ICT Sample Diluent Sodium assay were previously reviewed in k170320 on the single module Alinity c System using human serum and urine.

A precision study was performed to evaluate the precision of the Alinity c ICT Sample Diluent Sodium assay on the Alinity ci-series using human serum samples. Two panels were prepared by combining sodium stock solution with serum stripped of sodium to create two panels with target concentrations of 112 and 190 mmol/L. In addition to these panels, three levels of controls were tested using one reagent lot and one instrument. The samples were tested in replicates of four, two times per day on five different days for a total of 40 measurements per sample. The precision results on the Alinity ci-series are summarized below.

Alinity c ICT Sample Diluent Assay Sodium Precision (5-Day) on the Alinity ci-series

Sample	N	Mean (mmol/L)	Within-Run		Between-Run		Between-Day		Within-Lab	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Control 1	40	124	0.4	0.3	0.4	0.3	0.2	0.2	0.6	0.5
Control 2	40	150	0.3	0.2	0.3	0.2	0.6	0.4	0.7	0.5
Control 3	40	169	0.2	0.1	0.0	0.0	0.4	0.3	0.5	0.3
Panel 1	40	110	0.3	0.3	0.0	0.0	0.5	0.4	0.5	0.5
Panel 3	40	193	0.4	0.2	0.0	0.0	0.5	0.3	0.7	0.4

Alinity c ICT Sample Diluent Potassium 5-Day Precision Study on the Alinity ci-series

Precision studies for the Alinity c ICT Sample Diluent Potassium assay were previously reviewed in k170320 on the single module Alinity c System using human serum and urine.

A precision study was performed to evaluate the precision of the Alinity c ICT Sample Diluent Potassium assay on the Alinity ci-series using human serum samples. Two panels were prepared by combining potassium stock solution with serum stripped of potassium to create two panels with target concentrations of 2 and 9 mmol/L. In addition to these panels, three levels of controls were tested using one reagent lot and one instrument. The samples were tested in replicates of four, two times per day on five different days for a total of 40 measurements per sample. The precision results on the Alinity ci-series are summarized below.

Alinity c ICT Sample Diluent Potassium Assay Precision (5-Day) on the Alinity ci-series

Sample	N	Mean (mmol/L)	Within-Run		Between-Run		Between-Day		Within-Lab	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Control 1	40	2.9	0.00	0.0	0.02	0.5	0.00	0.0	0.02	0.5
Control 2	40	4.1	0.03	0.7	0.02	0.6	0.04	0.9	0.05	1.3
Control 3	40	7.1	0.04	0.5	0.02	0.3	0.04	0.5	0.06	0.8
Panel 1	40	1.9	0.04	2.0	0.02	0.8	0.03	1.6	0.05	2.7
Panel 4	40	9.0	0.05	0.6	0.06	0.6	0.06	0.7	0.10	1.1

Alinity c ICT Sample Diluent Chloride 5-Day Precision Study on the Alinity ci-series

Precision studies for the Alinity c ICT Sample Diluent Chloride assay were previously reviewed in k170320 on the single module Alinity c System using human serum and urine.

A precision study was performed to evaluate the precision of the Alinity c ICT Sample Diluent Chloride assay on the Alinity ci-series using human serum samples. Two panels were prepared by combining chloride stock solution with serum stripped of potassium to create two panels with target concentrations of 55 and 132 mmol/L. In addition to these panels, three levels of controls were tested using one reagent lot and one instrument. The samples were tested in replicates of four, two times per day on five different days for a total of 40 measurements per sample. The precision results on the Alinity ci-series are summarized below.

Alinity c ICT Sample Diluent Chloride Assay Precision (5-Day) on the Alinity ci-series

Sample	N	Mean (mmol/L)	Within-Run		Between-Run		Between-Day		Within-Lab	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Control 1	40	80	0.5	0.6	0.0	0.0	0.3	0.4	0.6	0.7
Control 2	40	98	0.2	0.2	0.5	0.5	0.1	0.1	0.6	0.6
Control 3	40	112	0.4	0.4	0.2	0.2	0.0	0.0	0.5	0.4
Panel 1	40	55	0.5	1.0	0.4	0.6	0.0	0.0	0.6	1.2
Panel 4	40	140	0.7	0.5	0.1	0.1	0.0	0.0	0.7	0.5

2. Linearity:

   Linearity was tested in k170317 (Alinity i Total β-hCG Reagent Kit; Alinity i System), k170316 (Alinity c Glucose Reagent Kit; Alinity c system), and k170320 (Alinity c ICT Sample Diluent).

3. Analytical Specificity/Interference:

   Analytical Specificity/Interference was tested in k170317 (Alinity i Total β-hCG Reagent Kit; Alinity i System), k170316 (Alinity c Glucose Reagent Kit; Alinity c System), and k170320 (Alinity c ICT Sample Diluent).

4. Assay Reportable Range:

   Linearity/Assay Reportable Range was tested in k170317 (Alinity i Total β-hCG Reagent Kit; Alinity i System), k170316 (Alinity c Glucose Reagent Kit; Alinity c System), and k170320 (Alinity c ICT Sample Diluent).

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Traceability was established in k170317 (Alinity i Total β-hCG Reagent Kit; Alinity i System). Traceability was established in k170316 (Alinity c Glucose Reagent Kit; Alinity c System) and k170320 (Alinity c ICT Sample Diluent).

6. Detection Limit:

   Limit of Blank, Limit of Detection and Limit of Quantitation was tested k170317 (Alinity i Total β-hCG Reagent Kit; Alinity i System) and in k170316 (Alinity c Glucose Reagent Kit; Alinity c System). The upper and lower measuring range limits were established by linearity studies in k170320 (Alinity c ICT Sample Diluent).

7. Assay Cut-Off:

   Qualitative Total β-hCG assay cut-off levels were established in k170317 (Alinity i Total β-hCG Reagent Kit; Alinity i System). Assay cut-off is not applicable per k170316 (Alinity c Glucose Reagent Kit; Alinity c System) and k170320 (Alinity c ICT Sample Diluent).

8. Accuracy (Instrument):

Accuracy was evaluated in the context of the method comparisons for the validated assays on the Alinity i System (k170317 (Alinity i Total β-hCG Reagent Kit; Alinity i System)) and the Alinity c System (in k170316 (Alinity c Glucose Reagent Kit; Alinity c System) and k170320 (Alinity c ICT Sample Diluent)). See method comparison studies for the Alinity ci-series below.

9. Carry-Over:

Alinity i β-hCG assay carry-over was established in k170317 (Alinity i Total β-hCG Reagent Kit; Alinity i System).

B Comparison Studies:

1. Method Comparison with Predicate Device:

Alinity i β-hCG assay Method Comparison

A total of 111 native human serum specimens spanning the measuring range of the assay (2.42 to 15,000 mIU/mL) were tested. The samples were tested in singlicate using one lot of reagents, calibrators, and controls on one Alinity ci-series instrument and on one Alinity i System in a single-module configuration over at least three days. No contrived samples were used. The table below shows the Deming Weighted Linear Regression results.

N	Alinity ci-Series (Y) (mIU/mL)		Alinity i System (X) (mIU/mL)		Correlation Coefficient (r)		Intercept		Slope	
	Min	Max	Min	Max	r	95% CI	Estimate	95% CI	Estimate	95% CI
111	2.61	14020.38	2.74	14998.6	1.00	(1.00, 1.00)	0.25	(0.03, 0.47)	0.98	(0.97, 0.99)

The table below shows the bias from the linear regression analysis at the assay's medical decision levels (MDL).

MDL (mIU/mL)	Predicted Concentration (mIU/mL)	Bias	Bias 95%CI	%Bias	%Bias 95%CI
5.00	5.15	0.15	(-0.11, 0.41)	3.0	(-2.1, 8.2)
25.00	24.75	-0.25	(-0.66, 0.15)	-1.0	(-2.6, 0.6)

Alinity c Glucose (Serum) Method Comparison

A total of 121 human serum specimens spanning the measuring range (5 to 800 mg/dL) of the assay were tested. 5% of the samples were contrived by adding glucose (at <5%) to a native human serum sample to create high glucose samples. The samples were tested in

singlicate using one lot of reagents, calibrators, and controls on one Alinity ci-series instrument and on one Alinity c System in a single-module configuration over at least three days. The table below shows the Passing-Bablok Linear Regression results.

N	Alinity ci-Series (Y) (mg/dL)		Alinity c System (X) (mg/dL)		Correlation Coefficient (r)		Intercept		Slope	
	Min	Max	Min	Max	r	95% CI	Estimate	95% CI	Estimate	95% CI
121	14	664	14	659	1.00	(1.00, 1.00)	0	(0, 0)	1.00	(1.00, 1.00)

The table below shows the bias from the linear regression analysis at the assay's medical decision levels (MDLs).

MDL (mg/dL)	Predicted Concentration (mg/dL)	Bias	Bias 95%CI	%Bias	%Bias 95%CI
40	40	0	(0, 0)	0.0	(-0.7, 0.3)
50	50	0	(0, 0)	0.0	(-0.6, 0.3)
100	100	0	(0, 0)	0.0	(-0.3, 0.3)
126	126	0	(0, 0)	0.0	(-0.2, 0.3)
600	600	0	(0, 2)	0.0	(0.0, 0.3)

Alinity c Glucose (Urine) Method Comparison

A total of 102 human urine specimens spanning the measuring range (1 to 800 mg/dL) of the assay were tested. 8.8% of the samples were contrived by adding glucose (at <5%) to a native human urine sample to create high glucose samples. The samples were tested in singlicate using one lot of reagents, calibrators, and controls on one Alinity ci-series instrument and on one Alinity c system in a single-module configuration over at least three days. The table below shows the Passing-Bablok Linear Regression results.

N	Alinity ci-Series (Y) (mg/dL)		Alinity c System (X) (mg/dL)		Correlation Coefficient (r)		Intercept		Slope	
	Min	Max	Min	Max	r	95% CI	Estimate	95% CI	Estimate	95% CI
102	1	695	1	705	1.00	(1.00, 1.00)	0	(0, 0)	0.99	(0.99, 1.00)

The table below shows the bias from the linear regression analysis at the assay's medical decision levels (MDLs).

MDL (mg/dL)	Predicted Concentration (mg/dL)	Bias	Bias 95%CI	%Bias	%Bias 95%CI
15	15	0	(0, 0)	-0.6	(-1.4, 0.1)

Alinity c ICT Sodium Method Comparison with the Alinity c System

A total of 107 human serum specimens spanning the measuring range (100 to 200 mmol/L) of the assay were tested. A total of 6.5% of the samples were contrived by adding sodium chloride analyte (at <5%) to a native human serum samples to create high sodium samples. The samples were tested in singlicate using one lot of reagents, calibrators, and controls on one Alinity ci-series instrument and on one Alinity c system in a single-module configuration over at least three days. The table below shows the Passing-Bablok Linear Regression results.

N	Alinity ci-Series (Y) (mmol/L)		Alinity c System (X) (mmol/L)		Correlation Coefficient (r)		Intercept		Slope	
	Min	Max	Min	Max	r	95% CI	Estimate	95% CI	Estimate	95% CI
107	120	196	120	198	1.00	(1.00, 1.00)	0	(0, 0)	1.00	(1.00, 1.00)

The table below shows the bias from the linear regression analysis at the assay's medical decision point.

MDL (mmol/L)	Predicted Concentration (mmol/L)	Bias	Bias 95%CI	%Bias	%Bias 95%CI
136	136	0	(0, 0)	0.0	(0.0, 0.0)
145	145	0	(0, 0)	0.0	(0.0, 0.0)

Alinity c ICT Potassium Method Comparison

A total of 105 human serum specimens spanning the measuring range (1.0 to 10.0 mmol/L) of the assay were tested. 5.7% of the samples were contrived by adding potassium chloride analyte (at <5%) to a native human serum samples to create high potassium samples. The samples were tested in singlicate using one lot of reagents, calibrators, and controls on one Alinity ci-series instrument and on one Alinity c system in a single-module configuration over at least three days. The table below shows the Passing-Bablok Linear Regression results.

N	Alinity ci-Series (Y) (mmol/L)		Alinity c System (X) (mmol/L)		Correlation Coefficient (r)		Intercept		Slope	
	Min	Max	Min	Max	r	95% CI	Estimate	95% CI	Estimate	95% CI
105	2.3	9.6	2.3	9.6	1.00	(1.00, 1.00)	0	(0, 0)	1.00	(1.00, 1.00)

The table below shows the bias from the linear regression analysis at the assay's medical decision levels.

MDL (mmol/L)	Predicted Concentration (mmol/L)	Bias	Bias 95%CI	%Bias	%Bias 95%CI
2.8	2.8	0.0	(0.0, 0.0)	0.0	(0.0, 0.0)
6.0	6.0	0.0	(0.0, 0.0)	0.0	(0.0, 0.0)

Alinity c ICT Chloride Method Comparison

A total of 107 human serum specimens spanning the measuring range (50 to 150 mmol/L) of the assay were tested. 6.5% of the samples were contrived by adding sodium chloride analyte (at <5%) to a native human serum samples to create high chloride samples. The samples were tested in singlicate using one lot of reagents, calibrators, and controls on one Alinity ci-series instrument and on one Alinity c system in a single-module configuration over at least 3 days. The table below shows the Passing-Bablok Linear Regression results.

N	Alinity ci-Series (Y) (mmol/L)		Alinity c System (X) (mmol/L)		Correlation Coefficient (r)		Intercept		Slope	
	Min	Max	Min	Max	r	95% CI	Estimate	95% CI	Estimate	95% CI
107	89	144	89	144	1.00	(1.00, 1.00)	0	(0, 0)	1.00	(1.00, 1.00)

The table below shows the bias from the linear regression analysis at the assay's medical decision levels.

MDL (mmol/L)	Predicted Concentration (mmol/L)	Bias	Bias 95%CI	%Bias	%Bias 95%CI
102	102	0	(0, 0)	0.0	(0.0, 0.0)
108	108	0	(0, 0)	0.0	(0.0, 0.0)

2. Matrix Comparison:
   For matrix comparison information for the Alinity i Total β-hCG Reagent Kit assay between Dipotassium EDTA, Lithium Heparin, Sodium Heparin, Lithium heparin plasma separator, Serum Separator, and Tripotassium EDTA, see k170317.

   For matrix comparison information for the Alinity c Glucose Reagent Kit assay between Serum Separator, Dipotassium EDTA, Lithium Heparin, Sodium Heparin, Sodium Fluoride/Potassium Oxalate, and Lithium heparin plasma separator, see k170316.

   For matrix comparison information for the Alinity c ICT Sample Diluent Sodium, Potassium, and Chloride assay between serum and Lithium Heparin/Sodium Heparin/ Lithium heparin serum separator/Serum Separator, see k170320.

C Clinical Studies:

1. Clinical Sensitivity:
   Not Applicable

2. Clinical Specificity:
   Not Applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):
   Not Applicable

D Clinical Cut-Off:

Not Applicable

E Expected Values/Reference Range:
Established in k170317 (Alinity i Total β-hCG Reagent Kit; Alinity i System), k170316 (Alinity c Glucose Reagent Kit; Alinity c system), and k170320 (Alinity c ICT Sample Diluent).

F Other Supportive Instrument Performance Characteristics Data:

Not Applicable

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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