510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K230391

B Applicant

Becton Dickinson and Company

C Proprietary and Established Names

BD MiniDraw™ Capillary Blood Collection System with BD MiniDraw™ SST™ Capillary Blood Collection Tube

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JKA	Class II	21 CFR 862.1675 - Blood Specimen Collection Device	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New device.

B Measurand:

Not applicable. Blood collection tube.

C Type of Test:

Not applicable.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

BD MiniDraw™ Capillary Blood Collection System with BD MiniDraw™ SST™ Capillary Blood Collection Tube is used to collect, separate, transport, and store capillary blood samples from individuals 18 years and older. The system is comprised of a capillary blood collection tube and the BD MiniDraw™ Finger Sleeve that is intended for use by a trained healthcare worker.

BD MiniDraw™ Capillary Blood Collection System with BD MiniDraw™ SST™ Capillary Blood Collection Tube is intended for sample collection used in the measurement of Alkaline Phosphatase (ALKP), Alanine Aminotransferase (ALT), Sodium (Na), Chloride (Cl), Albumin (ALB), Blood Urea Nitrogen (BUN), Calcium (Ca), Creatinine (CREAT), Total Bilirubin (TBIL), Total Protein (TP), High Density Lipoprotein (HDL), Low Density Lipoprotein (LDL), Total Cholesterol (CHOL), and Triglycerides (TRIG).

BD MiniDraw™ SST™ Capillary Blood Collection Tube is not intended for use with other parameters/analytes.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

If the patient's fingers do not fit in one of the four BD MiniDraw™ Finger Sleeve sizes, the MiniDraw™ SST™ System should not be used.

D Special Instrument Requirements:

Not applicable.

IV Device/System Characteristics:

A Device Description:

The BD MiniDraw™ Capillary Blood Collection System with BD MiniDraw™ SST™ Capillary Blood Collection Tube consists of the MiniDraw™ SST™ Tube and BD MiniDraw™ Finger Sleeve. None of the components of the candidate device are provided sterile. The MiniDraw™ SST™ Tube is a plastic blood collection tube intended to collect 435 to 635 µL of whole blood, indicated by two fill lines on the tube. The BD MiniDraw™ Finger Sleeve attaches the tube to the patient's finger during sample collection. The single-use Finger Sleeves come in four sizes.

The following items are provided separately: BD MiniDraw™ Finger Sizing Tool, BD MiniDraw™ Capillary Tube Adapter SST™, and BD MiniDraw™ Cap Removal Tool.

B Principle of Operation:

The BD MiniDraw™ Finger Sizing Tool is used to select the appropriately sized BD MiniDraw™ Finger Sleeve for the patient. After warming the patient's hand, the Finger Sleeve is attached to the MiniDraw™ SST™ Tube and then the finger sleeve is slid onto the patient's finger. The BD Microtainer® Contact-Activated Lancet (k223243), sold separately, is used to lance the finger. After puncture, the MiniDraw™ SST™ Tube is swung into position for blood collection. Immediately after the blood has been collected, the MiniDraw™ SST™ Tube is inverted 5 times to mix the blood with the additive. The MiniDraw™ SST™ Tube is placed in a cap-down orientation at room temperature for 45 minutes to allow for clotting. The MiniDraw SST™ Capillary Blood Collection Tube contains a silica-based clot activator solution and a gel that creates a barrier between serum and cells during centrifugation. After clotting is completed (<120 minutes from blood collection), the MiniDraw™ SST™ Tube should be centrifuged cap-down orientation. The recommended centrifugation conditions are: 4000 RCF (relative centrifuge force or g) for 2 minutes and 15 seconds.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Microtainer Brand Chemistry Tubes With Microgard Closure

B Predicate 510(k) Number(s):
K991702

C Comparison with Predicate(s):

Device & Predicate Device(s):	K230391	K991702
Device Trade Name	BD MiniDraw™ Capillary Blood Collection System with BD MiniDraw™ SST™ Capillary Blood Collection Tube	Microtainer Brand Chemistry Tubes With Microgard Closure
General Device Characteristic Similarities		
Intended Use	Collect, transport, and store fingerstick capillary blood specimens for downstream testing	Same
Sample Type	Capillary, fingerstick	Same
Additives	Clot activator and gel separator	Same
Tube Material	Polypropylene	Same
Sterilization Method	Not sterile	Same
General Device Characteristic Differences		
Centrifugation	Cap Down	Cap Up

Device & Predicate Device(s):	K230391	K991702
Intended Use Environment	Ancillary healthcare facilities, clinical and laboratory environments	Clinical and laboratory environments
Intended Population	18 years and older; limited by correct fit of the Finger Sleeve	All ages
Intended User	Trained healthcare workers: phlebotomists, clinicians, pharmacists, pharmacy technicians, and other healthcare workers trained in the use of the device	Phlebotomists and clinicians
Tube Closure	Cap: Polypropylene + Thermoplastic elastomer (TPE)	Polyethylene
Shelf Life	9 months	15 months

VI Standards/Guidance Documents Referenced:

EN ISO 14971:2019 Medical Devices - Application of risk management to medical devices

ASTM F1886/F1886M-16 Standard Test Method for Determining Section Integrity of Seals for Flexible Packaging by Visual Inspection

ISO 11607-1 Second edition 2019-02 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

ANSI AAMI IEC 62366-1 :2015+AMD1:2020 (Consolidated Text) Medical devices Part 1: Application of usability engineering to medical devices, including Amendment 1

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   a. Between Tube and Between Lot Variability

   A study was conducted to assess the total variability, lot-to-lot variation (between lots), and tube-to-tube (between tube) variation in the candidate device for the analytes specified in the indications for use (IFU). Samples were evaluated on two instrument platforms to confirm tube performance. At least three lots of the candidate device were

evaluated. The study conducted on Platform 1 was performed using samples collected from 138 subjects. The study conducted on Platform 2 was performed using samples collected from 79 subjects. Contrived samples were also prepared in an effort to cover extreme levels for the claimed analytes. Total, Between-Lot, and Between-Tube variability for each instrument platform are presented in the tables below.

Variance Components and Confidence Intervals (CI): Instrument Platform 1

Analyte	Source	Mean	SD	SD 95% Lower Bound	SD 95% Upper Bound	%CV	%CV 95% Lower Bound	%CV 95% Upper Bound
ALB (g/dL)	Total	3.955	0.025	0.022	0.028	0.6	0.6	0.7
	Lot		0.001	0	0.008	0	0	0.2
	Tube		0.025	0.023	0.026	0.6	0.6	0.7
ALKP (U/L)	Total	79.1	0.4	0.4	0.5	0.7	0.6	0.7
	Lot		0	0	0	0	0	0
	Tube		0.4	0.4	0.5	0.7	0.6	0.6
ALT (U/L)	Total	27.2	0.8	0.7	0.9	4.7	4.2	5.4
	Lot		0	0	0	0.2	0.2	0.2
	Tube		0.8	0.7	0.8	4.7	4.4	5.0
BUN (mg/dL)	Total	18.3	0.4	0.4	0.5	2.2	2	2.5
	Lot		0	0	0	0	0	0
	Tube		0.4	0.4	0.4	2.2	2.1	2.3
Ca (mg/dL)	Total	9.73	0.08	0.07	0.09	0.8	0.7	1
	Lot		0.02	0	0.03	0.2	0	0.3
	Tube		0.08	0.07	0.08	0.8	0.8	0.9
CHOL (mg/dL)	Total	177.2	0.8	0.7	0.9	0.4	0.4	0.5
	Lot		0.2	0	0.3	0.1	0	0.2
	Tube		0.7	0.7	0.8	0.4	0.4	0.4
Cl (mmol/L)	Total	105.28	0.4	0.36	0.46	0.4	0.3	0.4
	Lot		0.13	0.04	0.18	0.1	0	0.2
	Tube		0.38	0.36	0.4	0.4	0.3	0.4
CREAT (mg/dL)	Total	0.962	0.017	0.015	0.019	1.7	1.5	2
	Lot		0.002	0	0.006	0.2	0	0.6
	Tube		0.017	0.016	0.018	1.7	1.6	1.8
HDL (mg/dL)	Total	50.86	0.63	0.56	0.73	1.2	1.1	1.4
	Lot		0.17	0	0.26	0.3	0	0.5
	Tube		0.61	0.57	0.65	1.2	1.1	1.3
LDL (mg/dL)	Total	115.93	0.92	0.82	1.06	0.8	0.7	0.9
	Lot		0.13	0	0.32	0.1	0	0.3
	Tube		0.91	0.86	0.98	0.8	0.7	0.8
Na (mmol/L)	Total	139	0.5	0.5	0.6	0.4	0.3	0.4
	Lot		0.1	0	0.2	0.1	0	0.1
	Tube		0.5	0.5	0.5	0.4	0.3	0.4
TBIL (mg/dL)	Total	0.7419	0.0089	0.0079	0.0102	1.2	1.1	1.4
	Lot		0	0	0	0	0	0
	Tube		0.0089	0.0085	0.0093	1.2	1.1	1.3

Analyte	Source	Mean	SD	SD 95% Lower Bound	SD 95% Upper Bound	%CV	%CV 95% Lower Bound	%CV 95% Upper Bound
TP (g/dL)	Total	6.89	0.03	0.03	0.04	0.5	0.4	0.6
	Lot		0	0	0	0	0	0
	Tube		0.03	0.03	0.04	0.5	0.5	0.5
TRIG (mg/dL)	Total	144.7	1.2	1.1	1.4	0.9	0.8	1
	Lot		0.2	0	0.5	0.2	0	0.3
	Tube		1.2	1.1	1.3	0.8	0.8	0.9

Variance Components and Confidence Intervals (CI): Instrument Platform 2

Analyte	Source	Mean	SD	SD 95% Lower Bound	SD 95% Upper Bound	%CV	%CV 95% Lower Bound	%CV 95% Upper Bound
ALB (g/dL)	Total	3.949	0.048	0.041	0.057	1.2	1	1.5
	Lot		0.006	0.005	0.007	0.1	0.1	0.1
	Tube		0.047	0.043	0.053	1.2	1.1	1.3
ALKP (U/L)	Total	93.64	1.47	1.26	1.78	1.4	1.2	1.7
	Lot		0	0	0	0.4	0.4	0.5
	Tube		1.47	1.34	1.63	1.3	1.2	1.5
ALT (U/L)	Total	32.872	1.615	1.381	1.946	7.4	6.3	8.8
	Lot		0.271	0.242	0.307	0	0	0
	Tube		1.592	1.449	1.767	7.4	6.7	8.2
BUN (mg/dL)	Total	15.627	0.287	0.245	0.346	2	1.7	2.4
	Lot		0.046	0.041	0.052	0.7	0.6	0.8
	Tube		0.283	0.257	0.314	1.8	1.6	2
Ca (mg/dL)	Total	9.309	0.072	0.062	0.087	0.8	0.7	0.9
	Lot		0.016	0.014	0.018	0.2	0.2	0.2
	Tube		0.071	0.064	0.078	0.8	0.7	0.8
CHOL (mg/dL)	Total	176.39	1.82	1.55	2.2	1	0.8	1.2
	Lot		0.61	0.55	0.7	0.3	0.3	0.3
	Tube		1.71	1.55	1.9	0.9	0.9	1
Cl (mmol/L)	Total	103.23	0.58	0.5	0.7	0.6	0.5	0.7
	Lot		0.1	0.09	0.12	0.1	0.1	0.1
	Tube		0.57	0.52	0.64	0.6	0.5	0.6
CREAT (mg/dL)	Total	0.9685	0.0266	0.0227	0.0322	2.6	2.2	3.1
	Lot		0.0071	0.0063	0.0081	1.3	1.1	1.4
	Tube		0.0257	0.0233	0.0285	2.2	2	2.5
HDL (mg/dL)	Total	54.79	0.52	0.44	0.62	0.8	0.7	1
	Lot		0	0	0	0	0	0
	Tube		0.52	0.47	0.57	0.8	0.8	0.9
LDL (mg/dL)	Total	105.76	1.3	1.1	1.58	1.1	1	1.4
	Lot		0.54	0.48	0.62	0.4	0.3	0.4
	Tube		1.18	1.07	1.31	1.1	1	1.2
Na (mmol/L)	Total	138.32	0.68	0.58	0.82	0.5	0.4	0.6

Analyte	Source	Mean	SD	SD 95% Lower Bound	SD 95% Upper Bound	%CV	%CV 95% Lower Bound	%CV 95% Upper Bound
	Lot		0.2	0.18	0.23	0.1	0.1	0.2
	Tube		0.65	0.59	0.72	0.5	0.4	0.5
TBIL (mg/dL)	Total	0.7592	0.0326	0.0278	0.0394	4.1	3.5	5
	Lot		0.026	0.0232	0.0296	0.4	0.4	0.5
	Tube		0.0196	0.0178	0.0218	4.1	3.7	4.6
TP (g/dL)	Total	7.025	0.083	0.071	0.1	1.2	1	1.4
	Lot		0.027	0.024	0.03	0.3	0.3	0.4
	Tube		0.078	0.071	0.087	1.1	1	1.2
TRIG (mg/dL)	Total	172.48	3.39	2.89	4.1	1.8	1.6	2.2
	Lot		1.08	0.96	1.23	0.5	0.5	0.6
	Tube		3.21	2.92	3.57	1.8	1.6	2

b. Operator Variability

A study was performed to evaluate operator to operator variability of the candidate device for the analytes specified in the IFU. A total of 263 participants were enrolled in the study. For each participant, two trained health care workers (e.g., pharmacists, pharmacy technicians, phlebotomists) each collected one sample into a single candidate device. Results from the same patient were compared to determine variability between operators. Results from testing samples on Instrument Platform 1 are presented in the table below.

Instrument Platform 1

Analyte	Mean	SD (95% CI)	%CV (95% CI)
ALB (g/dL)	3.82	0.04 (0.04, 0.04)	1.1 (0.9, 1.2)
ALKP (U/L)	75.3	0.8 (0.7, 1.1)	1.1 (0.9, 1.7)
ALT (U/L)	25.3	0.9 (0.8, 1.1)	4.5 (3.8, 5.2)
BUN (mg/dL)	16.1	0.4 (0.4, 0.5)	2.7 (2.3, 3)
Ca (mg/dL)	9.55	0.09 (0.08, 0.12)	1 (0.8, 1.2)
CHOL (mg/dL)	183.9	1.5 (1.3, 1.7)	0.8 (0.7, 0.9)
Cl (mmol/L)	107.8	0.5 (0.4, 0.6)	0.5 (0.4, 0.6)
CREAT (mg/dL)	0.798	0.014 (0.012, 0.016)	1.9 (1.6, 2.2)
HDL (mg/dL)	52.17	0.85 (0.67, 1.3)	1.7 (1.3, 2.5)
LDL (mg/dL)	123.61	1.08 (0.96, 1.24)	0.9 (0.8, 1)

Analyte	Mean	SD (95% CI)	%CV (95% CI)
Na (mmol/L)	137.8	0.6 (0.6, 0.7)	0.5 (0.4, 0.5)
TBIL (mg/dL)	0.548	0.01 (0.009, 0.012)	2.4 (2, 3.2)
TP (g/dL)	6.67	0.05 (0.05, 0.06)	0.8 (0.7, 0.9)
TRIG (mg/dL)	174	5.2 (4.2, 6.9)	3.7 (2.9, 5)

Information was provided demonstrating that operator-to-operator variability is similar on Instrument Platform 2.

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

Extractables and leachables (E&L) and outgassing testing were performed on the candidate device components to identify chemicals that could potentially contaminate the specimen and interfere with downstream testing. Study protocols, acceptance criteria and results for this testing were provided and found to be acceptable.

4. Assay Reportable Range:

Not applicable.

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

a. Shelf-Life

Real Time stability testing of the BD MiniDraw™ Capillary Blood Collection System with the BD MiniDraw™ SST™ Capillary Blood Collection Tube showed that the candidate device is stable for 9 months when stored at 4 to 25 °C. The stability study protocol and acceptance criteria has been reviewed and found to be acceptable.

b. Analyte Stability

Analyte stability studies were conducted to assess the analyte within-tube stability for the analytes specified in the IFU. The study protocols and acceptance criteria have been reviewed and found to be acceptable. These studies demonstrated within-tube type stability in the candidate device for up to 4 hours at room temperature and up to 48 hours at refrigerated conditions. The following storage instructions are included in the device labeling:

- *Remove samples from centrifuge as soon as centrifugation is completed.*

- *Samples stored and transported at room temperature between 20 and 27 °C (68.0–80.6 °F) must be tested within 4 hours of collection.*
- *Samples stored and transported at refrigerated temperature between 2 and 8 °C (35.6–46.4 °F) must be tested within 48 hours of collection.*
- *Exposing samples to temperatures below 2 °C (35.6 °F) or above 27 °C (80.6 °F) for prolonged duration may impact analyte results. Avoid exposure to direct light during sample storage and transport.*

c. Transportation Study

A study was conducted to assess the analyte within-tube stability when exposed to simulated transportation conditions. Conditions evaluated included:

- Tube Orientation
- Extremes of temperature and humidity
- Vibration / Drop testing
- Altitude
- Light exposure
- Duration of transport

Study protocols and acceptance criteria have been reviewed, and performance was considered acceptable. The results of the study support that the tubes can be used to transport serum samples and that the physical tube integrity is maintained when subjected to the test conditions specified above. However, during prolonged exposure to high temperature and high humidity (i.e., extreme conditions outside the recommended transportation), some analytes are clinically impacted. To ensure appropriate handling during storage and transportation, the following instructions are included in the device labeling:

- *Samples stored and transported at room temperature between 20–27 °C (68.0–80.6 °F) must be tested within 4 hours of collection.*
- *Samples stored and transported at refrigerated temperature between 2–8 °C (35.6–46.4 °F) must be tested within 48 hours of collection.*
- *Exposing samples to temperatures below 2 °C (35.6 °F) or above 27 °C (80.6 °F) for prolonged duration may impact analyte results. Avoid exposure to direct light during sample storage and transport.*

d. Additional Bench Testing

i. A flex study was performed to evaluate the effect of various centrifugation conditions on sample quality and analyte stability in the candidate device. These included variations in the tube orientation (cap up or down), centrifugal force, and centrifugation time, acceleration, deceleration, and angle. Tube integrity and sample quality (i.e., barrier formation, hemolysis, red blood cells on barrier) were assessed and determined to be acceptable for all test conditions. Impact on downstream testing was assessed by calculating analyte bias between tubes exposed to test conditions and tubes handled according to the instructions for use. For all analytes tested and all test conditions, the mean bias between the test condition and the control condition was within the clinical acceptable limits (CAL). Separated serum volume and serum

separation efficiency (%) was also assessed and determined to be acceptable for all test conditions. As a result of this testing, the following caution is included in the labeling:

Tubes that are centrifuged in the cap-up orientation may result in blood clot and gel below the serum in the tube. Please process according to your facility's standard instructions for sampling from capillary tubes (i.e., aliquot into micro sample cups, etc.)

ii. Additional benchtop studies were performed to demonstrate device durability over shelf life, including: cap lid closure force, accidental drop seal, reverse centrifuge seal, transit vibration seal, cap / container pull-off, de-capping, tube to collector pull-off force, latch press force, tube to collector axial removal force, pivot attachment force, collector to finger cuff snap de-latch, friction retention, and packaging ship testing. Study protocols and acceptance criteria have been reviewed, and performance was considered acceptable.

6. Detection Limit:

Not applicable.

7. Assay Cut-Off:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

A study was performed to evaluate equivalence between the BD MiniDraw™ and BD Microtainer (k991702) and Greiner Bio-One Vacuette® Blood Collection Tubes with Clot Activator and Gel Separator (K081929) for the analytes claimed in the IFU.

Blood samples were collected at five collection sites representative of the various ancillary healthcare site settings of the intended use environment. These included a specialized collection site that collected blood from targeted disease state populations in an outpatient setting, retail pharmacies, and a patient service center.

Blood was collected from each participant into the capillary (candidate device and BD Microtainer® SST™) and venous (Greiner Vacuette Serum) study tubes. The operators (those collecting the capillary samples with the candidate device) were trained pharmacists and pharmacy technicians. Contrived samples were also prepared in an effort to cover the assay measurement ranges (AMR) for the analytes claimed in the IFU.

Samples were tested on two different instrument platforms. Results for samples collected in the candidate device were compared to results for samples collected in the BD Microtainer and to results for samples collected the Greiner Vacuette. Data was analyzed using Passing Bablok (PB), Deming (Dem), or Weighted Deming (W Dem) regression. Biases between

tube types were estimated with 95% intervals. Regression analyses are provided in the table below:

Instrument Platform 1

Analyte	Comparison	N	Range Tested	Reg Type	Slope (95% CI)	Intercept (95% CI)	r
ALB	vs BD Microtainer	100	1.01, 5.54	W Dem	0.98 (0.98, 0.99)	0.02 (0.01, 0.03)	0.996
	vs. Greiner Vacuette	105	1.01, 5.47	PB	1 (1, 1)	0 (-0.1, 0)	0.982
ALKP	vs BD Microtainer	104	31, 644	W Dem	1 (0.99, 1.01)	-0.06 (-0.76, 0.63)	1
	vs. Greiner Vacuette	110	31, 644	W Dem	0.99 (0.98, 1)	-0.24 (-0.81, 0.34)	1
ALT	vs BD Microtainer	104	8, 756	Dem	1 (1, 1)	-0.62 (-0.91, -0.32)	1
	vs. Greiner Vacuette	110	8, 756	Dem	1 (1, 1)	-0.79 (-1.07, -0.51)	1
BUN	vs BD Microtainer	99	8, 115	Dem	0.99 (0.98, 1)	0.01 (-0.21, 0.24)	0.999
	vs. Greiner Vacuette	104	6, 115	Dem	1 (1, 1.01)	0.08 (-0.22, 0.38)	0.998
Ca	vs BD Microtainer	102	2.7, 13.6	Dem	1 (0.98, 1.01)	-0.04 (-0.19, 0.1)	0.997
	vs. Greiner Vacuette	107	2.7, 13.6	PB	1 (1, 1.02)	-0.1 (-0.26, 0)	0.99
CHOL	vs BD Microtainer	102	51, 454	W Dem	0.98 (0.98, 0.99)	0.32 (-0.66, 1.31)	0.999
	vs. Greiner Vacuette	107	51, 454	PB	0.99 (0.98, 1)	-0.87 (-3, 1.58)	0.999
Cl	vs BD Microtainer	99	73.2, 146.0	Dem	1 (0.98, 1.02)	0.03 (-1.9, 1.96)	0.996
	vs. Greiner Vacuette	104	73.2, 146.0	Dem	0.99 (0.94, 1.03)	3.42 (-1.29, 8.13)	0.99
CREAT	vs BD Microtainer	100	0.23, 19.93	PB	1 (0.99, 1)	-0.01 (-0.01, 0)	1
	vs. Greiner Vacuette	105	0.23, 19.93	PB	1 (0.99, 1)	-0.05 (-0.05, -0.04)	1
HDL	vs BD Microtainer	97	21.5, 96.0	W Dem	0.97 (0.95, 0.99)	0.43 (-0.37, 1.23)	0.996
	vs. Greiner Vacuette	104	21.5, 108.6	W Dem	0.96 (0.94, 0.97)	0.31 (-0.35, 0.98)	0.997
LDL	vs BD Microtainer	100	32.8, 612.4	W Dem	0.99 (0.98, 0.99)	-0.18 (-0.65, 0.29)	1
	vs. Greiner Vacuette	107	32.8, 612.4	W Dem	0.99 (0.98, 1)	-1 (-2.39, 0.4)	1

Analyte	Comparison	N	Range Tested	Reg Type	Slope (95% CI)	Intercept (95% CI)	r
Na	vs BD Microtainer	102	90.8, 166.0	Dem	1 (0.98, 1.02)	-1.15 (-4.11, 1.82)	0.996
	vs. Greiner Vacuette	107	90.8, 166.0	PB	1 (1, 1.05)	-1 (-8.33, 0)	0.672
TBIL	vs BD Microtainer	97	0.170, 26.420	PB	1 (0.99, 1)	-0.01 (-0.01, 0)	1
	vs. Greiner Vacuette	104	0.170, 26.420	PB	0.98 (0.97, 0.99)	-0.01 (-0.02, -0.01)	1
TP	vs BD Microtainer	100	2.6, 10.2	W Dem	1 (0.98, 1.02)	-0.09 (-0.22, 0.05)	0.996
	vs. Greiner Vacuette	105	2.6, 9.8	W Dem	0.99 (0.98, 1)	0.03 (-0.03, 0.09)	0.99
TRIG	vs BD Microtainer	97	32, 730	PB	0.99 (0.98, 1)	-1.36 (-3, 0.77)	0.997
	vs. Greiner Vacuette	103	32, 730	PB	0.98 (0.96, 0.99)	2.89 (0.64, 5.55)	0.995

Instrument Platform 2

Analyte	Comparison	N	Range Tested	Reg Type	Slope (95% CI)	Intercept (95% CI)	r
ALB	vs BD Microtainer	95	1.3, 5.4	W Dem	0.98 (0.96, 0.99)	0.12 (0.04, 0.2)	0.986
	vs Greiner Vacuette	104	1.3, 5.3	W Dem	0.95 (0.91, 0.98)	0.14 (-0.02, 0.3)	0.977
ALKP	vs BD Microtainer	97	27, 841	W Dem	1.01 (0.99, 1.02)	-0.2 (-1.32, 0.91)	1
	vs Greiner Vacuette	109	27, 841	W Dem	0.99 (0.98, 1.01)	-0.6 (-1.47, 0.27)	1
ALT	vs BD Microtainer	90	10, 480	W Dem	1 (0.98, 1.02)	-0.42 (-0.97, 0.13)	1
	vs Greiner Vacuette	108	5, 480	W Dem	0.99 (0.98, 1)	0.09 (-0.16, 0.33)	1
BUN	vs BD Microtainer	94	3, 91	Dem	1.02 (1, 1.03)	-0.43 (-0.75, -0.11)	0.999
	vs Greiner Vacuette	103	3, 91	Dem	1.01 (0.98, 1.05)	-0.22 (-0.83, 0.39)	0.998
Cl	vs BD Microtainer	99	63.1, 138.1	Dem	1 (0.99, 1.02)	-0.49 (-2.17, 1.19)	0.996
	vs Greiner Vacuette	110	63.1, 138.1	Dem	1.01 (0.99, 1.03)	-0.47 (-2.6, 1.67)	0.994
Ca	vs BD Microtainer	97	2.8, 15.7	PB	1 (1, 1)	-0.1 (-0.1, 0)	0.994

Analyte	Comparison	N	Range Tested	Reg Type	Slope (95% CI)	Intercept (95% CI)	r
	vs Greiner Vacuette	107	2.8, 14.8	Dem	0.99 (0.97, 1.01)	-0.01 (-0.2, 0.18)	0.993
CHOL	vs BD Microtainer	92	60, 559	W Dem	1 (0.98, 1.02)	-1.04 (-4.9, 2.83)	0.998
	vs Greiner Vacuette	101	60, 409	W Dem	1 (0.97, 1.03)	-3.74 (-9.5, 2.02)	0.995
CREAT	vs BD Microtainer	99	0.3, 20.5	Dem	1 (0.99, 1.01)	-0.01 (-0.02, 0.01)	1
	vs Greiner Vacuette	108	0.3, 15.1	Dem	1.01 (1, 1.01)	-0.06 (-0.07, -0.04)	1
HDL	vs BD Microtainer	93	18, 117	W Dem	0.99 (0.97, 1.01)	0.44 (-0.39, 1.27)	0.998
	vs Greiner Vacuette	103	18, 117	W Dem	0.98 (0.96, 1)	0.32 (-0.81, 1.44)	0.997
LDL	vs BD Microtainer	94	38, 418	W Dem	0.99 (0.98, 1)	0.34 (-0.54, 1.21)	0.999
	vs Greiner Vacuette	104	38, 418	W Dem	0.98 (0.97, 0.99)	0.05 (-1.01, 1.11)	0.999
Na	vs BD Microtainer	98	86, 173	Dem	1.01 (0.99, 1.03)	-1.72 (-4.54, 1.09)	0.995
	vs Greiner Vacuette	107	86, 173	Dem	1.01 (0.97, 1.04)	-2.1 (-6.91, 2.7)	0.989
TBIL	vs BD Microtainer	91	0.2, 25.6	Dem	1 (0.97, 1.02)	0 (-0.02, 0.02)	1
	vs Greiner Vacuette	103	0.2, 25.6	Dem	0.98 (0.95, 1)	0 (-0.02, 0.02)	1
TP	vs BD Microtainer	96	2.0, 10.1	W Dem	1 (0.99, 1.01)	0 (-0.03, 0.03)	0.99
	vs Greiner Vacuette	107	2.0, 10.1	W Dem	0.99 (0.95, 1.02)	0.02 (-0.21, 0.24)	0.985
TRIG	vs BD Microtainer	92	36, 684	PB	0.99 (0.97, 1.01)	-2.51 (-5, 0.41)	0.995
	vs Greiner Vacuette	102	36, 684	W Dem	0.96 (0.91, 1.01)	3.95 (-1.82, 9.73)	0.997

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:

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.