510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K252040

B Applicant

Becton, Dickinson and Company

C Proprietary and Established Names

BD Vacutainer® Plasma Separator Tubes (PST™)
BD Vacutainer® Sodium Heparin Blood Collection Tubes

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:

Modification of existing 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 Vacutainer® Plasma Separator Tubes (PST™)

The BD Vacutainer® PST™ Blood Collection Tubes are evacuated, sterile, single-use, in vitro diagnostic medical devices. They are intended to be used by healthcare professionals for the collection, containment, and transport of human venous blood specimens, and the subsequent separation and storage of plasma for in vitro diagnostic testing.

BD Vacutainer® PST™ Blood Collection Tubes are used for testing in chemistry analytes in plasma samples.

BD Vacutainer® Sodium Heparin Blood Collection Tubes

The BD Vacutainer® Sodium Heparin Blood Collection Tube is a sterile, single-use, in vitro diagnostic medical device for the collection, containment, transport of human venous blood specimens, and the subsequent separation of plasma by centrifugation, for in vitro diagnostic testing. It is used in settings where a venous blood specimen is collected by a healthcare professional.

The BD Vacutainer® Sodium Heparin Blood Collection Tube is used for testing lithium.

Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

BD Vacutainer® Plasma Separator Tubes (PST™)
Do not use if foreign matter is present or if tube is damaged.

Follow your facility's procedures if clots or other visible obstructions are present in the plasma sample as this could lead to the inability to test the sample.

Separation of plasma from the cells should take place within 2 hours of collection to prevent potentially erroneous test results.

Any change in blood collection tube type, size, handling, processing, or storage condition for a particular laboratory assay should be evaluated by the laboratory to verify the current reference range or to establish a new reference range for each instrument/reagent system per the laboratory's standard procedures..

Venous blood gas samples collected with plastic tubes made from polyethylene terephthalate (PET), including BD Vacutainer® Plasma Separator Tubes (PST™), should not be used when testing carboxyhemoglobin (COHb). A clinically significant positive bias for COHb may occur.

BD Vacutainer® Plasma Separator Tubes (PST™) may contain trace levels of ethylbenzene and xylene. It has not been determined if the presence of trace levels of these or other compounds

will affect test results in chromatography-based assays and the performance of BD Vacutainer® Plasma Separator (PST™) with chromatographic assays has not been evaluated.

Hydrophobic drugs have been known to adsorb to the gel of gel separator tubes, which may result in lower measured drug concentrations. However, these effects depend on various factors including the chemical and physical properties of the drug, contact time with the gel, volume of the sample on the gel, storage temperature, and gel type. Users should consider these factors when evaluating the use of gel separator tubes for drug testing and monitoring. See Drug Absorption in the References section.

Do not use BD Vacutainer® Plasma Separator Tubes (PST™) for Lithium measurement.

BD Vacutainer® Sodium Heparin Blood Collection Tubes

Do not use if foreign matter is present or if tube is damaged

Examine tubes prior to use. Do not use the tube if the additive is missing, discolored, or if foreign matter or precipitate is present.

Separation of plasma from the cells should take place within 2 hours of collection to prevent potentially erroneous test results. Follow your facility's procedures if clots or other visible obstructions are present in the specimen as this could lead to the inability to test the specimen.

Any change in blood collection tube type, size, handling, processing, or storage condition for a particular laboratory assay should be evaluated by the laboratory to verify the current reference range or to establish a new reference range for each instrument/reagent system per the laboratory's standard procedures.

BD Vacutainer® Sodium Heparin Blood Collection Tubes may contain trace levels of ethylbenzene, formate, and xylene. It has not been determined if the presence of trace levels of these compounds will affect test results in chromatography-based assays and the performance of Vacutainer® Sodium Heparin Blood Collection Tubes with chromatographic assays has not been evaluated.

Do not use BD Vacutainer® Sodium Heparin Blood Collection Tubes containing Sodium Heparin for Sodium measurement.

BD Vacutainer® Sodium Heparin Blood Collection Tubes are only validated for use with Lithium in plasma and have not been evaluated for molecular or general chemistry testing in whole blood or plasma

C Special Instrument Requirements:

Not applicable

IV Device/System Characteristics:

A Device Description:

BD Vacutainer® Plasma Separator Tubes (PST™) and Sodium Heparin Blood Collection Tubes are plastic, sterile, single use tubes which use a controlled vacuum to pull a specific volume of blood into the tube. Each tube consists of 1) a plastic tube manufactured from PET (polyethylene terephthalate), 2) a BD Hemogard™ cap assembly or Conventional rubber stopper with lubricant, and 3) a spray-dried anti-coagulated formulated from lithium or sodium heparin. The BD Vacutainer® Plasma Separator Tubes (PST™) additionally includes an inert polymer separator gel. All stoppers/shields are color coded to reflect additive type and/or intended use.

BD Vacutainer® Plasma Separator Tubes (PST™) and BD Vacutainer® Sodium Heparin Blood Collection Tubes are available in various size configurations as applicable (13x75 mm, 13x100 mm and 16x100 mm), with nominal draw volumes ranging from 3mL to 10mL. The tubes contain additives dependent upon the specified fill volume and the desired additive to blood ratio for the tube.

B Principle of Operation:

The BD Vacutainer® Plasma Separator Tubes (PST™), and Sodium Heparin Blood Collection Tubes use controlled vacuum to draw a specific volume of blood into the sterile interior of the tube. Within the tube, an anticoagulant (lithium heparin or sodium heparin) prevents the blood from clotting and enables the separation of plasma for testing. In the BD Vacutainer® Plasma Separator Tubes (PST™) a separator gel is also present at the tube bottom. The density of this material causes it to move upward during centrifugation to form a barrier separating plasma from the cellular elements.

The tubes are compatible with the BD Vacutainer® Blood Collection Needles, Blood Collection Sets, Transfer Devices, Holders and Adapters. Once the vein of the patient has been penetrated using a standard needle, the collection tube is centered in the holder and pushed onto the needle, puncturing the stopper of the tube. Immediately after the blood has been drawn, the tube is gently inverted 8-10 times to mix the blood with the anticoagulant. The recommended centrifugation conditions are 1,100-1,300 RCF (relative centrifuge force or g) for 10 minutes for the BD Vacutainer® Plasma Separator Tubes (PST™) and 1,300 RCF for 10 minutes for the BD Vacutainer® Sodium Heparin Blood Collection Tubes.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Vacutainer® Brand Plus PST™ Plasma Separation Tube, Vacutainer® Brand Plus Sodium Heparin Tube

B Predicate 510(k) Number(s):

K945952, K944566

C Comparison with Predicate(s):

Device & Predicate Device(s):	K252040	K945952
Device Trade Name	BD Vacutainer® PST™ Blood Collection Tube	VACUTAINER® BRAND PLUS PST™ PLASMA SEPARATION TUBE
General Device Characteristic Similarities		
Intended Use/Indications For Use	Used for the collection, containment, and transport of human venous blood specimens, and the subsequent separation and storage of plasma for in vitro diagnostic testing.	Same
Evacuated Blood Collection Tube	Yes	Same
Sample Type	Plasma	Same
Additive Type	Lithium Heparin	Same
General Device Characteristic Differences		
Tube Draw Volumes	3 mL, 3.5mL, and 4.5mL	3 mL, 3.5mL, 4.5mL, 8 mL

Device & Predicate Device(s):	K252040	K944566
Device Trade Name	BD Vacutainer® Sodium Heparin Blood Collection Tube	VACUTAINER® BRAND PLUS SODIUM HEPARIN TUBE
General Device Characteristic Similarities		
Intended Use/Indications For Use	Evacuated blood collection tube for the collection, containment, transport of human venous blood specimens, and as required, the subsequent separation of plasma by centrifugation, for in vitro diagnostic testing	Same

Evacuated Blood Collection Tube	Yes	Same
Sample Type	Plasma	Same
Additive Type	Sodium Heparin	Same
General Device Characteristic Differences		
Tube Draw Volumes	4 mL, 6 mL, and 10 mL	2 mL, 4 mL, 6 mL, and 10 mL

VI Standards/Guidance Documents Referenced:

ISO 11137-1:2006/(R)2015 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013) and Amendment 2 (2019)].

ISO 11137-2 Third edition 2013-06 [Including AMD1:2022] Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose [Including Amendment 1 (2022)]

ISO 11137-3:2017 Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control.

ISO 11737-2:2019 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.

AAMI ST67:2019 Sterilization of health care products - Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled "sterile".

ISO 14971 Third Edition 2019-12 5-125. Medical Devices – Application of risk management to medical devices.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

The following table provides abbreviations for the analytes used in the validation testing of the candidate devices.

Abbreviation	Analyte	Abbreviation	Analyte
ALB	Albumin	IgA	Immunoglobulin A
ALKP	Alkaline Phosphatase	IgG	Immunoglobulin G
ALT	Alanine Aminotransferase	IgM	Immunoglobulin M
AMY	Amylase	K	Potassium
AST	Aspartate Aminotransferase	LDH	Lactate Dehydrogenase

Abbreviation	Analyte	Abbreviation	Analyte
BUN	Blood Urea Nitrogen	LDL	Low-Density Lipoprotein
C3	Complement Component 3	LH	Luteinizing Hormone
Ca	Calcium	Lip	Lipase
Chol	Cholesterol	Li	Lithium
CK	Creatine Kinase	Mg	Magnesium
CKMB	Creatine Kinase-MB	Na	Sodium
CL	Chloride	NT-proBNP	N-Terminal Pro-B-Type Natriuretic Peptide
CO2	Carbon Dioxide	Phos	Phosphorus
CORT	Cortisol	PROG	Progesterone
Creat	Creatinine	RF	Rheumatoid Factor
CRP	C-Reactive Protein	TBIL	Total Bilirubin
DBIL	Direct Bilirubin	TESTO	Testosterone
E2	Estradiol	TnI	Troponin I
Fe	Iron	TnT	Troponin T
FERR	Ferritin	Total T3	Total Triiodothyronine
FOLATE	Folate	Total T4	Total Thyroxine
Free T3	Free Triiodothyronine	TP	Total Protein
Free T4	Free Thyroxine	TPSA	Total Prostate-Specific Antigen
FSH	Follicle-Stimulating Hormone	TRF	Transferrin
GGT	Gamma-Glutamyl Transferase	Trig	Triglycerides
GLUC	Glucose	TSH	Thyroid-Stimulating Hormone
HAPT	Haptoglobin	UA	Uric Acid
HCG	Human Chorionic Gonadotropin	VIT B12	Vitamin B12
HDL	High-Density Lipoprotein	VIT D	Vitamin D
hsTnI	High-Sensitivity Troponin I		

1. Precision/Reproducibility:
   A multi-part study was conducted to evaluate repeatability (within tube), lot-to-lot reproducibility and tube-to-tube reproducibility of BD Vacutainer® Plasma Separator Tubes (PST™) and Sodium Heparin Blood Collection Tubes for select analytes. Testing of select analytes were conducted across the following instruments: Roche cobas e411, Roche cobas Integra 400 Plus, Beckman Coulter Access 2, Beckman Coulter AU480.

   BD Vacutainer® Plasma Separator Tubes (PST™)
   Blood was collected from each subject (n=62) into 6 BD Vacutainer® PST Tubes. Specimens were tested in duplicate per tube (except the initial 20 subjects who were tested in singlicate) with 2 tubes per lot across 3 lots on 1-2 instrument platforms for the following

select analytes: ALT, LDH, C3, Ca, Cl, K, Phos, TPSA, TBIL, TP, Gluc, Trig, Cortisol, Free T4, Total T4,Testosterone, IgG, TnT and hsTnI. Contrived samples were also prepared to cover the entire clinical measuring range for some analytes as necessary. Total, Between-Lot, Between-Tube, and Within-Tube variability for each instrument platform are presented in the tables below.

BD Vacutainer® Plasma Separator Tubes (PST™)

Test System	Analyte (Unit)	Mean	Variance Component	CV (%)	CV 95% CI
Beckman Coulter AU480	ALT (U/L)	24.2	Between Lots	2.4	2.1%, 2.9%
			Between Tubes	0	0%, 0%
			Within Tubes	4	3.5%, 4.7%
			Total	4.6	3.7%, 6.1%
Roche cobas Integra 400 Plus	ALT (U/L)	24.69	Between Lots	0.7	0.6%, 0.8%
			Between Tubes	0	0%, 0%
			Within Tubes	5.3	4.6%, 6.3%
			Total	5.4	4.3%, 7.1%
Beckman Coulter AU480	TBIL (mg/dL)	1.3	Between Lots	3.1	2.7%, 3.7%
			Between Tubes	3.6	2.4%, 4.4%
			Within Tubes	4	3.5%, 4.7%
			Total	6.2	5.1%, 8.1%
Roche cobas Integra 400 Plus	TBIL (mg/dL)	1.445	Between Lots	0.4	0.3%, 0.5%
			Between Tubes	2.7	0%, 4.2%
			Within Tubes	5.5	4.8%, 6.5%
			Total	6.2	4.9%, 8.2%
Roche cobas Integra 400 Plus	C3 (mg/dL)	129.15	Between Lots	0.4	0.3%, 0.4%
			Between Tubes	1.5	1.1%, 1.7%
			Within Tubes	1.2	1.1%, 1.4%
			Total	2	1.6%, 2.5%
Roche cobas 6000	C3 (mg/dL)	140	Between Lots	0.70	0.6%, 0.9%
			Between Tubes	1.20	0.7%, 1.5%
			Within Tubes	1.80	1.6%, 2.0%
			Total	2.20	1.8%, 3.0%
Beckman Coulter AU480	Ca (mg/dL)	8.88	Between Lots	0.2	0.1%, 0.2%
			Between Tubes	0.5	0.3%, 0.7%
			Within Tubes	0.8	0.7%, 0.9%
			Total	1	0.8%, 1.3%
Roche cobas Integra 400 Plus	Ca (mg/dL)	8.793	Between Lots	0	0%, 0%
			Between Tubes	0.3	0%, 1%
			Within Tubes	1.7	1.5%, 2%
			Total	1.8	1.4%, 2.3%
Beckman Coulter AU480	CL (mmol/L)	99.8	Between Lots	0.3	0.3%, 0.4%
			Between Tubes	0.4	0.3%, 0.5%
			Within Tubes	0.4	0.3%, 0.4%
			Total	0.7	0.5%, 0.9%
	CL (mmol/L)	97.87	Between Lots	0.4	0.3%, 0.4%
			Between Tubes	0.2	0.1%, 0.3%

Test System	Analyte (Unit)	Mean	Variance Component	CV (%)	CV 95% CI
Roche cobas Integra 400 Plus			Within Tubes	0.4	0.3%, 0.4%
			Total	0.6	0.5%, 0.7%
Beckman Coulter Access 2	CORT (ug/dL)	9.09	Between Lots	0.5	0.4%, 0.6%
			Between Tubes	2.3	0%, 3.2%
			Within Tubes	3.8	3.3%, 4.5%
			Total	4.5	3.6%, 5.9%
Roche cobas e411	CORT (ug/dL)	8.822	Between Lots	0.4	0.3%, 0.5%
			Between Tubes	0	0%, 0%
			Within Tubes	3.9	3.4%, 4.6%
			Total	3.9	3.2%, 5.1%
Beckman Coulter AU480	GLUC (mg/dL)	143.5	Between Lots	0	0%, 0%
			Between Tubes	2.8	2.4%, 3.2%
			Within Tubes	1.1	1%, 1.2%
			Total	3	2.5%, 3.9%
Roche cobas Integra 400 Plus	GLUC (mg/dL)	143.2	Between Lots	0	0%, 0%
			Between Tubes	2.7	2.2%, 3.2%
			Within Tubes	1.9	1.7%, 2.2%
			Total	3.4	2.7%, 4.3%
Beckman Coulter AU480	IgG (mg/dL)	1130.126	Between Lots	0	0%, 0%
			Between Tubes	1.4	1%, 1.7%
			Within Tubes	1.3	1.1%, 1.5%
			Total	1.9	1.5%, 2.5%
Roche cobas Integra 400 Plus	IgG (mg/dL)	1176.41	Between Lots	0	0%, 0%
			Between Tubes	1.3	1%, 1.6%
			Within Tubes	1.1	0.9%, 1.3%
			Total	1.7	1.4%, 2.2%
Beckman Coulter AU480	K (mmol/L)	3.9	Between Lots	1.7	1.5%, 2%
			Between Tubes	3.1	2.6%, 3.6%
			Within Tubes	0.9	0.8%, 1%
			Total	3.7	3%, 4.7%
Roche cobas Integra 400 Plus	K (mmol/L)	3.876	Between Lots	1.3	1.2%, 1.6%
			Between Tubes	2.5	2%, 2.8%
			Within Tubes	1.1	0.9%, 1.2%
			Total	3	2.4%, 3.9%
Beckman Coulter AU480	LDH (U/L)	147.9	Between Lots	2.1	1.8%, 2.6%
			Between Tubes	5.2	4.3%, 6%
			Within Tubes	1.3	1.1%, 1.6%
			Total	5.8	4.6%, 7.6%
Roche cobas Integra 400 Plus	LDH (U/L)	166.85	Between Lots	2.5	2.1%, 3%
			Between Tubes	0	0%, 0%
			Within Tubes	3.7	3.1%, 4.5%
			Total	4.4	3.6%, 5.9%
	Phos (mg/dL)	3.13	Between Lots	0.4	0.3%, 0.4%
			Between Tubes	0.6	0%, 1%

Test System	Analyte (Unit)	Mean	Variance Component	CV (%)	CV 95% CI
Beckman Coulter AU480			Within Tubes	1.6	1.4%, 1.8%
			Total	1.7	1.4%, 2.2%
Roche cobas Integra 400 Plus	Phos (mg/dL)	3.05	Between Lots	0.3	0.3%, 0.4%
			Between Tubes	0	0%, 0%
			Within Tubes	1.8	1.6%, 2.1%
			Total	1.8	1.5%, 2.4%
Beckman Coulter AU480	TP (g/dL)	7.09	Between Lots	0.2	0.2%, 0.3%
			Between Tubes	1.1	0.9%, 1.3%
			Within Tubes	0.7	0.6%, 0.8%
			Total	1.4	1.1%, 1.8%
Roche cobas Integra 400 Plus	TP (g/dL)	6.82	Between Lots	0.1	0.1%, 0.1%
			Between Tubes	1.1	0.8%, 1.3%
			Within Tubes	0.8	0.7%, 1%
			Total	1.4	1.1%, 1.8%
Beckman Coulter Access 2	TPSA (ng/mL)	2.825	Between Lots	3.8	3.1%, 4.7%
			Between Tubes	0	0%, 0%
			Within Tubes	4.8	4.2%, 5.6%
			Total	6.1	4.7%, 8.5%
Roche cobas e411	TPSA (ng/mL)	3.0411	Between Lots	0.5	0.4%, 0.6%
			Between Tubes	0	0%, 0%
			Within Tubes	2.1	1.8%, 2.4%
			Total	2.2	1.7%, 3%
Beckman Coulter Access 2	Total T4 (ug/dL)	8.328	Between Lots	1.3	1.1%, 1.5%
			Between Tubes	1.7	0%, 2.7%
			Within Tubes	3.6	3.1%, 4.3%
			Total	4.2	3.4%, 5.5%
Roche cobas e411	Total T4 (ug/dL)	7.382	Between Lots	1	0.9%, 1.3%
			Between Tubes	0	0%, 0%
			Within Tubes	4.3	3.7%, 5.1%
			Total	4.4	3.6%, 5.8%
Beckman Coulter Access 2	Free T4 (ng/dL)	0.836	Between Lots	0.2	0.2%, 0.3%
			Between Tubes	1.3	0%, 1.9%
			Within Tubes	2.5	2.2%, 2.9%
			Total	2.8	2.3%, 3.6%
Roche cobas e411	Free T4 (ng/dL)	1.2402	Between Lots	0.8	0.7%, 1%
			Between Tubes	0	0%, 0%
			Within Tubes	2.4	2.2%, 2.8%
			Total	2.6	2.1%, 3.3%
Beckman Coulter Access 2	TESTO (ng/dL)	2.697	Between Lots	1	0.9%, 1.2%
			Between Tubes	3.9	2.8%, 4.8%
			Within Tubes	4.3	3.8%, 4.9%
			Total	5.9	4.8%, 7.5%
Roche cobas e411	TESTO (ng/dL)	3.1862	Between Lots	0	0%, 0%
			Between Tubes	1.3	0%, 2.1%

Test System	Analyte (Unit)	Mean	Variance Component	CV (%)	CV 95% CI
			Within Tubes	3.3	2.9%, 3.8%
			Total	3.5	2.9%, 4.6%
Beckman Coulter AU480	Trig (mg/dL)	194.3	Between Lots	0	0%, 0%
			Between Tubes	1.1	0.8%, 1.3%
			Within Tubes	0.9	0.8%, 1.1%
			Total	1.4	1.2%, 1.9%
Roche cobas Integra 400 Plus	Trig (mg/dL)	179.3	Between Lots	0.1	0.1%, 0.1%
			Between Tubes	0.6	0%, 1.1%
			Within Tubes	1.5	1.3%, 1.8%
			Total	1.6	1.3%, 2.1%

BD Vacutainer® Sodium Heparin Blood Collection Tube

A study was conducted to evaluate the repeatability (within-tube), lot-to-lot (between lots), tube-to-tube (between tube) and total variation in the BD Vacutainer® Sodium Heparin Blood Collection Tube when testing lithium. To carry out the testing, plasma was drawn from 20 individual subjects using non-additive tubes, the plasma was then pooled per patient, and lithium was spiked into the pooled plasma of each subject. The samples were then transferred to six BD NaHep tubes per subject and tested. Three lots of tubes were used in the study. All samples were run in duplicate on two instrument platforms. The results are summarized in the table below.

BD Vacutainer® Sodium Heparin Blood Collection Tube

Test System	Analyte	Mean	Variance Component	CV%	CV 95% CI
Roche cobas 6000	Li	0.606 mmol/L	Between Lots	0	0%, 0%
			Between Tubes	0	NA
			Within Tubes	4.60%	4.1%, 5.2%
			Total	4.6%	3.5%, 6.7%
Siemens Atellica	Li	0.606 mmol/L	Between Lots	0.80	0.7%, 1.1%
			Between Tubes	0.00	NA
			Within Tubes	2.90	2.5%, 3.3%
			Total	3.00	2.3%, 4.3%

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

Benchtop studies were conducted to evaluate interference from stopper materials over the sample storage time. Study protocols, acceptance criteria and results for this study were provided and found to be acceptable.

4. Detection Limit and Assay Reportable Range:

Not applicable.

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

a. Specimen Stability
Multiple analyte stability studies were conducted to assess the analyte within-tube stability for representative analytes in BD Vacutainer® Plasma Separator Tubes (PST™). Within-tube stability was assessed in the BD Vacutainer® Plasma Separator Tubes (PST™) after 12 hour storage at room temperature for CO2 only, after 18 hour storage at room temperature for Glucose and CO2, and for all other analytes listed below after 24-hour storage at room temperature. In addition, within tube stability after 3 days of refrigerated and 7 days of refrigerated storage was assessed for all analytes except Glucose and CO2. Stability was also assessed in the BD Vacutainer® Sodium Heparin Blood Collection Tubes after 2 hour storage at room temperature for Lithium. Samples tested had analyte concentrations that covered the measuring range for the assays used for testing each analyte and important medical decision levels for each tested analyte. Systematic bias between the test storage condition and baseline (0-2 hours after collection) was assessed for each analyte, and it was determined that the bias observed in these studies supports the storage claims included in the devices' labeling.

BD Vacutainer® Plasma Separator Tubes (PST™)

Analyte	**Temperature Condition**	**Storage Duration**
CO_2	Room temperature (23-27°C)	12 hours
GLUC	Room temperature (23-27°C)	18 hours
ALB ALKP AMY AST BUN Ca CL Chol CK CREAT CKMB C3 CORT CRP DBIL E2 FERR	Room temperature (23-27°C)	24 hours

Folate FSH Free T4 Free T3 GGT HAPT HDL hsTnI HCG Fe IgA IgG IgM LH LDH Lip LDL Mg NT-ProBNP Phos K PROG RF TPSA TESTO Total T3 Total T4 TRF TSH Na TBIL TP Trig TnT UA VIT B12 VIT D		
ALKP AST C3 Fe LDH Phos	Refrigerated (2-8°C)	3 days
ALB ALT AMY BUN Ca	Refrigerated (2-8°C)	7 days

CL Chol CK Creat DBIL GGT Lip Mg Na TBIL TP Trig UA CKMB CORT E2 FERR Folate FSH Free T4 Free T3 HAPT hsTnI HCG IgA IgG IgM LH NT-ProBNP PROG RF TESTO TPSA Total T3 Total T4 TRF TSH TnT VIT B12 VIT D		

BD Vacutainer® Sodium Heparin Blood Collection Tubes

Analyte	**Temperature Condition**	**Storage Duration**
Li	Room temperature (23-27°C)	2 hours

b. Shelf Life

Real Time Shelf-life stability testing was conducted by using BD Vacutainer® Plasma Separator Tubes (PST™) and BD Vacutainer® Sodium Heparin Blood Collection Tubes. The results support the shelf-life claims of 12 months, and 16-17 months when stored at 25°C (and 40°C for 15 days to simulate extreme temperatures during shipping) for BD Vacutainer® Plasma Separator Tubes (PST™) and BD Vacutainer® Sodium Heparin Blood Collection Tubes respectively.

c. Additional bench testing

Benchtop studies were conducted to assess draw volume, X-value, stopper/shield separation, stopper leakage, tube leakage, drop breakage, centrifuge breakage, and the trace metal content prior to blood draw. The study protocols were reviewed, and performance was considered acceptable.

6. Assay Cut-Off:
   Not applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Not applicable

2. Matrix Comparison:
   Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:
   Not applicable

2. Clinical Specificity:
   Not applicable

3. Clinical Cut-Off:
   Not applicable

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

Routine chemistry analytes

A study was conducted to evaluate equivalence between BD Vacutainer® Plasma Separator Tubes (PST™) and Greiner Bio-One Vacuette Lithium Heparin Separator tubes for testing

representative analytes. A total of 180 participants were included in the study. Blood was collected from each study participant using standard phlebotomy techniques. In addition, contrived samples were prepared to cover the analytical measurement interval for the tested analytes. Samples were tested on two different instrument platforms (Beckman Coulter UniCel DxC AU480 and Roche cobas Integra 400 Plus). For each analyte and tube comparison, data was analyzed using Passing Bablok, Deming or Weighted Deming regression. Regression analyses for each tube type comparison were assessed and determined to demonstrate acceptable accuracy. Regression parameter estimates are provided in the tables below. Biases at important medical decision levels for each analyte between tube types were estimated with 95% confidence intervals and determined to be acceptable

Regression Parameter Estimates: BD Vacutainer® Plasma Separator Tubes (PST™) vs. Greiner Bio-One Vacuette Lithium Heparin Separator tubes

Instrument	**Analyte**	**Slope (95% CI)**	**Intercept (95% CI)**	**Correlation Coefficient**
Beckman Coulter AU480	ALB (g/dL)	0.99 (0.95, 1.04)	0.02 (-0.16, 0.21)	0.968
Roche cobas® Integra 400 Plus	ALB (g/dL)	0.98 (0.92, 1.04)	0.07 (-0.2, 0.34)	0.925
Beckman Coulter AU480	ALKP (U/L)	0.99 (0.97, 1)	0.71 (-0.12, 1.54)	0.997
Roche cobas® Integra 400 Plus	ALKP (U/L)	1 (0.97, 1.02)	-0.08 (-2.08, 1.92)	0.996
Beckman Coulter AU480	ALT (U/L)	0.99 (0.97, 1.01)	0.23 (-0.34, 0.79)	1
Roche cobas® Integra 400 Plus	ALT (U/L)	1 (0.99, 1.02)	-0.37 (-0.77, -0.04)	0.999
Beckman Coulter AU480	AMY (U/L)	1.02 (0.98, 1.05)	-0.59 (-1.92, 0.73)	0.986
Roche cobas® Integra 400 Plus	AMY (U/L)	1 (0.99, 1.01)	-0.23 (-0.78, 0.33)	0.998
Beckman Coulter AU480	AST (U/L)	1.05 (0.99, 1.11)	-0.64 (-1.52, 0.24)	0.998
Roche cobas® Integra 400 Plus	AST (U/L)	1.01 (0.98, 1.04)	-0.25 (-0.73, 0.23)	1
Beckman Coulter AU480	BUN (mg/dL)	1 (1, 1.02)	0.05 (-0.19, 0.1)	1
Roche cobas® Integra 400 Plus	BUN (mg/dL)	1.01 (1, 1.03)	-0.12 (-0.43, 0.1)	0.999
Beckman Coulter AU480	CK (mg/dL)	1 (1, 1.01)	1 (-0.55, 1)	0.996
Roche cobas® Integra 400 Plus	CK (mg/dL)	1 (0.98, 1.01)	-0.11 (-1.22, 1.01)	0.997
Beckman Coulter AU480	CL (mmol/L)	0.99 (0.93, 1.04)	1.53 (-3.9, 6.95)	0.951
Roche cobas® Integra 400 Plus	CL (mmol/L)	1.02 (0.99, 1.06)	-1.82 (-5.32, 1.69)	0.964

Instrument	Analyte	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient
Beckman Coulter AU480	CO2 (mmol/L)	0.97 (0.91, 1.02)	0.97 (-0.4, 2.34)	0.953
Roche cobas® Integra 400 Plus	CO2 (mmol/L)	1.03 (0.96, 1.1)	-1.03 (-2.6, 0.54)	0.935
Beckman Coulter AU480	Ca (mg/dL)	1 (0.93, 1.08)	0 (-0.71, 071)	0.985
Roche cobas® Integra 400 Plus	Ca (mg/dL)	0.97 (0.93, 1.01)	0.26 (-0.1, 0.62)	0.958
Beckman Coulter AU480	Chol (mg/dL)	1 (0.98, 1.02)	-0.22 (-4.04, 3.6)	0.995
Roche cobas® Integra 400 Plus	Chol (mg/dL)	1.01 (0.98, 1.03)	-1.94 (-6.45, 2.57)	0.99
Beckman Coulter AU480	Creat (mg/dL)	1.03 (1.01, 1.05)	0 (-0.02, 0.01)	1
Roche cobas® Integra 400 Plus	Creat (mg/dL)	0.99 (0.97, 1.01)	0.01 (-0.01, 0.03)	1
Beckman Coulter AU480	DBIL (mg/dL)	0.88 (0.81, 0.95)	0.01 (0, 0.02)	0.908
Roche cobas® Integra 400 Plus	DBIL (mg/dL)	1.07 (0.8, 1.33)	0 (-0.02, 0.01)	0.774
Beckman Coulter AU480	Fe (µg/dL)	1 (0.98, 1.02)	-1.71 (-2.87, -0.55)	0.998
Roche cobas® Integra 400 Plus	Fe (µg/dL)	1.02 (0.99, 1.05)	-1.86 (-3.64, -0.08)	0.996
Beckman Coulter AU480	GGT (U/L)	0.99 (0.98, 1.01)	0.39 (0, 0.78)	1
Roche cobas® Integra 400 Plus	GGT (U/L)	0.99 (0.98, 1)	0.03 (-0.2, 0.43)	1
Beckman Coulter AU480	GLUC (mg/dL)	1.02 (0.98, 1.06)	-0.92 (-4.82, 2.99)	0.992
Roche cobas® Integra 400 Plus	GLUC (mg/dL)	1.03 (1.01, 1.06)	-1.62 (-4.45, 1.2)	0.998
Beckman Coulter AU480	HDL (mg/dL)	1 (0.97, 1)	0 (-1, 1.12)	0.978
Roche cobas® Integra 400 Plus	HDL (mg/dL)	1.01 (0.98, 1.04)	-0.6 (-1.83, 0.63)	0.983
Beckman Coulter AU480	K (mmol/L)	0.96 (0.87, 1.06)	0.23 (-0.13, 0.59)	0.893
Roche cobas® Integra 400 Plus	K (mmol/L)	0.96 (0.85, 1.07)	0.25 (-0.15, 0.66)	0.875
Beckman Coulter AU480	LDH (U/L)	1.02 (1, 1.07)	-1.51 (-7.23, 2)	0.953
Roche cobas® Integra 400 Plus	LDH (U/L)	1.01 (0.96, 1.06)	-0.08 (-6.83, 6.67)	0.953
Beckman Coulter AU480	LDL (mg/dL)	0.99 (0.98, 1.01)	0.73 (-1.76, 3.22)	0.997

Instrument	Analyte	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient
Roche cobas® Integra 400 Plus	LDL (mg/dL)	1.03 (0.99, 1.07)	-3.75 (-8.55, 1.04)	0.995
Beckman Coulter AU480	Lip (U/L)	0.98 (0.92, 1.03)	0.55 (-0.77, 1.87)	0.986
Roche cobas® Integra 400 Plus	Lip (U/L)	1 (0.99, 1.01)	0 (-0.26, 0.27)	0.998
Beckman Coulter AU480	Mg (mg/dL)	0.99 (0.98, 1)	-0.01 (-0.03, 0.02)	0.995
Roche cobas® Integra 400 Plus	Mg (mg/dL)	0.99 (0.94, 1.04)	-0.03 (-0.13, 0.07)	0.965
Beckman Coulter AU480	Na (mmol/L)	1 (0.97, 1.03)	-0.27 (-4.36, 3.82)	0.97
Roche cobas® Integra 400 Plus	Na (mmol/L)	1 (0.99, 1.01)	0.86 (-0.58, 2.29)	0.996
Beckman Coulter AU480	Phos (mg/dL)	0.98 (0.92, 1.04)	0.1 (-0.07, 0.28)	0.963
Roche cobas® Integra 400 Plus	Phos (mg/dL)	0.99 (0.96, 1.02)	0.05 (-0.05, 0.14)	0.981
Beckman Coulter AU480	TBIL (mg/dL)	1 (0.99, 1.01)	-0.01 (-0.02, 0)	1
Roche cobas® Integra 400 Plus	TBIL (mg/dL)	1 (1, 1.04)	0 (-0.01, 0.01)	1
Beckman Coulter AU480	TP (g/dL)	0.98 (0.9, 1.06)	0.1 (-0.47, 0.68)	0.912
Roche cobas® Integra 400 Plus	TP (g/dL)	0.95 (0.88, 1.02)	0.36 (-0.16, 0.87)	0.956
Beckman Coulter AU480	Trig (mg/dL)	0.99 (0.98, 1.01)	-0.52 (-2.73, 1.69)	0.998
Roche cobas® Integra 400 Plus	Trig (mg/dL)	1 (0.99, 1.01)	-2.08 (-3.29, -0.87)	0.999
Beckman Coulter AU480	UA (mg/dL)	0.99 (0.95, 1.02)	0.07 (-0.1, 0.23)	0.982
Roche cobas® Integra 400 Plus	UA (mg/dL)	0.98 (0.95, 1.02)	0.09 (-0.06, 0.24)	0.988

Special Chemistry Analytes and Cardiac Markers

A study was conducted to evaluate equivalence between A) BD Vacutainer® Plasma Separator Tubes (PST™) and Greiner Bio-One Vacuette Lithium Heparin Separator and B) BD Vacutainer® Sodium Heparin Blood Collection Tubes and Greiner Sodium Heparin Blood Collection Tubes for testing special chemistry analytes and cardiac markers. Blood was collected from each study participant using standard phlebotomy techniques. In addition, contrived samples were prepared to cover the analytical measurement interval for the tested analytes. Samples were tested on two different instrument platforms for each analyte tested.

For each analyte and tube comparison, data was analyzed using Passing Bablok regression, Deming or Weighted Deming regression. Regression analyses for each tube type comparison were assessed and determined to demonstrate acceptable accuracy. Regression parameter estimates are provided in the tables below. Biases at important medical decision levels for each analyte between tube types were estimated with 95% confidence intervals and determined to be acceptable.

Regression Parameters for BD Vacutainer® Plasma Separator Tubes (PST™) vs. Greiner Bio-One Vacuette LiHep Separator

Instrument	**Analyte**	**N**	**Slope (95% CI)**	**Intercept (95% CI)**	**Correlation Coefficient**
OCD Vitros 5600	C3	130	0.99 (0.95, 1.03)	-0.6 (-4.83, 3.64)	0.985
Beckman Coulter DxC 700 AU	CKMB	121	1 (0.97, 1.03)	0.14 (-0.48, 0.76)	0.995
Roche cobas® e411	CKMB	125	1 (0.98, 1.01)	-0.01 (-0.05, 0.02)	0.999
OCD Vitros 5600	CORT	115	0.99 (0.99, 1)	0.31 (-1.15, 1.78)	0.998
Roche cobas® e411	CORT	116	0.98 (0.98, 0.99)	0.4 (-0.18, 0.98)	0.999
Beckman Coulter DxC 700 AU	CRP	128	1 (1, 1.01)	0 (-0.02, 0.01)	0.998
OCD Vitros 5600	CRP	133	1 (0.99, 1)	0 (0, 0.02)	0.999
OCD Vitros 3600/5600	E2	113	1.01 (0.98, 1.02)	2.96 (0.66, 7.09)	0.999
Siemens Dimension Vista 1500	E2	117	0.99 (0.98, 1.01)	-0.75 (-1.49, 0.41)	0.999
OCD Vitros 3600/5600	FERR	109	0.95 (0.94, 0.96)	0.09 (-0.04, 0.22)	0.999
Siemens Dimension Vista 1500	FERR	107	0.99 (0.98, 0.99)	-0.09 (-0.29, 0.11)	1
OCD Vitros 3600/5600	FOLATE	102	1.02 (0.98, 1.07)	0.35 (0, 0.75)	0.948
Siemens Dimension Vista 1500	FOLATE	129	1.02 (0.99, 1.04)	0.27 (-0.04, 0.6)	0.987
OCD Vitros 3600/5600	FSH	109	0.99 (0.99, 1)	-0.02 (-0.04, 0)	1
Siemens Dimension Vista 1500	FSH	112	1 (0.99, 1)	0.01 (-0.02, 0.05)	1

Instrument	Analyte	N	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient
Roche cobas® Integra 400 Plus	HAPT	100	1 (0.99, 1.01)	-0.45 (-1.67, 0.77)	0.998
OCD Vitros 5600	HAPT	100	1.01 (0.99, 1.02)	-0.72 (-2.56, 1.13)	0.996
OCD Vitros 3600/5600	HCG	85	1 (0.99, 1.01)	-0.04 (-0.16, 0.08)	1
Siemens Dimension Vista 1500	HCG	98	1 (0.99, 1.01)	0 (-0.01, 0.01)	1
Beckman Coulter DxC 700 AU	IgA	123	1 (1, 1.01)	-0.58 (-1.59, 0.43)	0.998
OCD Vitros 5600	IgA	121	0.97 (0.96, 0.98)	1.25 (-0.15, 2.65)	0.997
Beckman Coulter DxC 700 AU	IgG	127	1.03 (1.02, 1.04)	-18.38 (-28.29, -8.47)	0.998
OCD Vitros 5600	IgG	129	0.98 (0.96, 1)	7.78 (-8.56, 24.12)	0.993
Beckman Coulter DxC 700 AU	IgM	118	0.98 (0.95, 1.01)	1.5 (-1.11, 4.11)	0.999
OCD Vitros 5600	IgM	117	0.98 (0.97, 1)	-0.19 (-1.18, 0.8)	0.999
OCD Vitros 3600/5600	LH	107	1 (0.99, 1)	-0.04 (-0.07, -0.01)	1
Siemens Dimension Vista 1500	LH	111	1 (1, 1)	0 (-0.02, 0)	1
OCD Vitros 5600	NT-proBNP	126	0.99 (0.99, 1)	-0.07 (-0.85, 0.7)	1
Roche cobas® e411	NT-proBNP	119	1 (0.99, 1)	-2.23 (-4.51, 0.05)	1
OCD Vitros 3600/5600	PROG	125	1 (0.99, 1.01)	0.09 (0.04, 0.11)	1
Siemens Dimension Vista 1500	PROG	104	1 (0.98, 1.01)	0.05 (0.04, 0.07)	1
OCD Vitros 5600	TPSA	107	0.99 (0.98, 0.99)	0 (0, 0.01)	1
Roche cobas® e411	TPSA	111	0.99 (0.99, 1)	0 (0, 0.01)	1

Instrument	Analyte	N	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient
Beckman Coulter DxC 700 AU	RF	59	1.02 (1, 1.04)	-0.69 (-1.2, -0.19)	0.995
OCD Vitros 5600	RF	73	1 (0.99, 1.02)	-0.17 (-0.75, 0.41)	0.999
Beckman Coulter Access 2	Total T3	110	0.97 (0.9, 1.03)	0.06 (0.01, 0.11)	0.98
Roche cobas® e411	Total T3	112	0.96 (0.91, 1.01)	0.03 (-0.03, 0.1)	0.959
OCD Vitros 3600/5600	Free T3	112	1.04 (0.96, 1.11)	-0.15 (-0.58, 0.28)	0.967
Siemens Dimension Vista 1500	Free T3	117	1.01 (0.98, 1.03)	0 (-0.06, 0.07)	0.995
OCD Vitros 3600/5600	Total T4	109	1.01 (0.99, 1.03)	-1.01 (-3.24, 1.22)	0.994
Siemens Dimension Vista 1500	Total T4	116	1 (0.96, 1.04)	-0.05 (-0.38, 0.28)	0.979
Beckman Coulter Access 2	Free T4	109	1.04 (1.01, 1.07)	-0.03 (-0.06, 0)	0.987
Roche cobas® e411	Free T4	111	1 (0.98, 1.01)	0 (-0.02, 0.01)	0.997
OCD Vitros 5600	TESTO	128	1.07 (1.05, 1.08)	0.09 (0.06, 0.12)	0.998
Roche cobas® e411	TESTO	117	0.97 (0.96, 0.99)	0.01 (0, 0.02)	0.998
Roche cobas® Integra 400 Plus	TRF	100	0.99 (0.97, 1.01)	1.62 (-3.82, 7.05)	0.993
OCD Vitros 5600	TRF	102	0.99 (0.97, 1)	1.91 (-1.02, 4.84)	0.996
OCD Vitros 3600/5600	TSH	121	0.99 (0.98, 1)	0 (-0.01, 0.01)	1
Siemens Dimension Vista 1500	TSH	127	0.99 (0.98, 1)	0 (-0.01, 0.01)	1
Beckman Coulter Access 2	TnI	103	1.02 (1, 1.04)	0 (0, 0)	0.998
Roche cobas® e411	TnI	39	1.23 (1.12, 1.33)	-0.03 (-0.08, 0.03)	0.99

Instrument	Analyte	N	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient
Roche cobas® e411/e601	TnT	110	1.03 (1.01, 1.05)	0.2 (-0.26, 0.66)	1
OCD Vitros 3600/5600	VIT B12	110	0.99 (0.97, 1)	4.57 (0.82, 8.33)	0.998
Siemens Dimension Vista 1500	VIT B12	120	1.02 (1, 1.04)	-9.39 (-17.62, -1.16)	0.999
Beckman Coulter Access 2	VIT D	121	0.98 (0.95, 1.01)	0.67 (0, 1.34)	0.991
Roche cobas® e411	VIT D	113	0.99 (0.94, 1.03)	-0.51 (-1.52, 0.51)	0.987
Siemens ADVIA Centaur XPT	hsTnI	117	1 (1, 1.01)	-0.02 (-0.18, 0.13)	1
Beckman Coulter Access 2	hsTnI	132	1.01 (0.99, 1.02)	0.07 (-0.14, 0.29)	0.997

Regression Parameters for BD Vacutainer Sodium Heparin Blood Collection Tubes vs. Greiner Sodium Heparin Blood Collection Tubes

Instrument	Analyte	N	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient
Roche cobas® c501	Li	100	1 (0.99, 1.01)	0 (-0.01, 0.01)	0.998
Siemens Atellica	Li	88	1 (1, 1.01)	0 (-0.01, 0)	1

An additional study was conducted to evaluate equivalence between BD Vacutainer® Plasma Separator Tubes (PST™) and Greiner Bio-One Vacuette LiHep Separator Tubes for C3 testing. A total of 89 participants were enrolled in the study. Blood was collected from each study participant using standard phlebotomy techniques. In addition, contrived samples were prepared to cover the analytical measurement interval for the tested analytes. Data was analyzed using Weighted Deming regression. Regression analysis was assessed and determined to demonstrate acceptable accuracy. Regression parameter estimates are provided in the tables below. Bias at important medical decision levels was estimated with 95% confidence intervals and determined to be acceptable

Regression Parameters for 4.5mL BD Vacutainer® Plasma Separator Tubes (PST™) vs. 5.0mL Greiner Bio-One Vacuette LiHep Separator

Instrument	Analyte	N	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient
Roche cobas 6000	C3	89	1.01 (0.99, 1.03)	-0.92 (-3.53, 1.7)	0.994

D 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.