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

I Background Information:

A 510(k) Number

k213486

B Applicant

Abbott Laboratories

C Proprietary and Established Names

GLP systems Track

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
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
JQP	Class I	21 CFR 862.2100 - Calculator/data processing module for clinical use	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

The submission is to obtain clearance for the GLP systems Track, a laboratory automation system used with clinical laboratory analyzers such as the Alinity c System.

The manufacturer uses the performance of Sodium, Potassium, and Chloride assays within the Alinity c ICT Sample Diluent to demonstrate the GLP systems Track barcode sample ID transmission to the analyzer and analytical equivalence to manual sample introduction versus automated sample introduction on the analyzer.

B Measurand:

Sodium, Potassium, Chloride

C Type of Test:

Quantitative, potentiometric

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The GLP systems Track is a modular laboratory automation system designed to automate pre-analytical and post-analytical processing, including sample handling, in order to automate sample processing in clinical laboratories. The system consolidates multiple analytical instruments into a unified workflow.

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 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

Alinity c System

IV Device/System Characteristics:

A Device Description:

The GLP systems Track is a modular laboratory automation system (LAS) used to perform multiple pre-analytical and post-analytical steps to automate sample preparation and distribution processes in clinical laboratories. These processes include bar code identification of samples, centrifugation, aliquoting of samples, decapping of samples, transport of samples between processes (modules), delivery of samples to Abbott Alinity c-series laboratory analyzers, capping of samples, and storage of samples. The GLP systems Track consists of the track, modules, and specific analyzer interfaces used to connect analyzers and the control system. Each module includes a built-in touchscreen, a user interface that functions as a central operating and display element. Due to the modular nature of the LAS, customers may select modules and configurations to fit their laboratory needs.

B Principle of Operation:

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:

   GLP systems Track

2. Specimen Identification:

   Barcode identification of patient samples. GLP systems Track reads sample bar codes and electronically communicates sample identification number to the analyzers.

3. Specimen Sampling and Handling:

   The patient's sample tubes are loaded onto the GLP systems Track Input/Output Module (IOM) or BulkLoader Module to be centrifuged, de-capped, aliquoted, recapped and stored. The sample bar codes are read to direct the sample to a specific analyzer.

4. Calibration:

   Provided in k170320 (Alinity c ICT Sample Diluent)

5. Quality Control:

Provided in k170320 (Alinity c ICT Sample Diluent)

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

V Substantial Equivalence Information:

A Predicate Device Name(s):

ACCELERATOR APS

B Predicate 510(k) Number(s):

k093318

C Comparison with Predicate(s):

Device & Predicate Device(s):	k213486	k093318
Device Trade Name	GLP systems Track	ACCELERATOR APS
Intended Use/Indications For Use	Modular laboratory automation system designed to automate pre-analytical and post-analytical processing, including sample handling, in order to automate sample processing in clinical laboratories.	Same
Principle of Analyte Detection	An analyzer's detection method remains the same when interfaced to the subject device.	Same
Sample Containers	Primary tubes and secondary aliquot tubes.	Same
Sample Aspiration	Directly from tube presented to the aspiration point by the subject device.	Same
Sample Pre-Analytics	Centrifugation:	Same

Device & Predicate Device(s):	k213486	k093318
	GLP systems Track automatically centrifuges sample tubes. Samples may also be manually centrifuged by lab personnel prior to loading into the system. Decapping: GLP systems Track automatically decaps sample tubes. Samples may also be manually decapped by lab personnel prior to loading into the system. Aliquoting: GLP systems Track automatically aliquots samples from the primary sample to bar coded secondary tubes. Recapping/Resealing: GLP systems Track automatically recaps sample tubes. Samples may also be manually recapped/ resealed by lab personnel prior to loading into system. Storage: GLP systems Track automatically stores sample tubes in temperature-controlled storage. Samples may also be returned to IOM for lab personnel to manually store samples in lab.	
Sample Identification	GLP systems Track reads sample bar codes and electronically communicates sample ID to analyzers. The analyzer reads sample bar codes for samples loaded directly onto the analyzer or for samples transferred in a rack to the analyzer from the LAS.	Same
Test Orders	Unidirectional from Laboratory Information System or	Same

Device & Predicate Device(s):	k213486	k093318
	middleware to the analyzer.	
Test Results	Unidirectional from Laboratory Information System or middleware from the analyzer.	Same
LAS Communication	GLP systems Track communicates to the analyzer per each analyzer's LAS interface specification.	Same
General Device Characteristic Differences		
Sample Loading	GLP systems Track Input/Output Module (IOM) accepts samples loaded into sample racks. The BulkLoader Module accepts samples loaded into the bin. Samples may also be loaded directly into any analyzers that support local sample loading.	ACCELERATOR APS IOM accepts samples loaded into sample racks. Samples may also be loaded directly into any analyzers that support local sample loading.
Sample Transport	GLP systems Track transports sample CARs identified on the system by Near-Field Communication (NFC) tags. Samples may also be manually transported by lab personnel to analyzers.	ACCELERATOR APS transports sample carriers identified on the system by Radio Frequency identification (RFID) tags. Samples may also be manually transported by lab personnel to analyzers.

VI Standards/Guidance Documents Referenced:

AAMI ANSI BP22:2011 Blood Pressure Transducers (Section 4, p. 32)

UL 1642 5th Edition – Lithium Batteries (Section 17, p. 17-3)

UL 2054 2nd Edition – Household and Commercial Batteries (Section 17, p. 17-3)

IEC 62133-2 Edition l.0 2017-02 – Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements (Section 17, p. 17-3)

IEC 61010-1:2010 AMD1:2016 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements

IEC 61010-2-081:2019 - Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

IEC 61010-2-101:2018 - Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

EN 61326-2-6:2013 and 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 and collateral standards.

CLSI EP09c Measurement Procedure Comparison and Bias Estimation Using Patient Samples. 3rd Edition

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Provided in k170320 (Alinity c ICT Sample Diluent)

2. Linearity:

   Provided in k170320 (Alinity c ICT Sample Diluent)

3. Analytical Specificity/Interference:

   Provided in k170320 (Alinity c ICT Sample Diluent)

4. Assay Reportable Range:

   Provided in k170320 (Alinity c ICT Sample Diluent)

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

   Provided in k170320 (Alinity c ICT Sample Diluent)

6. Detection Limit:

   Provided in k170320 (Alinity c ICT Sample Diluent)

7. Assay Cut-Off:

   Not applicable

8. Accuracy (Instrument):

   Provided in k170320 (Alinity c ICT Sample Diluent)

9. Carry-Over:

   Not applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:

   A method comparison study was performed based on recommendations in CLSI EP09c.

   The method comparison study was performed to demonstrate equivalence between results for samples processed using the GLP systems Track and delivered to the Alinity c analyzer (investigational method) and samples directly loaded on the Alinity c analyzer by the operator (comparator method).

   A total of 100 human serum and plasma samples (50 of each specimen type) were obtained. The samples were tested for sodium, potassium, and chloride. A subset of samples were contrived, (either spiked with chemicals containing sodium, potassium, or chloride or diluted with deionized water) to obtain samples with concentrations at the upper end/lower end of the measuring interval of the assays.

   For the investigational and comparator method, the samples were tested using one lot of reagent, two lots of calibrator, and one lot of controls. For the investigational method samples were tested using one GLP systems Track SAL Alinity c-series module and processed using one Alinity c analyzer. For the comparator method, the samples were tested using one Alinity c analyzer. Each sample was tested in singlicate using both methods.

   Only samples with results that were within the respective measuring interval for both methods were included in the analysis. A Passing-Bablok evaluation was performed using all samples by comparing the result from the investigational method versus the result from the comparator method. The regression analysis results for each assay and specimen type are summarized in the table below:

Analyte	N	Sample Range (mmol/L)	Slope	Intercept	Correlation Coefficient (r)
Sodium Plasma	50	104.6-192.3	0.99	2.3	1.00
Sodium Serum	50	106.7-189.9	0.99	1.2	1.00
Potassium Plasma	50	1.1-9.6	1.00	0.0	1.00
Potassium Serum	50	1.1-9.5	1.00	0.0	1.00

Analyte	N	Sample Range (mmol/L)	Slope	Intercept	Correlation Coefficient (r)
Chloride Plasma	50	50.8-144.2	0.99	1.8	1.00
Chloride Serum	50	51.8-139.8	1.00	0.3	1.00

2. Matrix Comparison:

Not applicable

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:

Provided in 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.