510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K230855

B Applicant

Becton Dickinson and Company

C Proprietary and Established Names

BD Vacutainer® Serum Separator (SST™) 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:

The BD Vacutainer® Serum Separator (SST™) Blood Collection Tube is a sterile, single use tube used for the collection, containment, transport, and centrifugation of venous blood specimens to obtain and store serum for in vitro diagnostic testing. It is used in settings where a venous blood specimen is collected by a trained healthcare professional. The BD Vacutainer® Serum Separator (SST™) Blood Collection Tube is used for clinical laboratory testing in chemistry and for the monitoring of certain therapeutic drugs.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

Do not use BD Vacutainer® SST™ Tubes for trace element testing.

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

Examine tubes prior to use. Clot activator additive is visible in the tube and should appear as white dots. Do not use the tube if the additive is missing, discolored, or if foreign matter or precipitate is present.

Separation of serum from the cells should take place within 2 hours of collection to prevent erroneous test results, unless evidence is available supporting longer times from collection to serum separation.

Follow your facility's procedures if clots or other visible obstructions are present in the serum sample 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 procedure.

BD Vacutainer® SST™ Blood Collection Tubes may contain trace levels of acetone, hexane, and formate. It has not been determined if the presence of trace levels of these compounds will affect test results in chromatography-based assays.

Hydrophobic drugs have been known to demonstrate gel adsorption in 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 Adsorption in the References section.

D Special Instrument Requirements:

Not applicable.

IV Device/System Characteristics:

A Device Description:

The BD Vacutainer® Serum Separator (SST™) Blood Collection Tubes are plastic, evacuated, sterile, single use, in vitro diagnostic medical devices. The tubes are comprised of a plastic tube (polyethylene terephthalate, PET) containing an inert gel separator and a clot activator, and a closure (either a BD Vacutainer® Hemogard™ closure assembly or a conventional stopper). Tube stoppers are lubricated with silicone to facilitate stopper insertion. The interior of the tube is spray-coated with a silica clot activator that is mixed with a silicone surfactant. In addition to the clot activator, the tube contains an inert gel separator that provides a mechanical barrier to separate the serum from the rest of the blood components. The tubes are available in 13x75mm, 13x100mm and 16x100mm configurations with draw volumes ranging from 3.5 to 10 mL. The amount of gel can vary based on tube size.

B Principle of Operation:

The BD Vacutainer® Serum Separator (SST™) Blood Collection Tubes use controlled vacuum to draw a specific volume of blood into the sterile interior of the tube. Within the tube, a clot activator is present to help clot the red blood cells, isolating them from the serum and other blood components. The presence of a surfactant is intended to reduce adhesion of red blood cells and fibrin to the tube walls. The inert gel separator provides a mechanical barrier to separate the serum from the rest of the blood components. The density of the gel separator causes it to move upward during centrifugation to the serum-clot interface, where it forms a barrier separating serum from fibrin and red blood cells.

The tubes are compatible with 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 5 times to mix the blood with the additive. Blood should be allowed to clot for a minimum of 30 minutes before centrifugation, The recommended centrifugation conditions are 1,100-1,300 RCF (relative centrifuge force or g) for 10 or 15 minutes (depending on the tube catalog number).

V Substantial Equivalence Information:

A Predicate Device Name(s):
BD Vacutainer Plus SST Serum Separator Tube

B Predicate 510(k) Number(s):
K023075

C Comparison with Predicate(s):

Device & Predicate Device(s):	K230855	K023075
Device Trade Name	BD Vacutainer® Serum Separator (SST™) Blood Collection Tube	BD Vacutainer® SST Plus Tubes
General Device Characteristic Similarities		
Intended Use/ Indications For Use	Used for the collection, containment, transport, and centrifugation of venous blood specimens to obtain and store serum for in vitro diagnostic testing. It is used in settings where a venous blood specimen is collected by a trained healthcare professional.	Same
Evacuated Blood Collection Tube	Yes	Same
Tube Dimension	13x75 mm, 13x100 mm, 16x100 mm, 16x125 mm	Same
Tube Draw Volumes	3.5mL - 10mL	Same
Sample Type	Serum	Same
Additive Type	Silica clot activator	Same
Additive Application/Quantity	Clot Activator Spray Dried Clot Activator amounts range from 2.1-4.3 mg/mL	Same
Tube Material	PET (polyethylene terephthalate) plastic	Same
Sterilization Method	Gamma Irradiation	Same
General Device Characteristic Differences		
Sterility Assurance Level (SAL)	10^{-3}: 13x75mm Hemogard™, 16x100mm Conventional, 16x125mm Conventional	10^{-3}: 13x75mm Hemogard™, 13x100mm Hemogard™, 16x100mm Conventional, 16x125mm Conventional

Device & Predicate Device(s):	K230855	K023075
	10^{-3} or 10^{-6}: 13x100mm Hemogard™	
Shelf Life	5mL BD SST: 12 months 7.5 BD SST: 10 months	12 months

VI Standards/Guidance Documents Referenced:

- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems
- EN ISO 14971:2019 Medical Devices – Application of risk management to medical devices
- ANSI AAMI 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)]
- ANSI AAMI ISO 11137-2 Third edition 2013-06-01 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
- ANSI/AAMI/ISO 11137-3:2017 Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control
- ANSI/AAMI/ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
- ANSI/AAMI/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
- ANSI AAMI ST67:2019 Sterilization of health care products - Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled "sterile"

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Routine Chemistry Analytes
A study was conducted to evaluate repeatability (within tube), lot-to-lot reproducibility and tube-to-tube reproducibility of BD Vacutainer® SST™ Blood Collection Tubes for select routine chemistry analytes. Blood was collected from each subject (n=47) into 6 BD SST™ Tubes. Specimens were tested in duplicate per tube with 2 tubes per lot across 3 lots on two instrument platforms (Beckman Coulter DxC 680i and Roche Cobas 6000) for the following select chemistry analytes: alanine aminotransferase (ALT), total bilirubin (TBIL), calcium (Ca), chloride (CL), glucose (GLUC), phosphorus (Phos), potassium (K), total protein (TP), triglycerides (Trig), complement C3 (C3), cortisol (CORT), free thyroxine (Free T4), immunoglobulin G (IgG), lactate dehydrogenase (LDH), testosterone (TESTO), prostate specific antigen (PSA), and thyroxine (Total T4). Contrived samples were also prepared in an effort to cover extreme levels for the following analytes: Ca, CL, GLUC, K, LDH, Phos, and

TBIL. Total, Between-Lot, and Between-Tube variability for each instrument platform are presented in the tables below.

Precision Summary (%CV) on Beckman Coulter DxC for representative chemistry analytes:

Analyte (Unit)	Mean	Variance Component	CV (%)	CV 95% CI
ALT (U/L)	33.5	Between Lots	0.7	0%, 1.1%
		Between Tubes	0.2	0%, 0.9%
		Within Tubes	1.9	1.7%, 2.2%
		Total	2.1	1.6%, 2.9%
C3 (mg/dL)	142.59	Between Lots	0.5	0%, 0.7%
		Between Tubes	0.2	0%, 0.6%
		Within Tubes	1.2	1.1%, 1.4%
		Total	1.4	1.1%, 1.9%
Ca (mg/dL)	9.49	Between Lots	0	0%, 0%
		Between Tubes	0.2	0.1%, 0.3%
		Within Tubes	0.5	0.4%, 0.5%
		Total	0.5	0.4%, 0.7%
CL (mmol/L)	102.1	Between Lots	0	0%, 0%
		Between Tubes	0.1	0%, 0.2%
		Within Tubes	0.4	0.4%, 0.5%
		Total	0.5	0.4%, 0.7%
CORT (µg/dL)	10.948	Between Lots	1.7	0%, 2.5%
		Between Tubes	0	0%, 0%
		Within Tubes	4.3	4%, 4.8%
		Total	4.7	3.6%, 6.5%
Free T4 (ng/dL)	0.993	Between Lots	0.3	0%, 2%
		Between Tubes	2.2	0%, 3.1%
		Within Tubes	4.3	3.8%, 4.8%
		Total	4.8	3.7%, 6.8%
GLUC (mg/dL)	124.8	Between Lots	0.7	0%, 1.1%
		Between Tubes	0.8	0%, 1.1%
		Within Tubes	1.6	1.4%, 1.8%
		Total	1.9	1.5%, 2.6%
IgG (mg/dL)	1056.6	Between Lots	0.5	0%, 0.7%
		Between Tubes	0	0%, 0.6%
		Within Tubes	1.3	1.2%, 1.5%
		Total	1.4	1.1%, 2%
K (mmol/L)	4.13	Between Lots	1.3	0.8%, 1.6%
		Between Tubes	1.1	0.9%, 1.3%
		Within Tubes	0.7	0.6%, 0.8%
		Total	1.9	1.5%, 2.5%
LDH (U/L)	160.5	Between Lots	1.1	0%, 1.6%
		Between Tubes	1.6	1.3%, 1.9%
		Within Tubes	1.2	1.1%, 1.4%
		Total	2.4	1.9%, 3.3%

Analyte (Unit)	Mean	Variance Component	CV (%)	CV 95% CI
Phos (mg/dL)	3.6	Between Lots	0.1	0%, 0.6%
		Between Tubes	0.6	0%, 1%
		Within Tubes	1.5	1.3%, 1.7%
		Total	1.6	1.3%, 2.2%
PSA (ng/mL)	2.041	Between Lots	0.9	0%, 4/4%
		Between Tubes	7.2	5.3%, 8.7%
		Within Tubes	8.1	7.4%, 9%
		Total	10.9	8.8%, 14.3%
TBIL (mg/dL)	1.14	Between Lots	2.2	0%, 3.8%
		Between Tubes	2.9	0%, 4.4%
		Within Tubes	6.5	5.8%, 7.3%
		Total	7.5	5.8%, 10.4%
TESTO (ng/dL)	2.89	Between Lots	3.6	1.3%, 4.9%
		Between Tubes	5.2	4.3%, 6.1%
		Within Tubes	3.4	3.1%, 3.8%
		Total	7.2	5.9%, 9.5%
Total T4 (µg/dL)	9.469	Between Lots	0.7	0%, 1.8%
		Between Tubes	1.4	0%, 2.4%
		Within Tubes	4	3.6%, 4.5%
		Total	4.3	3.4%, 6.1%
TP (g/dL)	7.39	Between Lots	0.3	0%, 0.5%
		Between Tubes	0.4	0%, 0.6%
		Within Tubes	1	0.9%, 1.1%
		Total	1.1	0.9%, 1.5%
Trig (mg/dL)	157.1	Between Lots	0.7	0.1%, 1%
		Between Tubes	0.6	0%, 0.9%
		Within Tubes	1.3	1.2%, 1.5%
		Total	1.6	1.3%, 2.3%

Precision Summary (%CV) on Roche cobas 6000 for representative chemistry analytes:

Analyte (Unit)	Mean	Variance Component	CV (%)	CV 95% CI
ALT (U/L)	30.9	Between Lots	0.8	0%, 1.1%
		Between Tubes	0.3	0%, 0.9%
		Within Tubes	1.8	1.6%, 2.1%
		Total	2	1.6%, 2.8%
C3 (mg/dL)	134	Between Lots	0.2	0%, 0.5%
		Between Tubes	0	0%, 0%
		Within Tubes	1.2	1.1%, 1.4%
		Total	1.2	1%, 1.7%
Ca (mg/dL)	9.52	Between Lots	0.2	0%, 0.3%
		Between Tubes	0	0%, 0%
		Within Tubes	0.8	0.7%, 0.9%

Analyte (Unit)	Mean	Variance Component	CV (%)	CV 95% CI
		Total	0.8	0.6%, 1.1%
Cl (mmol/L)	101.89	Between Lots	0.2	0%, 0.4%
		Between Tubes	0.1	0%, 0.4%
		Within Tubes	0.8	0.7%, 0.9%
		Total	0.8	0.6%, 1.1%
CORT (µg/dL)	10.219	Between Lots	1.2	0.7%, 1.5%
		Between Tubes	0.4	0%, 0.9%
		Within Tubes	1.7	1.5%, 1.9%
		Total	2.1	1.6%, 3%
Free T4 (ng/dL)	1.2546	Between Lots	0.2	0%, 0.5%
		Between Tubes	0	0%, 0%
		Within Tubes	1.4	1.3%, 1.5%
		Total	1.4	1.1%, 2%
Gluc (mg/dL)	126.1	Between Lots	0.7	0%, 1%
		Between Tubes	1	0.7%, 1.2%
		Within Tubes	1	0.9%, 1.1%
		Total	1.6	1.3%, 2.2%
IgG (mg/dL)	1084	Between Lots	0.5	0%, 0.7%
		Between Tubes	0	0%, 0.6%
		Within Tubes	1.3	1.2%, 1.5%
		Total	1.4	1.1%, 2%
K (mmol/L)	4.29	Between Lots	1.3	0.8%, 1.7%
		Between Tubes	1.1	0.8%, 1.3%
		Within Tubes	1	0.9%, 1.2%
		Total	2	1.6%, 2.7%
LDH (U/L)	202.4	Between Lots	0.9	0%, 1.4%
		Between Tubes	1.7	1.4%, 2%
		Within Tubes	1.1	1%, 1.2%
		Total	2.3	1.8%, 3.2%
Phos (mg/dL)	3.32	Between Lots	0	0%, 0%
		Between Tubes	0.5	0%, 0.8%
		Within Tubes	1.4	1.3%, 1.6%
		Total	1.5	1.2%, 2%
PSA (ng/mL)	3.3604	Between Lots	0	0%, 0%
		Between Tubes	0	0%, 0%
		Within Tubes	3.2	2.9%, 3.5%
		Total	3.2	2.5%, 4.4%
TBIL (mg/dL)	0.9	Between Lots	0	0%, 0%
		Between Tubes	0	0%, 0%
		Within Tubes	4.1	3.8%, 4.5%
		Total	4.1	3.2%, 5.7%
TESTO (ng/dL)	3.6217	Between Lots	2.3	0%, 3.5%
		Between Tubes	4	3%, 4.8%
		Within Tubes	3.9	3.6%, 4.4%
		Total	6.1	4.9%, 8%

Analyte (Unit)	Mean	Variance Component	CV (%)	CV 95% CI
Total T4 (µg/dL)	7.795	Between Lots	0	0%, 0%
		Between Tubes	0	0%, 0%
		Within Tubes	2.2	2%, 2.4%
		Total	2.2	1.7%, 3%
TP (g/dL)	7.27	Between Lots	0.2	0%, 0.5%
		Between Tubes	0.2	0%, 0.5%
		Within Tubes	1	0.9%, 1.2%
		Total	1.1	0.9%, 1.5%
Trig (mg/dL)	160.1	Between Lots	0	0%, 0%
		Between Tubes	0.5	0%, 0.7%
		Within Tubes	1.1	1%, 1.3%
		Total	1.2	1%, 1.7%

Therapeutic Drug Monitoring
A study was conducted to evaluate the clinical performance of BD Vacutainer® SST™ Blood Collection Tubes for repeatability (within tube), lot-to-lot reproducibility and tube-to-tube reproducibility for therapeutic drug testing. 25 participants were enrolled. Blood was collected from each participant into eight 10-mL BD Vacutainer® No Additive tubes for a total blood volume of 80 mL. Samples were prepared with spiking material and transferred into the study tubes for centrifuging, handling, and testing. Testing was performed for acetaminophen and vancomycin on the Beckman Coulter DxC 680i and Roche Cobas® 6000.

Precision Summary (%CV) on Beckman Coulter DxC 680i:

Analyte (Unit)	Mean	Variance Component	CV (%)	CV 95% CI
ACET	114.52	Between Lots	0	0%, 0%
		Between Tubes	0	0%, 0%
		Within Tubes	2.8	2.6%, 3.1%
		Total	2.8	2.2%, 3.9%
VANCO	47.094	Between Lots	0.7	0%, 1.9%
		Between Tubes	2.9	2.1%, 3.5%
		Within Tubes	2.5	2.2%, 2.8%
		Total	3.9	3%, 5.4%

Precision Summary (%CV) on Roche cobas® 6000:

Analyte (Unit)	Mean	Variance Component	CV (%)	CV 95% CI
ACET	97.87	Between Lots	0.4	0%, 0.9%
		Between Tubes	0.7	0%, 1.1%
		Within Tubes	1.7	1.5%, 1.9%
		Total	1.9	1.5, 2.7%

Analyte (Unit)	Mean	Variance Component	CV (%)	CV 95% CI
VANCO	49.81	Between Lots	1.8	1%, 2.3%
		Between Tubes	0	0%, 0%
		Within Tubes	2.8	2.6%, 3.1%
		Total	3.3	2.6%, 4.7%

Information was provided to support testing for valproic acid.

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. Assay Reportable Range:

Not applicable.

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

a. Shelf-Life

Real Time stability testing of the BD Vacutainer® SST™ Blood Collection Tubes showed that the candidate device is stable for 10-12 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

Multiple analyte stability studies were conducted to assess the analyte within-tube stability for representative chemistry analytes and certain therapeutic drugs in the BD Vacutainer® SST™ Blood Collection Tubes. Within-tube stability was assessed in the 5.0 mL and 7.5 mL BD Tubes after 18-hour storage at room temperature for Glucose and CO_2 only, and for all other chemistry analytes at 24-hour storage at room temperature. In addition, within-tube stability after 3 days and 7 days of refrigerated storage was assessed for all analytes except Glucose and CO_2. For TDMs, within-tube stability was assessed after 24 and 48 hours storage at room temperature (23-27°C), and also after storage at refrigerated temperature (2-8°C) for an additional 5 days for a total of 7 days of storage. Analyte stability was tested on a minimum of two instrument platforms. The study protocols and acceptance criteria have been reviewed and found to be acceptable. These studies support the following storage instructions included in the device labeling:

Analyte*	Storage Conditions	Analyte Stability
Albumin (ALB) Alkaline Phosphatase (ALKP) Amylase (AMY) Aspartate Aminotransferase (AST) Blood Urea Nitrogen (BUN) Calcium (Ca) Cholesterol (Chol) Creatine Kinase (CK) Creatinine (Creat) Direct Bilirubin (DBIL) Gamma Glutamyltransferase (GGT) High Density Lipoprotein (HDL) Iron (Fe) Lactate Dehydrogenase (LDH) Lipase (Lip) Low Density Lipoprotein (LDL) Magnesium (Mg) Phosphorus (Phos) Potassium (K) Total Bilirubin (TBIL) Total Protein (TP) Triglycerides (Trig) Uric Acid (UA)	Storage at room temperature (23-27 °C) for the first 24 hours, then Refrigerated storage (2-8 °C) for an additional 6 days	7 days
Alanine Aminotransferase (ALT) Sodium (Na)	Storage at room temperature (23-27 °C) for the first 24 hours, then Refrigerated storage (2-8 °C) for an additional 2 days	3 days
Beta Human Chorionic Gonadotropin (BHCG) Chloride (CL) Complement C3 (C3) Cortisol (CORT) C-Reactive Protein (CRP) Creatine Kinase-MB Fraction (CKMB) Estradiol (E2) Ferritin (FERR) Follicle Stimulating Hormone (FSH) Free Thyroxine (Free T4) Free Triiodothyronine (Free T3) Glucose (GLUC) Haptoglobin (HAPT)	Storage at room temperature (23-27 °C)	24 hours

Analyte*	Storage Conditions	Analyte Stability
Immunoglobulin A (IgA) Immunoglobulin G (IgG) Immunoglobulin M (IgM) Luteinizing Hormone (LH) N-terminal Pro B-type Natriuretic Peptide (PBNP) Progesterone (PROG) Prostate Specific Antigen (PSA) Testosterone (TESTOS) Thyroid Stimulating Hormone (TSH) Total Thyroxine (Total T4) Total Triiodothyronine (Total T3) Transferrin (TRF) Troponin I (TnI) (conventional assay) Troponin T (TnT) Vitamin B12 (VIT B12) Vitamin D (VIT D)		
Carbon Dioxide (CO_2)	Storage at room temperature (23-27 °C)	18 hours
Acetaminophen (ACET)	Storage at room temperature (23-27 °C) for the first 48 hours, then Refrigerated storage (2-8 °C) for an additional 5 days	7 days
Valproic Acid (VAL) Vancomycin (VANCO)	Storage at room temperature (23-27 °C)	48 hours

*Based on the results of BD within-tube stability testing, it is recommended that Folate and Troponin I (high sensitivity assay) be tested immediately.

c. Additional bench testing on the candidate device

Benchtop studies were conducted to assess draw volume, X-value, 2nd stopper pullout, stopper/shield separation, stopper leakage, tube leakage, breakage resistance during drop testing, breakage resistance during centrifugation testing, barrier formation and packaging performance during shipping and handling. The study protocols were 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:

   See Clinical Studies in section C.3. below.

2. Matrix Comparison:

   Not applicable. These tubes are for serum only.

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):

   Routine Chemistry Analytes
   A study was conducted to evaluate equivalence between the BD Vacutainer® Serum Separator (SST™) Blood Collection Tubes (5.0 and 7.5 mL) and Greiner Bio-One Vacuette® Z Serum Separator Clot Activator Blood Collection Tubes (5.0 mL and 7.0 mL, respectively) for testing representative chemistry analytes.

   A total of 168 participants were enrolled in the study. Blood was collected from each participant into the required study tubes using standard phlebotomy techniques. In addition, contrived samples were prepared in an effort to obtain results that spanned the analytical measurement range for the tested analytes.

   Samples were tested on two different instrument platforms (Beckman Coulter UniCel DxC AU480 and Roche cobas Integra 400+). For each analyte and tube comparison, data was analyzed using Passing Bablok (PB), Deming (D) or weighted Deming (WD) regression. Biases between tube types were estimated with 95% confidence intervals. Regression analyses for a representative tube using each instrument platform are provided in the tables below.

   Regression Parameter Estimates: Beckman Coulter UniCel DxC AU480, for the comparison 5.0 mL BD SST™ vs. 5.0 mL Greiner Serum

Analyte	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient	Regression
ALB	-0.01 (-0.24, 0.05)	1 (0.98, 1.05)	0.991	PB
ALKP	0 (-1, 1.83)	1 (0.97, 1)	0.999	PB
ALT	0.06 (-0.56, 0.67)	0.99 (0.96, 1.01)	0.999	WD

Analyte	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient	Regression
AMY	0 (-0.05, 1)	1 (1, 1)	0.999	PB
AST	0.02 (-0.59, 0.63)	1 (0.97, 1.03)	1	WD
BUN	-0.1 (-0.1, 0.23)	1 (0.98, 1)	0.998	PB
Ca	0 (-0.1, 0.68)	1 (0.93, 1)	0.974	PB
Chol	0 (-3.03, 2.18)	1 (0.99, 1.02)	0.995	PB
CK	0 (-0.88, 0.94)	1 (0.99, 1.01)	0.999	PB
CL	0 (-1, 10.1)	1 (0.9, 1)	0.986	PB
CO2	-1 (-2.75, 0)	1 (1, 1.1)	0.946	PB
Creat	0.01 (0, 0.04)	1 (0.96, 1)	1	PB
DBIL	0 (0, 0)	0.99 (0.99, 1)	1	D
Fe	0 (-0.84, 1.06)	1 (0.99, 1.01)	0.999	PB
GGT	-0.21 (-0.88, 0.46)	0.99 (0.97, 1.01)	1	WD
GLUC	0.86 (-1, 3.3)	0.99 (0.96, 1)	0.999	PB
HDL	0.44 (-0.64, 1.53)	1 (0.97, 1.02)	0.997	WD
K	-0.1 (-0.1, 0.51)	1 (0.87, 1)	0.845	PB
LDH	-1 (-3.36, 5.9)	1 (0.95, 1.02)	0.987	PB
LDL	0 (-1, 2.23)	1 (0.98, 1.01)	0.991	PB
Lip	0.47 (-1.71, 2.64)	0.99 (0.92, 1.06)	0.996	WD
Mg	-0.13 (-0.22, -0.04)	1.02 (0.98, 1.06)	0.993	D
Na	0 (-1, 1.94)	1 (0.99, 1)	0.99	PB
Phos	0 (-0.1, 0.25)	1 (0.91, 1)	0.988	PB
TBIL	-0.01 (-0.03, 0.01)	1 (0.96, 1.05)	1	WD
TP	0 (-0.1, 0.17)	1 (0.98, 1)	0.982	PB
Trig	0 (-2.42, 0.06)	1 (1, 1.01)	0.999	PB
UA	-0.07 (-0.14, 0.01)	1.02 (1, 1.03)	0.997	WD

PB = Passing Bablok, WD = Weighted Deming, D = Deming

Regression Parameter Estimates: Roche cobas Integra 400+, for the comparison 5.0 mL BD SST™ vs. 5.0 mL Greiner Serum

Analyte	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient	Regression
ALB	-0.01 (-0.16, 0.14)	0.99 (0.96, 1.03)	0.954	WD
ALKP	0.39 (-1.25, 1.9)	1 (0.98, 1.02)	0.998	PB
ALT	0.26 (-0.1, 0.74)	0.98 (0.96, 1)	0.998	PB
AMY	0.13 (-0.51, 0.71)	0.99 (0.98, 1.01)	0.997	PB
AST	0.27 (-0.1, 0.76)	0.99 (0.96, 1)	1	PB
BUN	0.1 (-0.1, 0.38)	0.99 (0.97, 1)	0.996	PB
Ca	0 (-1.5, 0)	1 (1, 1.15)	0.918	PB
Chol	1 (-4.87, 2.24)	1 (0.99, 1.03)	0.995	PB
CK	0.38 (-0.5, 0.82)	1 (0.99, 1.01)	0.983	PB
CL	7.35 (0.96, 15.52)	0.93 (0.85, 0.99)	0.995	PB
CO2	-0.32 (-1.91, 1.1)	1.02 (0.95, 1.09)	0.961	PB
Creat	0 (-0.03, 0)	1 (1, 1.03)	1	PB

Analyte	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient	Regression
DBIL	0 (0, 0)	1 (1, 1.01)	0.999	PB
Fe	0.81 (-0.56, 2.89)	1 (0.97, 1.01)	0.999	PB
GGT	0 (-0.21, 0.27)	1 (0.99, 1.01)	0.999	PB
GLUC	1.14 (-1, 3.85)	0.99 (0.96, 1)	0.998	PB
HDL	0 (-0.77, 0.5)	1 (1, 1.02)	0.992	PB
K	0.18 (-0.04, 0.5)	0.95 (0.87, 1)	0.981	PB
LDH	1.48 (-3.68, 8.42)	0.99 (0.95, 1.02)	0.991	PB
LDL	0 (-1.26, 1.68)	1 (0.99, 1.02)	0.997	PB
Lip	-0.05 (-0.56, 0.39)	1 (0.99, 1.02)	0.999	PB
Mg	-0.1 (-0.1, 0.06)	1 (0.93, 1)	0.96	PB
Na	0.6 (-5.17, 11.41)	1 (0.92, 1.04)	0.995	PB
Phos	-0.1 (-0.1, 0.15)	1 (0.93, 1)	0.989	PB
TBIL	0 (-0.04, 0.01)	1 (0.98, 1.08)	1	PB
TP	0 (0, 0.45)	1 (0.93, 1)	0.986	PB
Trig	0 (-1.42, 0.86)	1 (0.99, 1.01)	0.999	PB
UA	-0.01 (-0.11, 0.09)	0.99 (0.97, 1.02)	0.982	WD

Special Chemistry Analytes and Cardiac Markers (PAS-18SUST028)
A study was conducted to evaluate the equivalence of BD Vacutainer® Serum Separator (SST™) Blood Collection Tubes (5.0 and 7.5 mL) in comparison with Greiner Bio-One Vacuette® Z Serum Separator Clot Activator Blood Collection Tubes (5.0 mL and 7.0 mL, respectively) for testing special chemistry analytes and cardiac markers.

A total of 495 participants were enrolled in the study. Blood was collected from each participant into the required study tubes using standard phlebotomy techniques. In addition, contrived samples were prepared in an effort to cover the analytical measurement range. Testing was initiated within four hours of sample collection.

Samples were tested on at least two different instrument platforms for each analyte tested:

Instrument	Analyte	Abbreviation
3, 4, 6	Beta Human Chorionic Gonadotropin	BHCG
3, 6	C-reactive Protein	CRP
3, 4, 6	Creatine Kinase-MB Fraction	CKMB
3, 6	Complement C3	C3
3, 7	Cortisol	CORT
3, 6	Estradiol	E2
3, 4, 6	Ferritin	FERR
3, 6	Folate	FOLATE
3, 6	Follicle Stimulating Hormone	FSH
3, 4, 6	Free Thyroxine	Free T4
3, 6	Free Triiodothyronine	Free T3
3, 6	Haptoglobin	HAPT
1, 2, 6	High sensitivity Troponin I	hsTnI

Instrument	Analyte	Abbreviation
3, 6	Immunoglobulin A	IgA
3, 6	Immunoglobulin G	IgG
3, 6	Immunoglobulin M	IgM
3, 4, 6	Luteinizing Hormone	LH
3, 6	N-terminal Pro B-type Natriuretic Peptide	PBNP
3, 4, 6	Progesterone	PROG
3, 7	Prostate Specific Antigen	PSA
3, 6	Testosterone	TESTOS
3, 4, 6	Thyroid Stimulating Hormone	TSH
3, 6	Total Thyroxine	Total T4
3, 7	Total Triiodothyronine	Total T3
3, 6	Transferrin	TRF
3, 6	Vitamin B12	VIT B12
3, 4, 7	Vitamin D	VIT D

1 – Beckman Coulter UniCel® DxI 800
2 – Beckman Coulter Access® 2
3 – Ortho Clinical Diagnostics (OCD) Vitros 5600
4 – Roche cobas® e411
5 – Roche cobas® e601
6 – Siemens Dimensions Vista® 1500
7 – Siemens ADVIA Centaur® XP

For each analyte and tube comparison, data was analyzed using Passing Bablok regression or Deming regression (weighted or unweighted). Biases between tube types were estimates with 95% intervals. Regression analyses for a representative tube comparison are provided in the tables below.

Regression Parameters for 5.0 mL BD vs 5.0 mL Greiner Serum

Instrument	Analyte	N	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
OCD Vitros 5600 (Part A)	BHCG	100	0.02 (0.01, 0.04)	0.99 (0.99, 1)	1
Siemens Dimension Vista 1500	BHCG	110	0 (-0.02, 0.02)	0.99 (0.98, 1)	0.996
OCD Vitros 5600 (Part A)	C3	148	-0.57 (-1.63, 0.49)	0.99 (0.98, 1)	0.995
Siemens Dimension Vista 1500	C3	168	0.67 (-1.13, 2.47)	0.96 (0.95, 0.98)	0.979
OCD Vitros 5600 (Part A)	CKMB	132	0.05 (-0.01, 0.1)	1.03 (1, 1.04)	1
Siemens Dimension Vista 1500	CKMB	116	0.01 (-0.06, 0.11)	0.99 (0.99, 1)	1
OCD Vitros 5600 (Part A)	CORT	112	0 (-0.01, 0.01)	1.01 (1, 1.01)	0.999
Siemens ADVIA Centaur XP	CORT	151	-0.03 (-0.17, 0.11)	1.01 (0.99, 1.03)	0.994

Instrument	Analyte	N	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
OCD Vitros 5600 (Part A)	CRP	113	-0.1 (-0.1, -0.08)	1 (0.99, 1)	0.998
Siemens Dimension Vista 1500	CRP	118	0.1 (-0.08, 0.25)	0.98 (0.97, 1)	0.998
OCD Vitros 5600 (Part A)	E2	123	13.35 (10, 17.61)	1.03 (1.01, 1.05)	0.999
Siemens Dimension Vista 1500	E2	133	0.86 (-0.57, 1.78)	0.98 (0.96, 1)	0.981
OCD Vitros 5600 (Part A)	FERR	113	-0.1 (-0.3, 0.1)	1.01 (1, 1.02)	0.999
Siemens Dimension Vista 1500	FERR	116	-0.02 (-0.15, 0.11)	1 (0.99, 1.01)	0.999
OCD Vitros 5600 (Part A)	FOLATE	122	0.2 (-0.03, 0.59)	1 (0.95, 1.04)	0.971
Siemens Dimension Vista 1500	FOLATE	112	0.15 (-0.27, 0.52)	1.02 (0.99, 1.07)	0.982
OCD Vitros 5600 (Part A)	FSH	115	-0.11 (-0.29, 0.07)	0.95 (0.93, 0.97)	0.999
Siemens Dimension Vista 1500	FSH	112	0.02 (-0.03, 0.07)	1 (0.99, 1.01)	1
OCD Vitros 5600 (Part A)	Free T3	123	0.18 (-0.04, 0.41)	0.97 (0.93, 1.01)	0.999
Siemens Dimension Vista 1500	Free T3	127	0.04 (-0.1, 0.17)	1.01 (0.95, 1.06)	0.998
OCD Vitros 5600 (Part A)	Free T4	151	0 (0, 0)	1 (1, 1)	0.998
Siemens Dimension Vista 1500	Free T4	139	0 (0, 0.01)	1 (1, 1)	0.998
OCD Vitros 5600 (Part A)	HAPT	138	0.5 (-1, 2)	1 (0.99, 1.02)	0.997
Siemens Dimension Vista 1500	HAPT	156	0.01 (-0.01, 0.02)	0.98 (0.97, 1)	0.994
Beckman UniCel DxI	hsTnI	110	-0.09 (-0.24, 0.07)	0.98 (0.97, 1)	0.998
Siemens Dimension Vista 1500	hsTnI	116	0.01 (-0.14, 0.22)	1 (0.99, 1.01)	1
OCD Vitros 5600 (Part A)	IgA	121	-2.17 (-4.41, 0.06)	1.02 (1.01, 1.04)	0.996
Siemens Dimension Vista 1500	IgA	148	-0.64 (-2.65, 1.37)	0.99 (0.97, 1)	0.996
OCD Vitros 5600 (Part A)	IgG	130	7.15 (-9.6, 23.9)	1 (0.97, 1.02)	0.99
Siemens Dimension Vista 1500	IgG	162	-7.01 (-18.3, 4.28)	1 (0.99, 1.02)	0.995
OCD Vitros 5600 (Part A)	IgM	118	0.01 (-0.63, 0.66)	1 (0.99, 1.01)	1

Instrument	Analyte	N	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
Siemens Dimension Vista 1500	IgM	146	-1.01 (-2.61, 0.59)	1.01 (0.99, 1.03)	0.999
OCD Vitros 5600 (Part A)	LH	126	-0.07 (-0.13, -0.02)	0.95 (0.94, 0.96)	0.997
Siemens Dimension Vista 1500	LH	125	0 (0, 0.03)	1 (0.99, 1)	0.998
OCD Vitros 5600 (Part A)	PBNP	117	0.97 (0.14, 1.79)	0.98 (0.97, 0.99)	0.998
Siemens Dimension Vista 1500	PBNP	110	0.2 (-0.12, 0.53)	0.99 (0.99, 1)	0.999
OCD Vitros 5600 (Part A)	PROG	117	0.11 (0.08, 0.13)	1.01 (1, 1.01)	0.995
Siemens Dimension Vista 1500	PROG	118	0.06 (0.05, 0.07)	1.01 (1, 1.02)	0.999
OCD Vitros 5600 (Part A)	PSA	124	0 (0, 0)	1 (1, 1)	1
Siemens ADVIA Centaur XP	PSA	103	-0.01 (-0.01, 0.01)	1.01 (1, 1.02)	1
OCD Vitros 5600 (Part A)	T3	140	1.3 (-0.25, 2.84)	1.08 (1.06, 1.09)	0.996
Siemens ADVIA Centaur XP	T3	138	-0.01 (-0.08, 0.07)	1.02 (0.94, 1.09)	0.994
OCD Vitros 5600 (Part A)	T4	140	-0.06 (-0.14, 0.03)	1.01 (1, 1.02)	0.998
Siemens Dimension Vista 1500	T4	139	0.3 (-0.18, 0.5)	1 (0.97, 1.06)	0.979
OCD Vitros 5600 (Part A)	TESTOS	119	3.58 (2.57, 4.52)	1.08 (1.06, 1.1)	0.998
Siemens Dimension Vista 1500	TESTOS	121	0.08 (-0.02, 1.11)	0.99 (0.98, 1)	0.999
Roche Cobas e601	TnT	110	0.06 (-0.26, 0.37)	0.9 7 (0.96, 0.99)	1
OCD Vitros 5600 (Part A)	TRF	147	1.51 (-4.84, 7.87)	1 (0.97, 1.02)	0.997
Siemens Dimension Vista 1500	TRF	161	0.02 (-0.01, 0.05)	0.99 (0.98, 1.01)	0.995
OCD Vitros 5600 (Part A)	TSH	134	-0.01 (-0.03, 0)	0.99 (0.98, 1.01)	1
Siemens Dimension Vista 1500	TSH	158	0.02 (0, 0.04)	0.95 (0.91, 0.99)	0.997
OCD Vitros 5600 (Part A)	VIT B12	126	-9.41 (-14.85, -3.96)	1.05 (1.03, 1.07)	0.993
Siemens Dimension Vista 1500	VIT B12	141	1.14 (-9.5, 11.78)	1 (0.98, 1.02)	0.998
OCD Vitros 5600 (Part A)	VIT D	112	0.75 (-0.61, 1.94)	0.92 (0.9, 0.95)	0.993

Instrument	Analyte	N	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
Siemens ADVIA Centaur XP	VIT D	130	-0.56 (-1.89, 0.38)	0.94 (0.91, 0.99)	0.983

Regression Parameters for 7.5 mL BD vs 7.0 mL Greiner Serum

Instrument	Analyte	Total Pairs	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
OCD Vitros 5600 (Part A)	BHCG	103	0.08 (-0.24, 0.39)	0.99 (0.99, 1)	0.998
Siemens Dimension Vista 1500	BHCG	109	-0.01 (-0.02, 0.01)	1.01 (1, 1.02)	0.996
OCD Vitros 5600 (Part A)	C3	147	0.54 (-0.58, 1.65)	0.98 (0.97, 0.99)	0.994
Siemens Dimension Vista 1500	C3	171	-0.07 (-1.85, 1.71)	0.98 (0.96, 1)	0.98
OCD Vitros 5600 (Part A)	CKMB	134	0.01 (-0.01, 0.1)	1.02 (1, 1.04)	1
Siemens Dimension Vista 1500	CKMB	119	-0.01 (-0.08, 0.1)	1.01 (1, 1.02)	1
OCD Vitros 5600 (Part A)	CORT	114	0.02 (-0.07, 0.11)	1.02 (1, 1.03)	0.999
Siemens ADVIA Centaur XP	CORT	153	0.05 (-0.06, 0.16)	1.01 (1, 1.03)	0.994
OCD Vitros 5600 (Part A)	CRP	116	0 (-0.1, 0)	1 (1, 1.02)	0.999
Siemens Dimension Vista 1500	CRP	120	0.11 (-0.16, 0.3)	1 (0.99, 1.01)	0.999
OCD Vitros 5600 (Part A)	E2	125	17.03 (13.78, 20.37)	1.02 (1.01, 1.04)	0.999
Siemens Dimension Vista 1500	E2	137	1.32 (-0.33, 2.49)	0.98 (0.97, 1)	0.999
OCD Vitros 5600 (Part A)	FERR	114	0.06 (-0.1, 0.23)	1 (0.99, 1.01)	0.999
Siemens Dimension Vista 1500	FERR	117	0.09 (-0.08, 0.27)	1 (0.99, 1)	1
OCD Vitros 5600 (Part A)	FOLATE	125	0 (-0.44, 0.31)	1 (0.96, 1.05)	0.971
Siemens Dimension Vista 1500	FOLATE	118	-0.11 (-0.62, 0.3)	1.03 (0.99, 1.07)	0.986
OCD Vitros 5600 (Part A)	FSH	113	-0.06 (-0.19, 0.06)	0.93 (0.92, 0.95)	0.999
Siemens Dimension Vista 1500	FSH	116	0.08 (0.02, 0.13)	0.99 (0.98, 1)	1
OCD Vitros 5600 (Part A)	Free T3	125	0.28 (0.15, 0.4)	0.96 (0.94, 0.98)	0.997

Instrument	Analyte	Total Pairs	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
Siemens Dimension Vista 1500	Free T3	131	0.04 (0.02, 0.07)	1.02 (1.01, 1.02)	0.998
OCD Vitros 5600 (Part A)	Free T4	151	0 (0, 0)	1 (1, 1)	0.997
Siemens Dimension Vista 1500	Free T4	142	0.01 (-0.02, 0.01)	1 (1, 1.03)	0.998
OCD Vitros 5600 (Part A)	HAPT	139	0.31 (-1.06, 1.67)	1 (0.98, 1.01)	0.995
Siemens Dimension Vista 1500	HAPT	160	-0.01 (-0.03, 0)	1.01 (1, 1.02)	0.996
Beckman UniCel DxI	hsTnI	112	-0.07 (-0.22, 0.04)	0.98 (0.97, 0.99)	1
Siemens Dimension Vista 1500	hsTnI	117	0.01 (-0.11, 0.22)	1 (0.99, 1.01)	1
OCD Vitros 5600 (Part A)	IgA	122	-0.57 (-2.25, 1.12)	1 (0.99, 1.02)	0.998
Siemens Dimension Vista 1500	IgA	151	-2.16 (-5.23, 0.91)	1.01 (0.99, 1.02)	0.997
OCD Vitros 5600 (Part A)	IgG	132	4.14 (-11.86, 20.14)	1 (0.98, 1.01)	0.997
Siemens Dimension Vista 1500	IgG	165	5.29 (-6.53, 17.11)	1 (0.98, 1.01)	0.994
OCD Vitros 5600 (Part A)	IgM	117	0.11 (-0.94, 1.16)	1 (0.98, 1.01)	0.999
Siemens Dimension Vista 1500	IgM	148	0.31 (-1.36, 1.99)	1 (0.97, 1.02)	0.999
OCD Vitros 5600 (Part A)	LH	125	-0.03 (-0.09, 0.03)	0.94 (0.93, 0.95)	0.999
Siemens Dimension Vista 1500	LH	126	-0.01 (-0.03, 0.1)	1 (1, 1.01)	0.999
OCD Vitros 5600 (Part A)	PBNP	118	0.36 (-0.21, 0.94)	0.98 (0.97, 0.99)	0.996
Siemens Dimension Vista 1500	PBNP	111	0.1 (-0.04, 0.23)	1 (0.99, 1)	0.999
OCD Vitros 5600 (Part A)	PROG	119	0.11 (0.07, 0.15)	1.01 (1, 1.02)	0.999
Siemens Dimension Vista 1500	PROG	121	0.09 (0.07, 0.11)	1 (0.99, 1.01)	0.999
OCD Vitros 5600 (Part A)	PSA	125	0 (0, 0)	1 (1, 1)	1
Siemens ADVIA Centaur XP	PSA	102	0 (-0.01, 0.01)	1 (0.99, 1.01)	0.999
OCD Vitros 5600 (Part A)	Total T3	141	1.09 (-0.87, 3.04)	1.06 (1.04, 1.08)	0.997
Siemens ADVIA Centaur XP	Total T3	141	0.02 (-0.05, 0.09)	0.98 (0.92, 1.04)	0.99

Instrument	Analyte	Total Pairs	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
OCD Vitros 5600 (Part A)	Total T4	142	-0.02 (-0.06, 0.01)	1.02 (1.01, 1.02)	0.998
Siemens Dimension Vista 1500	Total T4	142	0.15 (-0.31, 0.51)	1 (0.96, 1.04)	0.98
OCD Vitros 5600 (Part A)	TESTOS	118	3.65 (2.93, 5.17)	1.08 (1.06, 1.1)	0.998
Siemens Dimension Vista 1500	TESTOS	120	0.08 (0, 0.59)	1 (0.99, 1)	0.999
Roche Cobas e601	TnT	112	0.16 (-0.16, 0.48)	0.96 (0.93, 1)	1
OCD Vitros 5600 (Part A)	TRF	147	-0.75 (-3.92, 2.42)	1.01 (0.99, 1.02)	0.997
Siemens Dimension Vista 1500	TRF	165	-0.01 (-0.03, 0.02)	1 (0.99, 1.01)	0.995
OCD Vitros 5600 (Part A)	TSH	136	0 (-0.01, 0)	0.99 (0.99, 1)	1
Siemens Dimension Vista 1500	TSH	161	0 (-0.02, 0.02)	0.98 (0.96, 1.01)	0.999
OCD Vitros 5600 (Part A)	VIT B12	125	-5.28 (-11.39, 0.83)	1.03 (1, 1.05)	0.989
Siemens Dimension Vista 1500	VIT B12	144	4.05 (-6.69, 14.8)	1 (0.98, 1.02)	0.998
OCD Vitros 5600 (Part A)	VIT D	110	-1.1 (-2.2, 0.3)	0.94 (0.89, 0.98)	0.977
Siemens ADVIA Centaur XP	VIT D	132	-0.78 (-2.48, 0.48)	0.95 (0.9, 1.01)	0.987

Therapeutic Drug Monitoring:
A study was conducted to evaluate the equivalence of BD Vacutainer® Serum Separator (SST™) Blood Collection Tubes (5.0 and 7.5 mL) in comparison with Greiner Bio-One Vacuette® Z Serum Separator Clot Activator Blood Collection Tubes (5.0 mL and 7.0 mL, respectively) for therapeutic drugs. The following therapeutic drug assays were tested: Acetaminophen, Valproic acid, and Vancomycin. In addition, contrived samples were prepared in an effort to cover the analytical measurement range. Testing of each drug was performed on the Beckman Coulter DxC 680i and Roche Cobas® 6000. For each analyte and tube comparison, Deming Regression (weighted or unweighted) or Passing-Bablok Regression was used. Representative data is provided below.

Regression Parameters: 7.5 mL BD Serum vs 7.0 mL Greiner Serum

Instrument	Drug	Total Pairs	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
Beckman Coulter DxC 680i	ACET	80	0.07 (-0.52, 0.65)	1 (0.99, 1.01)	0.999
Roche cobas® 6000	ACET	77	0.01 (-0.19, 0.21)	1 (0.99, 1)	0.999
Beckman Coulter DxC 680i	VAL	80	-0.51 (-1.98, 0.63)	1.01 (0.99, 1.03)	0.997

Roche cobas® 6000	VAL	80	0.52 (-0.37, 1.4)	0.99 (0.97, 1)	0.998
Beckman Coulter DxC 680i	VANCO	79	0.08 (-0.21, 0.48)	0.99 (0.97, 1.01)	0.994
Roche cobas® 6000	VANCO	72	0.37 (-0.15, 0.69)	0.98 (0.97, 1)	0.975

Regression Parameters: 7.5 mL BD Serum vs 7.0 mL Greiner Serum

Instrument	Drug	Total Pairs	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
Beckman Coulter DxC 680i	ACET	80	-0.05 (-0.83, 0.73)	0.99 (0.97, 1)	0.999
Roche cobas® 6000	ACET	77	-0.04 (-0.17, 0.09)	1 (0.99, 1)	1
Beckman Coulter DxC 680i	VAL	80	-0.45 (-1.47, 0.6)	1 (0.98, 1.01)	0.998
Roche cobas® 6000	VAL	80	-1.11 (-1.65, -0.57)	1.02 (1, 1.03)	0.996
Beckman Coulter DxC 680i	VANCO	79	0.1 (-0.28, 0.44)	1 (0.98, 1.02)	0.997
Roche cobas® 6000	VANCO	71	-0.04 (-0.47, 0.39)	1 (0.99, 1.02)	0.997

To mitigate the risk of inaccurate test results for hydrophobic drugs, the following statement has been added to the labeling:
"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 Adsorption in the References Section."

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.