



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY**

I Background Information:

A 510(k) Number

K252344

B Applicant

Becton, Dickinson and Company

C Proprietary and Established Names

BD Vacutainer® Serum Blood Collection Tubes; BD Vacutainer® Rapid Serum Tubes (RST)

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® Serum Blood Collection Tubes:

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

BD Vacutainer® Rapid Serum Tubes (RST):

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

C Special Conditions for Use Statement(s):

Rx – For Prescription Use Only

BD Vacutainer® Serum Blood Collection Tubes:

Warning: BD Vacutainer® Serum Blood Collection Tubes should not be used for Potassium (K) testing due to demonstrated variability based on preanalytical factors.

Storage of glass tubes containing blood at or below 0°C may result in tube breakage.

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 serum sample as this could lead to the inability to test the sample.

When serum is required for testing, separation of serum from the clot should take place within 2 hours of collection to prevent potentially erroneous test results.

Whenever changing any manufacturer's blood collection tube type, size, handling, processing or storage condition for a particular laboratory assay, the laboratory personnel should review the tube manufacturer's data and their own data to establish/verify the reference range for a specific instrument/reagent system. Based on such information, the laboratory can then decide if changes are appropriate.

BD Vacutainer® Serum Blood Collection Tubes may contain trace levels of formate and hexane. 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® Serum Blood Collection Tubes with chromatographic assays has not been evaluated.

In clinical studies, when BD Serum Non-Separator tubes were compared to a Serum Separator tube for Potassium testing, the largest observed bias at the Critical Value (CV) of 2.8 mmol/L was a unit bias of -0.483 mmol/L and the largest observed bias at the Critical Value (CV) of 6.2 mmol/L was a unit bias of 0.735 mmol/L. Potassium results may be affected by preanalytical variables associated with prolonged contact between serum and cellular components. These variables include, but are not limited to, delayed centrifugation, specimen agitation, and delayed testing. Because potassium is sensitive to prolonged cellular contact, such conditions can lead to altered potassium measurements.

BD Vacutainer® Rapid Serum Tubes (RST):

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 serum sample as this could lead to the inability to test the sample.

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

Whenever changing any manufacturer's blood collection tube type, size, handling, processing or storage condition for a particular laboratory assay, the laboratory personnel should review the tube manufacturer's data and their own data to establish/verify the reference range for a specific instrument/reagent system. Based on such information, the laboratory can then decide if changes are appropriate.

The performance of BD Vacutainer® RST™ Tubes with chromatographic assays has not been evaluated.

BD Vacutainer® RST™ Blood Collection Tubes are not recommended for amino acid determinations.

Therapeutic drug monitoring (TDM), blood banking, and infectious disease performance have not been established.

Clot time has not been established for patients on heparin therapy, direct thrombin inhibitor therapy or with Factor I deficiency. As a result, the use of the BD Vacutainer® RST™ Tube in these patients is not recommended.

The flow properties of the barrier material are temperature-related. Centrifuge the tubes between 23°C and 27°C (73-81°F).

Tubes should not be re-centrifuged once barrier has formed.

D Special Instrument Requirements:

Not applicable.

IV Device/System Characteristics:

A Device Description:

BD Vacutainer® Serum Blood Collection Tubes are plastic or glass, evacuated, sterile, single-use in vitro diagnostic medical devices. The tube is comprised of either plastic or glass coated with a silicone surfactant. Depending on configuration, the tube utilizes either a conventional rubber stopper or Hemogard cap assembly. The interior walls of BD Vacutainer® Serum plastic tubes are spray coated with a silica clot activator, to promote specimen clotting. The tubes are available in 13x75mm, 13x100mm and 16x100mm configurations with draw volumes ranging from 3.0 to 10 mL.

BD Vacutainer® Rapid Serum Tubes (RST) are plastic, evacuated, single-use, in vitro diagnostic medical devices. The tube is comprised of a plastic tube coated with a silicone surfactant and utilizes a Hemogard cap assembly. The interior of the tube wall is coated with thrombin to promote rapid clotting. The tube contains an inert gel barrier polymer at the bottom. During centrifugation, this material moves upward to the serum-clot interface, forming a barrier that separates serum from the clot. The tubes are available in a 13x100mm configuration with draw volume of 5.0 mL.

B Principle of Operation:

The BD Vacutainer® Serum Blood Collection Tubes utilize vacuum-assisted blood collection combined with clot formation to collect and process blood samples. The tubes are comprised of a sterile, glass or plastic tube that contains a silica clot activator to promote clot formation. When the tube is connected to a needle inserted into a vein, the internal vacuum creates a pressure difference that automatically draws a specific volume of blood. Once filled, the tubes are gently inverted 5 to 6 times then kept in an upright orientation for at least 60 minutes to allow for clotting.

BD Vacutainer® Rapid Serum Tubes use thrombin to reduce the time required to clot the samples. Once filled, the tubes are gently inverted 5 to 6 times then kept in an upright orientation for at least 5 minutes to allow for clotting.

Both tube types are designed to undergo centrifugation following clot formation, to separate serum from red blood cells and other cellular components, enabling downstream testing. The BD RST additionally contains an inert gel separator that migrates to the serum-clot interface during centrifugation, forming a mechanical barrier that isolates the serum from the clot. The recommended centrifugation conditions are:

Serum tube: 1,300 RCF (relative centrifugal force or g) for 10 minutes

RST tube: 1500 RCF for 10 minutes or 2,000 RCF for 5 min or 4,000 RCF for 3 min.

The tubes are compatible with BD Vacutainer® Serum Blood Collection Needles, Blood Collection Sets, Transfer Devices, Holders, and Adapters.

V Substantial Equivalence Information:

A Predicate Device Name(s):

BD Vacutainer® Brand PLUS (Plastic) Serum and SST® Serum Separator Blood Collection Tubes, BD Vacutainer® Rapid Serum Tube Blood Collection Tube with Hemogard™ Closure

B Predicate 510(k) Number(s):

K960250, K101502,

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K252344</u>	<u>K960250</u>
Device Trade Name	BD Vacutainer® Serum Blood Collection Tubes	BD Vacutainer® Brand PLUS (Plastic) Serum and SST® Serum Separator Blood Collection Tubes
General Device Characteristic Similarities		
Intended Use	Used by trained healthcare professionals for the collection, containment and transport of human venous blood specimens, and the subsequent separation and storage of serum for in vitro diagnostic testing of chemistry analytes.	Same
Tube Dimension	13 x 75 mm, 13 x 100 mm 16 x 100 mm	Same
Sample Type	Serum	Same
Additive Type	Silica Clot Activator	Same
Tube Material	PET (polyethylene terephthalate) plastic or Soda Lime Glass	Same
Sterilization Method	Gamma Irradiation	Same

Device & Predicate Device(s):	<u>K252344</u>	<u>K960250</u>
General Device Characteristic Differences		
Tube Draw Volumes	3.0mL, 4.0mL, 5.0mL, 6.0mL, and 10.0mL	3.5mL – 10.0mL
Labeling warning against potassium testing	Yes	No

Device & Predicate Device(s):	<u>K252344</u>	<u>K101502</u>
Device Trade Name	BD Vacutainer® Rapid Serum Tubes (RST)	BD Vacutainer® Rapid Serum Tube Blood Collection Tube with Hemogard™ Closure
General Device Characteristic Similarities		
Intended Use/Indications For Use	Used by trained healthcare professionals for the collection, containment and transport of human venous blood specimens, and the subsequent separation of serum for in vitro diagnostic testing of chemistry analytes.	Same
Sample Type	Serum	Same
Additive Type	Thrombin Clot activator	Same
Separator gel	Polyacrylic gel	Same
Tube Material	PET (polyethylene terephthalate) plastic	Same
Sterilization Method	Gamma Irradiation	Same
Tube Dimension	13 x 100 mm	Same
Tube Draw Volumes	5mL	Same
General Device Characteristic Differences		
Shelf Life	15 months	12 months

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 11137-2:2013/(R)2019 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose.

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.

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

ISO 14971: 2019-12 Medical devices-Application of risk management to medical devices

ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products.

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	hsTnI	High Sensitivity Troponin I
ALKP	Alkaline Phosphatase	IgA	Immunoglobulin A
ALT	Alanine Aminotransferase	IgG	Immunoglobulin G
AMY	Amylase	IgM	Immunoglobulin M
AST	Aspartate Aminotransferase	K	Potassium
BUN	Blood Urea Nitrogen	LDH	Lactate Dehydrogenase
C3	Complement Component 3	LDL	Low-Density Lipoprotein
Ca	Calcium	LH	Luteinizing Hormone
Chol	Cholesterol	Lip	Lipase
CK	Creatine Kinase	Mg	Magnesium
CKMB	Creatine Kinase-MB	Na	Sodium
CL	Chloride	NT-proBNP	N-Terminal Pro B-Type Natriuretic Peptide
CO ₂	Carbon Dioxide	Phos	Phosphorus
CORT	Cortisol	PROG	Progesterone
Creat	Creatinine	RF	Rheumatoid Factor
CRP	C-Reactive Protein	TBIL	Total Bilirubin

Abbreviation	Analyte	Abbreviation	Analyte
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
HAPTO	Haptoglobin	UA	Uric Acid
HCG	B-Human Chorionic Gonadotropin	Vit B12	Vitamin B12
HDL	High-Density Lipoprotein	Vit D	Vitamin D

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® Serum Plastic Blood Collection Tubes, BD Vacutainer® Serum Glass Blood Collection Tubes and BD Vacutainer® RST Blood Collection Tubes for select routine and specialty chemistry analytes. Testing of select analytes was conducted across the following instruments: Roche cobas® Integra 400 Plus, Beckman Coulter AU480, Roche cobas e411, Beckman Coulter Access 2, Siemens Atellica and Roche cobas 6000.

BD Vacutainer® Serum Plastic Blood Collection Tubes

Blood was collected from each subject (n=55) into 6 BD Vacutainer® Serum Plastic Tubes. Specimens were tested with 2 tubes per lot across 3 lots on 2 instrument platforms for the following select routine and special chemistry analytes: ALT, C3, Ca, CL, CORT, GLUC, IgG, LDH, Phos, Free T4, Total T4, TBIL, TESTO, TP, TPSA and Trig. Contrived samples (less than 15%) were also used to cover the clinically relevant 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:

Test System	Analyte (Unit)	Mean	Variance Component	SD	SD 95% CI	CV (%)	CV 95% CI
Beckman Coulter AU480	ALT (U/L)	20.4	Between Lots	0.3	0.2, 0.3	0.9%	0.8%, 1.1%
			Between Tubes	0.7	0.6, 0.8	3.4%	2.5%, 4.2%
			Within Tubes	0.5	0.4, 0.6	3.2%	2.8%, 3.8%
			Total	0.9	0.7, 1.2	4.8%	3.9%, 6.2%
	ALT (U/L)	20.55	Between Lots	0.1	0.09, 0.12	2.2%	1.9%, 2.6%
			Between Tubes	0.81	0.63, 0.96	0.4%	0%, 2.5%

Test System	Analyte (Unit)	Mean	Variance Component	SD	SD 95% CI	CV (%)	CV 95% CI
Roche cobas Integra 400 Plus			Within Tubes	0.58	0.51, 0.69	4.5%	3.9%, 5.3%
			Total	1.01	0.81, 1.32	5%	4.1%, 6.6%
Roche cobas Integra 400 Plus	C3 (mg/dL)	143.3	Between Lots	1.7	1.5, 2	1.2%	1%, 1.4%
			Between Tubes	1.1	0, 1.7	0.5%	0%, 0.9%
			Within Tubes	2.1	1.8, 2.5	1.5%	1.3%, 1.7%
			Total	2.9	2.4, 3.8	1.9%	1.6%, 2.5%
Roche cobas Integra 400 Plus	C3 (mg/dL)	135.91	Between Lots	1.27	1.09, 1.53	0.9%	0.8%, 1%
			Between Tubes	1.63	1.06, 2.05	0.9%	0.2%, 1.3%
			Within Tubes	1.79	1.56, 2.11	1.4%	1.2%, 1.7%
			Total	2.74	2.22, 3.58	1.9%	1.6%, 2.5%
Beckman Coulter AU480	Ca (mg/dL)	9.19	Between Lots	0.04	0.04, 0.05	0.5%	0.4%, 0.6%
			Between Tubes	0	0, 0	0%	0%, 0%
			Within Tubes	0.11	0.09, 0.13	1.2%	1%, 1.4%
			Total	0.12	0.09, 0.15	1.2%	1%, 1.6%
Roche cobas Integra 400 Plus	Ca (mg/dL)	9.569	Between Lots	0.014	0.012, 0.016	0.2%	0.1%, 0.2%
			Between Tubes	0.122	0.088, 0.148	1.2%	0.8%, 1.5%
			Within Tubes	0.114	0.099, 0.133	1.3%	1.1%, 1.5%
			Total	0.167	0.136, 0.218	1.8%	1.4%, 2.3%
Beckman Coulter AU480	CL (mmol/L)	99.1	Between Lots	0.3	0.2, 0.3	0.2%	0.2%, 0.3%
			Between Tubes	0.7	0.5, 0.9	0.7%	0.5%, 0.9%
			Within Tubes	0.7	0.6, 0.8	0.7%	0.6%, 0.8%
			Total	1	0.8, 1.4	1%	0.8%, 1.3%
Roche cobas Integra 400 Plus	CL (mmol/L)	98.01	Between Lots	0.46	0.39, 0.55	0.4%	0.4%, 0.5%
			Between Tubes	0.16	0, 0.36	0.1%	0%, 0.4%
			Within Tubes	0.6	0.52, 0.7	0.6%	0.5%, 0.7%
			Total	0.77	0.62, 1.01	0.8%	0.6%, 1%
Beckman Coulter AU480	CORT (µg/dL)	9.814	Between Lots	0.02	0.017, 0.024	1%	0.9%, 1.2%
			Between Tubes	0.157	0, 0.249	0%	0%, 0%
			Within Tubes	0.347	0.303, 0.404	3.6%	3.2%, 4.2%
			Total	0.381	0.309, 0.495	3.8%	3.1%, 4.9%
Roche cobas e411	CORT (µg/dL)	9.173	Between Lots	0.016	0.014, 0.02	0.5%	0.4%, 0.6%
			Between Tubes	0	0, 0	0%	0%, 0%
			Within Tubes	0.267	0.233, 0.312	2.5%	2.2%, 3%
			Total	0.267	0.216, 0.35	2.6%	2.1%, 3.4%
Beckman Coulter AU480	Free T4 (ng/dL)	0.912	Between Lots	0.012	0.01, 0.014	1.4 %	1.2%, 1.7%
			Between Tubes	0.009	0, 0.016	0 %	0%, 0%
			Within Tubes	0.025	0.022, 0.029	3.1%	2.7%, 3.5%
			Total	0.03	0.024, 0.038	3.4%	2.7%, 4.3%
Roche cobas e411	Free T4 (ng/dL)	1.2481	Between Lots	0.0127	0.011, 0.0152	0.7%	0.6%, 0.8%
			Between Tubes	0	0, 0	0 %	0%, 0%
			Within Tubes	0.0407	0.0356, 0.0474	3 %	2.6%, 3.5%
			Total	0.0426	0.0347, 0.0551	3.1%	2.5%, 4%

Test System	Analyte (Unit)	Mean	Variance Component	SD	SD 95% CI	CV (%)	CV 95% CI
Beckman Coulter AU480	GLUC (mg/dL)	129.8	Between Lots	0.7	0.6, 0.8	0%	0%, 0%
			Between Tubes	1.8	1.3, 2.2	1.8%	1.5%, 2.2%
			Within Tubes	1.7	1.5, 2	1.1%	1%, 1.3%
			Total	2.6	2.1, 3.4	2.2%	1.8%, 2.8%
Roche cobas Integra 400 Plus	GLUC (mg/dL)	126.2	Between Lots	0.7	0.6, 0.8	0.6%	0.5%, 0.8%
			Between Tubes	0.8	0, 1.6	1.7%	1.2%, 2%
			Within Tubes	2.7	2.3, 3.1	1.6%	1.4%, 1.9%
			Total	2.8	2.3, 3.7	2.4%	2%, 3.1%
Beckman Coulter AU480	IgG (mg/dL)	1121.898	Between Lots	28.203	24.255, 33.7	2.2%	1.9%, 2.7%
			Between Tubes	0	0, 0	0%	0%, 0%
			Within Tubes	15.201	13.268, 17.799	1.2%	1.1%, 1.4%
			Total	32.039	26.031, 41.679	2.5%	2.1%, 3.3%
Roche cobas Integra 400 Plus	IgG (mg/dL)	1184.05	Between Lots	11.89	10.22, 14.21	1%	0.8%, 1.2%
			Between Tubes	0	0, 0	0%	0%, 0%
			Within Tubes	17.9	15.62, 20.96	1.6%	1.4%, 1.9%
			Total	21.49	17.44, 28	1.9%	1.5%, 2.5%
Beckman Coulter AU480	LDH (U/L)	149.5	Between Lots	0	0.0	0%	0%, 0%
			Between Tubes	10.4	8.7, 11.9	6.8%	5.7%, 7.7%
			Within Tubes	2	1.7, 2.3	1.2%	1%, 1.4%
			Total	10.6	8.6, 13.8	6.9%	5.6%, 8.9%
Roche cobas Integra 400 Plus	LDH (U/L)	167.55	Between Lots	0	0, 0	0%	0%, 0%
			Between Tubes	6.85	4.51, 8.58	4%	2.6%, 5%
			Within Tubes	7.05	6.06, 8.42	4.2%	3.6%, 5%
			Total	9.83	7.96, 12.86	5.8%	4.7%, 7.5%
Beckman Coulter AU480	Phos (mg/dL)	3.48	Between Lots	0.04	0.03, 0.04	1%	0.8%, 1.2%
			Between Tubes	0.07	0.06, 0.09	1.6%	1.1%, 2%
			Within Tubes	0.05	0.04, 0.06	1.8%	1.5%, 2.1%
			Total	0.1	0.08, 0.12	2.6%	2.1%, 3.4%
Roche cobas® Integra 400 Plus	Phos (mg/dL)	3.15	Between Lots	0.03	0.03, 0.04	0.9%	0.8%, 1.1%
			Between Tubes	0.05	0.03, 0.06	1.4%	0.6%, 1.9%
			Within Tubes	0.06	0.05, 0.07	2.1%	1.8%, 2.4%
			Total	0.08	0.07, 0.11	2.7%	2.2%, 3.5%
Beckman Coulter AU480	TBIL (mg/dL)	1.22	Between Lots	0.01	0.01, 0.01	0.9%	0.8%, 1.1%
			Between Tubes	0	0, 0.02	5.7%	4.7%, 6.5%
			Within Tubes	0.03	0.02, 0.03	1.9%	1.6%, 2.2%
			Total	0.03	0.03, 0.04	6%	4.9%, 8%
Roche cobas Integra 400 Plus	TBIL (mg/dL)	1.24	Between Lots	0.026	0.022, 0.032	4.3%	3.6%, 5.1%
			Between Tubes	0.055	0.043, 0.064	5%	2.6%, 6.6%
			Within Tubes	0.029	0.025, 0.035	6.3%	5.4%, 7.5%
			Total	0.067	0.054, 0.09	9.1%	7.3%, 12.1%
Beckman Coulter AU480	TESTO (ng/dL)	2.565	Between Lots	0.055	0.047, 0.067	2.1 %	1.8%, 2.6%
			Between Tubes	0	0., 0	2.7 %	1.8%, 3.4%
			Within Tubes	0.093	0.08, 0.11	2.7 %	2.4%, 3.3%

Test System	Analyte (Unit)	Mean	Variance Component	SD	SD 95% CI	CV (%)	CV 95% CI
			Total	0.108	0.086, 0.144	4.4 %	3.5%, 5.9%
Roche cobas e411	TESTO (ng/dL)	3.4577	Between Lots	0.0625	0.0513, 0.08	1.5 %	1.3%, 2%
			Between Tubes	0	0, 0	0 %	0%, 0%
			Within Tubes	0.1005	0.0864, 0.1201	2.4 %	2.1%, 2.9%
			Total	0.1184	0.0901, 0.1725	2.8 %	2.2%, 4.2%
Beckman Coulter AU480	Total T4 (µg/dL)	9.872	Between Lots	0.171	0.147, 0.204	1.7%	1.5%, 2%
			Between Tubes	0.221	0, 0.334	1.4%	0%, 2.5%
			Within Tubes	0.443	0.388, 0.516	3.7%	3.3%, 4.4%
			Total	0.524	0.426, 0.679	4.4%	3.5%, 5.7%
Roche cobas e411	Total T4 (µg/dL)	7.994	Between Lots	0.075	0.065, 0.09	0.9%	0.8%, 1.1%
			Between Tubes	0	0, 0	0 %	0%, 0%
			Within Tubes	0.222	0.194, 0.26	2.8 %	2.5%, 3.3%
			Total	0.234	0.19, 0.306	3 %	2.4%, 3.9%
Beckman Coulter AU480	TP (g/dL)	7.08	Between Lots	0.06	0.05, 0.07	0.8%	0.7%, 0.9%
			Between Tubes	0.04	0.02, 0.05	0.5%	0%, 0.7%
			Within Tubes	0.06	0.05, 0.07	0.9%	0.8%, 1%
			Total	0.09	0.07, 0.12	1.3%	1%, 1.6%
Roche cobas Integra 400 Plus	TP (g/dL)	6.83	Between Lots	0.04	0.03, 0.05	0.6%	0.5%, 0.7%
			Between Tubes	0.08	0.05, 0.09	0.9%	0.4%, 1.2%
			Within Tubes	0.08	0.07, 0.1	1.3%	1.1%, 1.5%
			Total	0.12	0.1, 0.16	1.6%	1.3%, 2.1%
Beckman Coulter AU480	TPSA (ng/mL)	3.578	Between Lots	0	0.0	2.9%	2.4%, 3.7%
			Between Tubes	0.047	0, 0.094	1.3%	0%, 2.1%
			Within Tubes	0.147	0.128, 0.173	2.9%	2.6%, 3.4%
			Total	0.155	0.119, 0.221	4.3%	3.3%, 6.2%
Roche cobas® e411	TPSA (ng/mL)	3.9024	Between Lots	0.0262	0.0216, 0.0332	1.4%	1.1%, 1.8%
			Between Tubes	0	0, 0	0%	0%, 0%
			Within Tubes	0.1367	0.1187, 0.1612	2%	1.7%, 2.4%
			Total	0.1392	0.1065, 0.2008	2.4%	1.9%, 3.5%
Beckman Coulter AU480	Trig (mg/dL)	187.4	Between Lots	1.9	1.6, 2.3	1.1 %	1%, 1.4%
			Between Tubes	1.7	0, 2.6	1.6 %	1.2%, 2%
			Within Tubes	3.2	2.3, 3.9	1.2 %	1.1%, 1.5%
			Total	4.1	3.3, 5.5	2.4 %	1.9%, 3.1%
Roche cobas Integra 400 Plus	Trig (mg/dL)	186.2	Between Lots	1.8	1.5, 2.1	0 %	0%, 0%
			Between Tubes	5.7	4.5, 6.7	4.4 %	3.6%, 5.2%
			Within Tubes	3.4	2.9, 4.1	2.2 %	1.9%, 2.6%
			Total	6.8	5.5, 9.1	5 %	4%, 6.6%

BD Vacutainer® Serum Glass Blood Collection Tubes

Blood was collected from each subject (n=39) into 6 BD Vacutainer® Serum Glass tubes.

Specimens were tested in duplicate per tube with 2 tubes per lot across 3 lots on two instrument platforms (except for C3) for the following select routine and special chemistry analytes: ALT, C3, Ca, CL, CORT, GLUC, IgG, K, LDH, Phos, Free T4, Total T4, TBIL, TESTO, TP, TPSA and Trig. Contrived samples (less than 15%) were also used to cover the clinically relevant 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:

Test System	Analyte (Unit)	Mean	Variance Component	SD	SD 95% CI	CV (%)	CV 95% CI
Siemens Atellica	ALT (U/L)	36.2	Between Lots	0.5	0.4, 0.6	1.4%	1.2%, 1.7%
			Between Tubes	0.2	0, 0.4	0.0%	0.0%, 0.0%
			Within Tubes	0.6	0.6, 0.7	2.6%	2.4%, 2.9%
			Total	0.8	0.7, 1.1	3.0%	2.4%, 3.9%
Roche cobas 6000	ALT (U/L)	31	Between Lots	0.4	0.4, 0.5	1.5%	1.3%, 1.8%
			Between Tubes	0.2	0.1, 0.3	0.9%	0.4%, 1.2%
			Within Tubes	0.4	0.4, 0.4	1.6%	1.5%, 1.8%
			Total	0.6	0.5, 0.9	2.4%	1.9%, 3.1%
Roche cobas 6000	C3 (mg/dL)	136.2	Between Lots	1.8	1.6, 2.2	1.3%	1.1%, 1.6%
			Between Tubes	1.4	1.1, 1.7	1.0%	0.8%, 1.3%
			Within Tubes	1.6	1.5, 1.8	1.2%	1.1%, 1.3%
			Total	2.9	2.3, 3.7	2.1%	1.7%, 2.7%
Siemens Atellica	Ca (mg/dL)	9.56	Between Lots	0.04	0.03, 0.04	0.4%	0.3%, 0.4%
			Between Tubes	0.04	0.01, 0.06	0.5%	0.2%, 0.7%
			Within Tubes	0.09	0.08, 0.1	1.0%	0.9%, 1.1%
			Total	0.11	0.09, 0.14	1.1%	0.9%, 1.4%
Roche cobas 6000	Ca (mg/dL)	9.47	Between Lots	0.04	0.03, 0.04	0.4%	0.3%, 0.5%
			Between Tubes	0.04	0.01, 0.05	0.4%	0.2%, 0.6%
			Within Tubes	0.08	0.07, 0.08	0.8%	0.7%, 0.9%
			Total	0.09	0.07, 0.12	1.0%	0.8%, 1.3%
Siemens Atellica	CL (mmol/L)	103.89	Between Lots	0.21	0.18, 0.25	0.2%	0.2%, 0.2%
			Between Tubes	0.22	0.11, 0.3	0.2%	0.1%, 0.3%
			Within Tubes	0.39	0.36, 0.44	0.4%	0.3%, 0.4%
			Total	0.5	0.41, 0.65	0.5%	0.4%, 0.6%
Roche cobas 6000	CL (mmol/L)	102.7	Between Lots	0.21	0.18, 0.25	0.2%	0.2%, 0.2%
			Between Tubes	0	0.0	0.0%	0.0%, 0.0%
			Within Tubes	0.57	0.52, 0.63	0.6%	0.5%, 0.6%
			Total	0.61	0.5, 0.78	0.6%	0.5%, 0.8%
Siemens Atellica	CORT (µg/dL)	11.653	Between Lots	0.566	0.486, 0.678	4.2%	3.6%, 5.0%
			Between Tubes	0.331	0.265, 0.386	2.6%	2.1%, 3.0%
			Within Tubes	0.26	0.237, 0.288	2.0%	1.8%, 2.2%
			Total	0.705	0.573, 0.917	5.3%	4.3%, 6.9%
Roche cobas 6000	CORT (µg/dL)	12.826	Between Lots	0.536	0.46, 0.642	3.6%	3.1%, 4.3%
			Between Tubes	0.339	0.262, 0.402	1.9%	1.4%, 2.3%
			Within Tubes	0.321	0.293, 0.355	2.1%	1.9%, 2.3%
			Total	0.711	0.576, 0.928	4.6%	3.7%, 6.0%
Siemens Atellica	Free T4 (ng/dL)	1.178	Between Lots	0.017	0.014, 0.02	1.6%	1.3%, 1.9%
			Between Tubes	0.015	0.01, 0.019	1.2%	0.8%, 1.5%

Test System	Analyte (Unit)	Mean	Variance Component	SD	SD 95% CI	CV (%)	CV 95% CI
			Within Tubes	0.02	0.018, 0.022	1.7%	1.6%, 1.9%
			Total	0.03	0.025, 0.039	2.6%	2.2%, 3.4%
Roche cobas 6000	Free T4 (ng/dL)	1.2651	Between Lots	0.0072	0.0062, 0.0087	0.6%	0.5%, 0.7%
			Between Tubes	0	0.0	0.0%	0.0%, 0.0%
			Within Tubes	0.0207	0.0189, 0.0228	1.6%	1.5%, 1.8%
			Total	0.0219	0.0177, 0.0285	1.7%	1.4%, 2.2%
Siemens Atellica	GLUC (mg/dL)	89.2	Between Lots	2.4	2, 2.8	3.4%	2.9%, 4.1%
			Between Tubes	1.6	1.3, 1.8	1.8%	1.5%, 2.0%
			Within Tubes	0.5	0.5, 0.6	0.6%	0.5%, 0.6%
			Total	2.9	2.3, 3.7	3.9%	3.2%, 5.0%
Roche cobas 6000	GLUC (mg/dL)	90.8	Between Lots	2.6	2.2, 3.1	3.6%	3.1%, 4.3%
			Between Tubes	1.6	1.3, 1.8	1.7%	1.4%, 2.0%
			Within Tubes	1	0.9, 1.1	1.1%	1.0%, 1.2%
			Total	3.2	2.6, 4.2	4.2%	3.4%, 5.4%
Siemens Atellica	IgG (mg/dL)	1141.5	Between Lots	19.2	16.5, 23	1.4%	1.2%, 1.6%
			Between Tubes	16.4	12.5, 19.5	1.3%	0.9%, 1.5%
			Within Tubes	16.1	14.7, 17.8	1.4%	1.3%, 1.6%
			Total	30	24.3, 39.1	2.3%	1.9%, 3.1%
Roche cobas 6000	IgG (mg/dL)	1136.6	Between Lots	15.1	12.9, 18	1.1%	1.0%, 1.3%
			Between Tubes	14.5	10.5, 17.6	1.0%	0.7%, 1.3%
			Within Tubes	17.1	15.6, 18.9	1.4%	1.3%, 1.6%
			Total	27	21.9, 35.3	2.1%	1.7%, 2.7%
Siemens Atellica	LDH (U/L)	182.5	Between Lots	6	5.1, 7.1	3.2%	2.7%, 3.8%
			Between Tubes	4.8	4.1, 5.4	2.7%	2.3%, 3.0%
			Within Tubes	1.3	1.2, 1.4	0.7%	0.6%, 0.8%
			Total	7.8	6.3, 10	4.2%	3.4%, 5.4%
Roche cobas 6000	LDH (U/L)	190.4	Between Lots	5.9	5.1, 7.1	3.0%	2.6%, 3.6%
			Between Tubes	4.7	3.9, 5.4	2.5%	2.1%, 2.9%
			Within Tubes	2.5	2.3, 2.8	1.3%	1.2%, 1.4%
			Total	7.9	6.5, 10.3	4.2%	3.4%, 5.4%
Siemens Atellica	Phos (mg/dL)	3.27	Between Lots	0.01	0.01, 0.02	0.4%	0.3%, 0.4%
			Between Tubes	0.02	0.01, 0.03	0.7%	0.3%, 0.9%
			Within Tubes	0.04	0.04, 0.04	1.3%	1.2%, 1.4%
			Total	0.05	0.04, 0.06	1.5%	1.2%, 2.0%
Roche cobas 6000	Phos (mg/dL)	3.2	Between Lots	0.02	0.02, 0.03	0.7%	0.6%, 0.8%
			Between Tubes	0.02	0.01, 0.03	0.7%	0.1%, 0.9%
			Within Tubes	0.04	0.04, 0.05	1.4%	1.3%, 1.6%
			Total	0.05	0.04, 0.07	1.7%	1.4%, 2.2%
Siemens Atellica	TBIL (mg/dL)	0.7702	Between Lots	0.0114	0.0098, 0.0137	1.4%	1.2%, 1.7%
			Between Tubes	0.008	0.0066, 0.0092	1.0%	0.8%, 1.2%

Test System	Analyte (Unit)	Mean	Variance Component	SD	SD 95% CI	CV (%)	CV 95% CI
			Within Tubes	0.0047	0.0043, 0.0052	0.7%	0.6%, 0.7%
			Total	0.0147	0.0119, 0.0193	1.9%	1.5%, 2.4%
Roche cobas 6000	TBIL (mg/dL)	0.59	Between Lots	0	0, 0	0.6%	0.5%, 0.7%
			Between Tubes	0.01	0, 0.02	1.9%	0.0%, 3.1%
			Within Tubes	0.03	0.03, 0.03	5.5%	5.0%, 6.1%
			Total	0.03	0.03, 0.04	5.9%	4.8%, 7.7%
Siemens Atellica	TESTO (ng/dL)	331.538	Between Lots	6.612	5.675, 7.922	2.0%	1.8%, 2.5%
			Between Tubes	5.46	3.308, 6.977	2.0%	1.5%, 2.4%
			Within Tubes	8.343	7.614, 9.228	2.0%	1.8%, 2.2%
			Total	11.964	9.681, 15.666	3.5%	2.8%, 4.6%
Roche cobas 6000	TESTO (ng/dL)	353.437	Between Lots	6.456	5.541, 7.736	3.5%	3.0%, 4.2%
			Between Tubes	2.984	0, 5.244	0.0%	0.0%, 0.0%
			Within Tubes	9.983	9.112, 11.038	5.9%	5.4%, 6.6%
			Total	12.257	9.918, 16.051	6.9%	5.6%, 9.1%
Siemens Atellica	Total T4 (µg/dL)	7.57	Between Lots	0.09	0.08, 0.11	1.4%	1.2%, 1.7%
			Between Tubes	0.11	0.05, 0.14	1.4%	0.7%, 1.9%
			Within Tubes	0.19	0.17, 0.21	2.6%	2.4%, 2.9%
			Total	0.23	0.19, 0.3	3.3%	2.7%, 4.2%
Roche cobas 6000	Total T4 (µg/dL)	7.324	Between Lots	0.036	0.031, 0.043	0.5%	0.4%, 0.6%
			Between Tubes	0.054	0, 0.087	0.8%	0.0%, 1.3%
			Within Tubes	0.157	0.143, 0.173	2.1%	1.9%, 2.4%
			Total	0.17	0.138, 0.22	2.3%	1.9%, 3.0%
Siemens Atellica	TP (g/dL)	7.43	Between Lots	0.09	0.08, 0.11	1.2%	1.1%, 1.5%
			Between Tubes	0.07	0.06, 0.08	1.0%	0.8%, 1.1%
			Within Tubes	0.03	0.03, 0.04	0.4%	0.4%, 0.5%
			Total	0.12	0.1, 0.16	1.6%	1.3%, 2.1%
Roche cobas 6000	TP (g/dL)	7.5	Between Lots	0.1	0.08, 0.11	1.3%	1.1%, 1.5%
			Between Tubes	0.06	0.04, 0.08	0.8%	0.4%, 1.0%
			Within Tubes	0.09	0.08, 0.1	1.2%	1.1%, 1.3%
			Total	0.14	0.12, 0.18	1.9%	1.6%, 2.4%
Siemens Atellica	TPSA (ng/mL)	2.083	Between Lots	0.055	0.046, 0.066	3.2%	2.7%, 3.8%
			Between Tubes	0.027	0.017, 0.035	4.1%	3.2%, 4.8%
			Within Tubes	0.037	0.033, 0.041	3.0%	2.7%, 3.4%
			Total	0.071	0.057, 0.095	6.0%	4.8%, 8.0%
Roche cobas 6000	TPSA (ng/mL)	2.997	Between Lots	0.0348	0.0292, 0.043	1.2%	1.0%, 1.5%
			Between Tubes	0.0159	0, 0.0342	0.3%	0.0%, 0.9%
			Within Tubes	0.0664	0.0598, 0.0747	1.9%	1.8%, 2.2%
			Total	0.0767	0.0601, 0.1058	2.3%	1.8%, 3.2%
Siemens Atellica	Trig (mg/dL)	136	Between Lots	1.7	1.5, 2.1	2.0%	1.7%, 2.4%
			Between Tubes	1.7	1.4, 1.9	1.0%	0.9%, 1.2%
			Within Tubes	0.8	0.7, 0.9	0.7%	0.6%, 0.8%
			Total	2.5	2.1, 3.3	2.4%	1.9%, 3.1%

Test System	Analyte (Unit)	Mean	Variance Component	SD	SD 95% CI	CV (%)	CV 95% CI
Roche cobas 6000	Trig (mg/dL)	138.8	Between Lots	1.8	1.5, 2.1	2.0%	1.7%, 2.4%
			Between Tubes	1.2	0.8, 1.5	0.8%	0.5%, 1.1%
			Within Tubes	1.8	1.6, 1.9	1.2%	1.1%, 1.3%
			Total	2.8	2.3, 3.7	2.5%	2.0%, 3.3%

BD Vacutainer® RST Blood Collection Tubes

Blood was collected from each subject (n=66) into 6 BD Vacutainer® RST Tubes. Specimens were tested with 2 tubes per lot across 3 lots on 2 instrument platforms for the following select routine and special chemistry analytes: ALT, C3, Ca, CL, CORT, Free T4, GLUC, IgG, K, LDH, Phos, Free T4, Total T4, TBIL, TESTO, TP, TPSA and Trig. Contrived samples (less than 15%) were also used to cover the clinically relevant 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:

Test System	Analyte (Unit)	Mean	Variance Component	SD	SD 95% CI	CV (%)	CV 95% CI
Beckman Coulter AU480	ALT (U/L)	30.2	Between Lots	0	0, 0	0.3 %	0.3%, 0.4%
			Between Tubes	0.4	0, 0.7	2.8%	1.9%, 3.5%
			Within Tubes	0.9	0.8, 1.1	2.6%	2.2%, 3.2%
			Total	1	0.8, 1.3	3.8 %	3.1%, 5.1%
Roche cobas Integra 400 Plus	ALT (U/L)	30.26	Between Lots	0.38	0.32, 0.46	0 %	0%, 0%
			Between Tubes	0.34	0, 0.51	3.4 %	2.5%, 4.1%
			Within Tubes	0.59	0.5, 0.71	2.6 %	2.2%, 3.1%
			Total	0.78	0.62, 1.04	4.3 %	3.4%, 5.7%
Beckman Coulter AU480	TBIL (mg/dL)	1.88	Between Lots	0	0, 0	0 %	0%, 0%
			Between Tubes	0.02	0.01, 0.03	6.2 %	5.1%, 7.1%
			Within Tubes	0.03	0.02, 0.03	1.8 %	1.5%, 2.1%
			Total	0.03	0.03, 0.05	6.4 %	5.1%, 8.5%
Roche cobas Integra 400 Plus	TBIL (mg/dL)	2.074	Between Lots	0.025	0.021, 0.03	0 %	0%, 0%
			Between Tubes	0.074	0.058, 0.086	5.9 %	4.5%, 7.1%
			Within Tubes	0.036	0.031, 0.043	3.8 %	3.3%, 4.5%
			Total	0.086	0.068, 0.116	7.1 %	5.6%, 9.5%
Roche cobas Integra 400 Plus	C3 (mg/dL)	140	Between Lots	0.5	0.4, 0.6	0.4 %	0.3%, 0.5%
			Between Tubes	0	0, 0	0 %	0%, 0%
			Within Tubes	2.3	2, 2.7	1.5 %	1.3%, 1.8%
			Total	2.4	1.9, 3.1	1.6 %	1.3%, 2.1%
Roche cobas Integra 400 Plus	C3 (mg/dL)	128.48	Between Lots	1.05	0.9, 1.26	0.7 %	0.6%, 0.8%
			Between Tubes	0.6	0, 1.11	0.4 %	0%, 0.8%
			Within Tubes	1.66	1.45, 1.96	1.3 %	1.2%, 1.6%
			Total	2.06	1.66, 2.7	1.5 %	1.2%, 2%
Beckman Coulter AU480	Ca (mg/dL)	9.61	Between Lots	0.01	0.01, 0.01	0.1 %	0.1%, 0.1%
			Between Tubes	0.01	0, 0.05	0.3 %	0%, 0.6%
			Within Tubes	0.1	0.09, 0.11	1 %	0.9%, 1.1%
			Total	0.1	0.08, 0.13	1 %	0.8%, 1.3%
	Ca (mg/dL)	9.574	Between Lots	0	0, 0	0 %	0%, 0%

Test System	Analyte (Unit)	Mean	Variance Component	SD	SD 95% CI	CV (%)	CV 95% CI
Roche cobas Integra 400 Plus			Between Tubes	0.037	0, 0.076	0 %	0%, 0%
			Within Tubes	0.122	0.107, 0.143	1.4 %	1.2%, 1.6%
			Total	0.128	0.103, 0.167	1.4 %	1.1%, 1.8%
Beckman Coulter AU480	CL (mmol/L)	99.5	Between Lots	0.8	0.6, 0.9	0.4 %	0.4%, 0.5%
			Between Tubes	0.6	0.5, 0.7	0.7 %	0.6%, 0.9%
			Within Tubes	1.1	0.9, 1.4	0.6 %	0.5%, 0.7%
			Total	1.1	0.9, 1.4	1 %	0.8%, 1.4%
Roche cobas Integra 400 Plus	CL (mmol/L)	100.98	Between Lots	0.59	0.51, 0.72	1.1%	1%, 1.3%
			Between Tubes	0	0, 0	0%	0%, 0%
			Within Tubes	2.78	2.4, 3.3	5.1%	4.4%, 6.1%
			Total	2.84	2.29, 3.73	5.3%	4.3%, 6.8%
Beckman Coulter AU480	CORT (µg/dL)	9.051	Between Lots	0	0, 0	0%	0%, 0%
			Between Tubes	0.255	0.142, 0.332	3%	1.9%, 3.8%
			Within Tubes	0.317	0.274, 0.376	3.2%	2.8%, 3.8%
			Total	0.407	0.328, 0.537	4.4%	3.5%, 5.8%
Roche cobas e411	CORT (µg/dL)	8.902	Between Lots	0.323	0.276, 0.389	2.2%	1.9%, 2.7%
			Between Tubes	0.139	0, 0.205	0.8%	0%, 1.8%
			Within Tubes	0.248	0.214, 0.294	2.8%	2.5%, 3.4%
			Total	0.43	0.346, 0.568	3.7%	3%, 4.9%
Beckman Coulter AU480	Free T4 (ng/dL)	0.882	Between Lots	0.013	0.011, 0.015	1.5%	1.3%, 1.8%
			Between Tubes	0.014	0, 0.02	1.1%	0%, 2%
			Within Tubes	0.024	0.021, 0.028	2.9%	2.5%, 3.5%
			Total	0.031	0.025, 0.04	3.5%	2.8%, 4.5%
Roche cobas e411	Free T4 (ng/dL)	1.2538	Between Lots	0.0169	0.0145, 0.0203	1.2%	1%, 1.4%
			Between Tubes	0	0, 0	0%	0%, 0%
			Within Tubes	0.0363	0.0315, 0.0427	2.8%	2.4%, 3.3%
			Total	0.04	0.0325, 0.052	3%	2.5%, 3.9%
Beckman Coulter AU480	GLUC (mg/dL)	137.4	Between Lots	0.8	0.7, 0.9	1%	0.9%, 1.2%
			Between Tubes	0.8	0, 1.4	1.6%	1.3%, 2%
			Within Tubes	2.1	1.8, 2.5	1.2%	1.1%, 1.4%
			Total	2.4	1.9, 3.1	2.3%	1.9%, 3%
Roche cobas Integra 400 Plus	GLUC (mg/dL)	133.5	Between Lots	0.5	0.5, 0.6	0.5%	0.4%, 0.6%
			Between Tubes	1.5	1.1, 1.9	1.8%	1.5%, 2.1%
			Within Tubes	1.5	1.3, 1.8	0.9%	0.8%, 1%
			Total	2.2	1.8, 2.9	2.1%	1.7%, 2.7%
Beckman Coulter AU480	IgG (mg/dL)	1247.448	Between Lots	5.978	5.12, 7.184	0.4%	0.3%, 0.5%
			Between Tubes	12.471	3.307, 17.323	1.0%	0.4%, 1.3%
			Within Tubes	19.588	17.021, 23.073	1.4%	1.2%, 1.7%
			Total	23.978	19.363, 31.5	1.8%	1.4%, 2.3%
Roche cobas	IgG (mg/dL)	1257.89	Between Lots	9.89	8.48, 11.89	1%	0.8%, 1.2%
			Between Tubes	14.13	9.08, 17.8	0.9%	0.4%, 1.2%
			Within Tubes	15.66	13.61, 18.44	1.3%	1.1%, 1.5%

Test System	Analyte (Unit)	Mean	Variance Component	SD	SD 95% CI	CV (%)	CV 95% CI
Integra 400 Plus			Total	23.3	18.81, 30.62	1.8%	1.5%, 2.4%
Beckman Coulter AU480	K (mmol/L)	4.93	Between Lots	0.02	0.02, 0.02	0.3%	0.3%, 0.4%
			Between Tubes	0.11	0.09, 0.13	2.7%	2.2%, 3.1%
			Within Tubes	0.05	0.04, 0.06	1.1%	0.9%, 1.2%
			Total	0.12	0.1, 0.16	2.9%	2.3%, 3.8%
Roche cobas Integra 400 Plus	K (mmol/L)	4.977	Between Lots	0.013	0.011, 0.016	0.2%	0.2%, 0.2%
			Between Tubes	0.097	0.074, 0.155	2.6%	2.1%, 3%
			Within Tubes	0.075	0.066, 0.088	0.9%	0.8%, 1.1%
			Total	0.123	0.1, 0.161	2.8%	2.2%, 3.6%
Beckman Coulter AU480	LDH (U/L)	142.8	Between Lots	0.4	0.4, 0.5	0.4%	0.3%, 0.5%
			Between Tubes	4.5	3.5, 5.3	2.9%	2.3%, 3.4%
			Within Tubes	2.4	2, 2.9	1.5%	1.3%, 1.9%
			Total	5.1	4.1, 6.9	3.3%	2.7%, 4.5%
Roche cobas Integra 400 Plus	LDH (U/L)	162.24	Between Lots	0.77	0.65, 0.94	0.5%	0.5%, 0.6%
			Between Tubes	4.61	3.7, 5.37	2.6%	2.1%, 3.1%
			Within Tubes	2.05	1.74, 2.49	1.4%	1.2%, 1.7%
			Total	5.1	4.07, 6.84	3%	2.4%, 4%
Beckman Coulter AU480	Phos (mg/dL)	3.6	Between Lots	0.02	0.01, 0.02	0.3%	0.3%, 0.4%
			Between Tubes	0.05	0.03, 0.06	1.2%	0.6%, 1.6%
			Within Tubes	0.05	0.04, 0.06	1.7%	1.5%, 2%
			Total	0.07	0.06, 0.09	2.1%	1.7%, 2.7%
Roche cobas Integra 400 Plus	Phos (mg/dL)	3.39	Between Lots	0.01	0.01, 0.01	0.3%	0.3%, 0.4%
			Between Tubes	0.08	0.07, 0.1	2.3%	1.9%, 2.7%
			Within Tubes	0.05	0.04, 0.05	1.4%	1.2%, 1.6%
			Total	0.1	0.08, 0.13	2.7%	2.2%, 3.5%
Beckman Coulter AU480	TESTO (ng/dL)	1.919	Between Lots	0.004	0.003, 0.005	3.4%	2.9%, 4.2%
			Between Tubes	0	0, 0	2.6%	0%, 4%
			Within Tubes	0.081	0.069, 0.097	4.8%	4.1%, 5.7%
			Total	0.081	0.064, 0.109	6.4%	5.1%, 8.7%
Roche cobas e411	TESTO (ng/dL)	2.805	Between Lots	0	0, 0	0.7%	0.6%, 0.9%
			Between Tubes	0.0759	0.0452, 0.0974	2.8%	1.9%, 3.5%
			Within Tubes	0.0695	0.0566, 0.0868	2.1%	1.7%, 2.6%
			Total	0.1023	0.0787, 0.146	3.6%	2.7%, 5.1%
Beckman Coulter AU480	Total T4 (µg/dL)	9.939	Between Lots	0.501	0.403, 0.662	1.6%	1.4%, 1.9%
			Between Tubes	0.217	0.185, 0.264	2.9%	1.6%, 3.8%
			Within Tubes	0.269	0.112, 0.363	3.5%	3%, 4.2%
			Total	0.363	0.31, 0.437	4.8%	3.9%, 6.3%
Roche cobas e411	Total T4 (µg/dL)	8.526	Between Lots	0.258	0.22, 0.313	2.4%	2%, 2.9%
			Between Tubes	0.219	0.093, 0.295	0%	0%, 0%
			Within Tubes	0.294	0.251, 0.354	4%	3.4%, 4.8%
			Total	0.448	0.36, 0.593	4.7%	3.8%, 6.2%
			Between Lots	0.03	0.03, 0.04	0.5%	0.4%, 0.5%

Test System	Analyte (Unit)	Mean	Variance Component	SD	SD 95% CI	CV (%)	CV 95% CI
Beckman Coulter AU480	TP (g/dL)	7.27	Between Tubes	0.08	0.06, 0.09	1%	0.7%, 1.2%
			Within Tubes	0.06	0.05, 0.07	0.9%	0.7%, 1%
			Total	0.1	0.08, 0.14	1.4%	1.1%, 1.8%
Roche cobas Integra 400 Plus	TP (g/dL)	6.92	Between Lots	0.04	0.03, 0.05	0.6%	0.5%, 0.7%
			Between Tubes	0.07	0.05, 0.09	0.9%	0.7%, 1.1%
			Within Tubes	0.06	0.05, 0.07	0.8%	0.7%, 1%
			Total	0.1	0.08, 0.13	1.4%	1.1%, 1.8%
Beckman Coulter AU480	TPSA (ng/mL)	2.277	Between Lots	0	0, 0	1.4%	1.1%, 1.7%
			Between Tubes	0	0.0	1.3%	0%, 2.1%
			Within Tubes	0.209	0.182, 0.247	2.9%	2.5%, 3.4%
			Total	0.209	0.161, 0.299	3.4%	2.6%, 4.9%
Roche cobas e411	TPSA (ng/mL)	2.5856	Between Lots	0.0006	0.0005, 0.0008	0.4%	0.3%, 0.5%
			Between Tubes	0	0, 0	1.3%	0.9%, 1.7%
			Within Tubes	0.0939	0.0816, 0.1106	1.3%	1.2%, 1.6%
			Total	0.0939	0.0722, 0.1341	1.9%	1.5%, 2.8%
Beckman Coulter AU480	Trig (mg/dL)	188.8	Between Lots	4.7	4, 5.8	0.3%	0.2%, 0.3%
			Between Tubes	3.5	2.6, 4.2	1.5%	1%, 1.9%
			Within Tubes	2.6	2.2, 3.1	1.4%	1.2%, 1.7%
			Total	6.4	5.1, 8.6	2.1%	1.7%, 2.8%
Roche cobas Integra 400 Plus	Trig (mg/dL)	176.6	Between Lots	3.7	3.2, 4.5	0.5%	0.4%, 0.6%
			Between Tubes	2.6	2, 3.1	1.3%	0.9%, 1.6%
			Within Tubes	1.7	1.5, 2.1	1.2%	1.1%, 1.5%
			Total	4.9	3.9, 6.6	1.9%	1.5%, 2.5%

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® RST™ Blood Collection Tubes.

Within-tube stability was assessed in the BD Vacutainer® RST™ Tubes after 6 hours storage at room temperature for progesterone, 12 hours storage at room temperature for CO₂, LDL and triglycerides, 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 CO₂, GLUC, HDL and LDL. Stability was also assessed in the BD Vacutainer® Serum Plastic Blood Collection Tubes and the BD Vacutainer® Serum Glass Blood Collection Tubes after 2 hour storage at room temperature for all analytes. 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. The study protocols and acceptance criteria have been reviewed and found to be acceptable. These studies support the storage claims included in the devices' labeling.

Analyte	Temperature Condition	Storage Duration
CO ₂	Room temperature (23-27°C)	12 hours
ALB ALKP ALT AMY AST BUN C3 Ca Chol CK CKMB CL CORT Creat CRP DBIL E2 Fe FERR Folate Free T3 Free T4 FSH GGT GLUC HAPTO HCG HDL hsTnI	Room temperature (23-27°C)	24 hours

Analyte	Temperature Condition	Storage Duration
IgA IgG IgM K LDH LDL LH Lip Mg Na NT-proBNP Phos PROG RF TBIL TESTO TnT Total T3 Total T4 TP TPSA TRF Trig TSH UA Vit B12 Vit D		
K	Refrigerated (2-8°C)	3 days
ALB ALKP ALT AMY AST BUN Ca Chol CK CL Creat DBIL Fe GGT	Refrigerated (2-8°C)	7 days

Analyte	Temperature Condition	Storage Duration
LDH Lip Mg Na Phos TBIL TP Trig UA		

b. Shelf-Life

Real Time Shelf-life stability testing was conducted by using BD Vacutainer® Serum Plastic Blood Collection Tubes, BD Vacutainer® Serum Glass Blood Collection Tubes and BD Vacutainer® Rapid Serum Blood Collection Tube (RST). The results support the following shelf-life claims, when stored at 4-25°C (and 40°C for 15 days to simulate extreme temperatures during shipping):

- BD Vacutainer® Serum Plastic Blood Collection Tubes for 16-24 months (depending on the tube model)
- BD Vacutainer® Serum Glass Blood Collection Tubes for 24 months
- BD Vacutainer® Rapid Serum Blood Collection Tube (RST) for 15 months.

c. Additional bench testing on the candidate device

Benchtop studies were conducted to assess draw volume, X-value, 2nd stopper pullout, stopper/shield separation (on products with a Hemogard™ shield component), stopper leakage, tube leakage, breakage resistance during drop testing (on plastic tubes only) and breakage resistance during centrifugation testing. BD RST products, which contain a gel component, were also evaluated for barrier formation during centrifugation and for barrier integrity after simulated transport. Additionally, ship testing was conducted to assess the functional performance of the packaging materials. 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:

See Clinical Studies in section C.4 below.

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 multi-part study was conducted to evaluate clinical equivalence between BD Vacutainer® Serum Plastic Tubes, BD Vacutainer® Serum Glass Tubes and BD Vacutainer® RST™ Blood Collection Tubes and cleared comparator serum separator tubes for testing representative analytes. A total of 180 participants were included in the study, with at least 100 patient samples within the measuring range of each assay tested. Blood was collected from each study participant using standard phlebotomy techniques. In addition, contrived samples were prepared to cover the clinically relevant range for the tested analytes. Samples were tested on two different instrument platforms (Beckman Coulter 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 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® Serum Plastic Tubes vs. comparator tubes:

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
Beckman Coulter AU480	ALB (g/dL)	1.04 (1, 1.09)	-0.18 (-0.42, 0)	0.939	PB
Roche cobas® Integra 400 Plus	ALB (g/dL)	0.99 (0.91, 1.07)	0.02 (-0.33, 0.38)	0.919	WD
Beckman Coulter AU480	ALKP (U/L)	1 (0.99, 1.02)	-0.42 (-1.71, 0.86)	0.995	WD
Roche cobas® Integra 400 Plus	ALKP (U/L)	0.99 (0.97, 1.02)	-0.19 (-2.41, 2.03)	0.995	WD

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
Beckman Coulter AU480	ALT (U/L)	1.01 (0.97, 1.05)	0.5 (-0.17, 1.17)	0.998	WD
Roche cobas® Integra 400 Plus	ALT (U/L)	1 (0.98, 1.02)	-0.7 (-1.2, -0.2)	0.99	PB
Beckman Coulter AU480	AMY (U/L)	1.02 (1, 1.05)	-1.14 (-2.23, -0.04)	0.988	WD
Roche cobas® Integra 400 Plus	AMY (U/L)	1.01 (0.99, 1.02)	-0.73 (-1.53, 0.06)	0.998	WD
Beckman Coulter AU480	AST (U/L)	1 (1, 1.11)	0 (-1.67, 0)	0.995	PB
Roche cobas® Integra 400 Plus	AST (U/L)	1 (0.94, 1.05)	-0.1 (-1.28, 1.07)	1	WD
Beckman Coulter AU480	BUN (mg/dL)	1 (1, 1.03)	0.2 (-0.13, 0.3)	0.998	PB
Roche cobas® Integra 400 Plus	BUN (mg/dL)	1 (0.99, 1.03)	0.2 (-0.16, 0.3)	0.999	PB
Beckman Coulter AU480	Ca (mg/dL)	1.02 (0.93, 1.1)	-0.18 (-0.99, 0.63)	0.972	D
Roche cobas® Integra 400 Plus	Ca (mg/dL)	1 (0.93, 1.06)	0 (-0.49, 0.64)	0.96	PB
Beckman Coulter AU480	Chol (mg/dL)	1.05 (0.99, 1.1)	-7.96 (-17.68, 1.76)	0.975	WD
Roche cobas® Integra 400 Plus	Chol (mg/dL)	1.02 (1, 1.05)	-5.41 (-10.01, -0.81)	0.991	WD
Beckman Coulter AU480	CK (U/L)	1.02 (1, 1.04)	-0.19 (-1.52, 1.15)	0.998	WD
Roche cobas® Integra 400 Plus	CK (U/L)	1 (1, 1.01)	-0.33 (-0.94, 0.28)	1	WD
Beckman Coulter AU480	CL (mmol/L)	0.97 (0.91, 1.03)	3 (-2.94, 8.94)	0.937	D
Roche cobas® Integra 400 Plus	CL (mmol/L)	0.9 (0.79, 1)	10.68 (0.4, 22.12)	0.873	PB
Beckman Coulter AU480	CO ₂ (mmol/L)	0.94 (0.86, 1.03)	1.41 (-0.63, 3.44)	0.904	WD
Roche cobas® Integra 400 Plus	CO ₂ (mmol/L)	1.08 (0.98, 1.18)	-1.49 (-3.86, 0.89)	0.878	WD
Beckman Coulter AU480	Creat (mg/dL)	1.03 (1, 1.06)	-0.02 (-0.04, 0)	0.999	WD
Roche cobas® Integra 400 Plus	Creat (mg/dL)	0.98 (0.95, 1.02)	0.03 (0, 0.06)	0.999	WD
Beckman Coulter AU480	DBIL (mg/dL)	0.98 (0.81, 1.14)	-0.01 (-0.02, 0.01)	0.851	D

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
Roche cobas® Integra 400 Plus	DBIL (mg/dL)	1.19 (0.66, 1.72)	-0.01 (-0.04, 0.02)	0.816	WD
Beckman Coulter AU480	Fe (mg/dL)	1 (1, 1.04)	-1 (-2.79, 0)	0.979	PB
Roche cobas® Integra 400 Plus	Fe (mg/dL)	1.06 (0.99, 1.14)	-4.07 (-8.78, 0.64)	0.995	WD
Beckman Coulter AU480	GGT (U/L)	0.99 (0.97, 1.01)	-0.31 (-0.85, 0.22)	1	WD
Roche cobas® Integra 400 Plus	GGT (U/L)	1 (0.98, 1.01)	-0.05 (-0.39, 0.28)	1	PB
Beckman Coulter AU480	GLUC (mg/dL)	0.99 (0.95, 1.03)	-1.25 (-5.42, 2.92)	0.993	WD
Roche cobas® Integra 400 Plus	GLUC (mg/dL)	1.02 (1, 1.06)	-3.36 (-6.86, -1)	0.997	PB
Beckman Coulter AU480	HDL (mg/dL)	1.03 (0.99, 1.07)	-1.13 (-2.58, 0.32)	0.983	WD
Roche cobas® Integra 400 Plus	HDL (mg/dL)	1 (0.97, 1.03)	-0.37 (-1.8, 1.06)	0.971	WD
Beckman Coulter AU480	LDH (U/L)	1.08 (0.98, 1.17)	-9.28 (-19.91, 1.36)	0.922	WD
Roche cobas® Integra 400 Plus	LDH (U/L)	1.07 (1.01, 1.14)	-9.27 (-18.03, -0.51)	0.904	WD
Beckman Coulter AU480	LDL (mg/dL)	1.03 (1, 1.07)	-2.74 (-6.98, 1.49)	0.982	WD
Roche cobas® Integra 400 Plus	LDL (mg/dL)	1.03 (0.99, 1.06)	-2.43 (-6.29, 1.43)	0.992	WD
Beckman Coulter AU480	Lip (U/L)	0.99 (0.96, 1.02)	-0.07 (-0.53, 0.39)	0.989	WD
Roche cobas® Integra 400 Plus	Lip (U/L)	1 (0.99, 1.01)	0.04 (-0.36, 0.44)	0.999	WD
Beckman Coulter AU480	Mg (mg/dL)	1.01 (0.95, 1.06)	-0.01 (-0.11, 0.1)	0.983	D
Roche cobas® Integra 400 Plus	Mg (mg/dL)	1.01 (0.97, 1.06)	-0.07 (-0.17, 0.03)	0.944	D
Beckman Coulter AU480	Na (mmol/L)	1.02 (0.97, 1.06)	-1.87 (-8.01, 4.28)	0.939	D
Roche cobas® Integra 400 Plus	Na (mmol/L)	0.97 (0.83, 1.04)	5.52 (-4.22, 24.51)	0.953	PB
Beckman Coulter AU480	Phos (mg/dL)	1.01 (0.96, 1.05)	-0.19 (-0.37, -0.01)	0.968	D
Roche cobas® Integra 400 Plus	Phos (mg/dL)	0.98 (0.92, 1.04)	0.08 (-0.13, 0.28)	0.983	D

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
Beckman Coulter AU480	TBIL (mg/dL)	1.01 (1, 1.01)	0.01 (-0.01, 0.03)	0.999	D
Roche cobas® Integra 400 Plus	TBIL (mg/dL)	1.02 (1, 1.08)	0 (-0.03, 0.01)	0.999	PB
Beckman Coulter AU480	TP (g/dL)	1.02 (0.91, 1.13)	-0.14 (-0.89, 0.6)	0.891	WD
Roche cobas® Integra 400 Plus	TP (g/dL)	0.99 (0.93, 1.04)	0.06 (-0.32, 0.45)	0.948	WD
Beckman Coulter AU480	Trig (mg/dL)	0.99 (0.97, 1.01)	0.4 (-2.01, 2.8)	0.997	WD
Roche cobas® Integra 400 Plus	Trig (mg/dL)	0.99 (0.98, 1)	-0.08 (-1.66, 1.5)	0.999	WD
Beckman Coulter AU480	UA (mg/dL)	0.99 (0.96, 1.01)	-0.01 (-0.15, 0.14)	0.99	WD
Roche cobas® Integra 400 Plus	UA (mg/dL)	1 (0.99, 1.02)	0.01 (-0.08, 0.1)	0.995	WD

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

Regression Parameter Estimates: BD Vacutainer® Serum Glass Tubes vs. comparator tubes:

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
Beckman Coulter AU480	ALB (g/dL)	1.02 (0.99, 1.05)	-0.07 (-0.22, 0.05)	0.967	PB
Roche cobas® Integra 400 Plus	ALB (g/dL)	1.01 (0.96, 1.07)	-0.05 (-0.28, 0.19)	0.942	WD
Beckman Coulter AU480	ALKP (U/L)	1.02 (1, 1.05)	-1.04 (-2.73, 0.64)	0.995	WD
Roche cobas® Integra 400 Plus	ALKP (U/L)	1.01 (0.99, 1.02)	0.04 (-1.02, 1.29)	0.992	PB
Beckman Coulter AU480	ALT (U/L)	1.01 (0.97, 1.05)	0.33 (-0.26, 0.92)	0.998	WD
Roche cobas® Integra 400 Plus	ALT (U/L)	1 (0.96, 1.04)	0.22 (-0.37, 0.8)	0.996	WD
Beckman Coulter AU480	AMY (U/L)	0.99 (0.96, 1.02)	-0.04 (-1.1, 1.03)	0.991	WD
Roche cobas® Integra 400 Plus	AMY (U/L)	1 (0.99, 1.01)	0.04 (-0.41, 0.5)	0.999	WD
Beckman Coulter AU480	AST (U/L)	1.03 (0.99, 1.06)	-0.37 (-0.98, 0.25)	0.999	WD
Roche cobas® Integra 400 Plus	AST (U/L)	1 (0.96, 1.04)	0.14 (-0.68, 0.96)	1	WD
Beckman Coulter AU480	BUN (mg/dL)	1 (1, 1.02)	0.1 (-0.12, 0.2)	0.999	PB

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
Roche cobas® Integra 400 Plus	BUN (mg/dL)	1 (0.98, 1.01)	0.1 (-0.09, 0.33)	0.998	PB
Beckman Coulter AU480	Ca (mg/dL)	1.04 (1.01, 1.08)	-0.49 (-0.86, -0.11)	0.963	D
Roche cobas® Integra 400 Plus	Ca (mg/dL)	0.96 (0.87, 1)	0.33 (-0.1, 1.26)	0.939	PB
Beckman Coulter AU480	Chol (mg/dL)	1 (0.97, 1.03)	0.89 (-5.15, 6.93)	0.987	WD
Roche cobas® Integra 400 Plus	Chol (mg/dL)	1.01 (0.99, 1.03)	-0.69 (-4, 2.62)	0.991	WD
Beckman Coulter AU480	CK (U/L)	1.01 (1, 1.02)	0.09 (-1.11, 1.29)	0.999	WD
Roche cobas® Integra 400 Plus	CK (U/L)	1 (1, 1.01)	-0.06 (-0.86, 0.73)	1	WD
Beckman Coulter AU480	CL (mmol/L)	0.97 (0.93, 1.02)	2.33 (-2.13, 6.79)	0.935	D
Roche cobas® Integra 400 Plus	CL (mmol/L)	1 (0.94, 1.06)	0.1 (-5.94, 6.12)	0.943	PB
Beckman Coulter AU480	CO ₂ (mmol/L)	0.94 (0.88, 1.01)	0.76 (-0.91, 2.43)	0.925	WD
Roche cobas® Integra 400 Plus	CO ₂ (mmol/L)	0.93 (0.86, 0.99)	1.12 (-0.4, 2.65)	0.947	WD
Beckman Coulter AU480	Creat (mg/dL)	1.03 (1, 1.05)	-0.02 (-0.04, 0)	0.999	WD
Roche cobas® Integra 400 Plus	Creat (mg/dL)	1.01 (0.99, 1.04)	-0.01 (-0.03, 0.01)	0.999	WD
Beckman Coulter AU480	DBIL (mg/dL)	1.04 (1, 1.08)	0 (0, 0.01)	0.965	D
Roche cobas® Integra 400 Plus	DBIL (mg/dL)	0.75 (0.57, 0.93)	0.01 (0, 0.02)	0.877	WD
Beckman Coulter AU480	Fe (mg/dL)	1 (0.98, 1.03)	0.16 (-1.28, 1.6)	0.994	WD
Roche cobas® Integra 400 Plus	Fe (mg/dL)	1.02 (1, 1.04)	-0.71 (-1.94, 0.52)	0.993	WD
Beckman Coulter AU480	GGT (U/L)	1 (0.98, 1.02)	-0.23 (-0.77, 0.31)	1	WD
Roche cobas® Integra 400 Plus	GGT (U/L)	1.01 (1, 1.02)	-0.25 (-0.53, 0.1)	1	PB
Beckman Coulter AU480	GLUC (mg/dL)	0.99 (0.96, 1)	-1.04 (-3, 1.98)	0.989	PB
Roche cobas® Integra 400 Plus	GLUC (mg/dL)	1.01 (0.99, 1.03)	-3.43 (-6.02, -0.84)	0.997	WD
Beckman Coulter AU480	HDL (mg/dL)	1.04 (1, 1.09)	-0.65 (-2.44, 1.13)	0.989	WD

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
Roche cobas® Integra 400 Plus	HDL (mg/dL)	1 (0.96, 1.03)	-0.04 (-1.5, 1.43)	0.976	WD
Beckman Coulter AU480	LDH (U/L)	1.01 (0.92, 1.09)	-2.65 (-13.11, 7.81)	0.933	WD
Roche cobas® Integra 400 Plus	LDH (U/L)	1.03 (0.99, 1.07)	-3.6 (-9.71, 2.51)	0.973	WD
Beckman Coulter AU480	LDL (mg/dL)	1 (0.99, 1.02)	1 (-1.56, 2.28)	0.983	PB
Roche cobas® Integra 400 Plus	LDL (mg/dL)	1 (0.97, 1.02)	0.7 (-2.27, 3.67)	0.995	WD
Beckman Coulter AU480	Lip (U/L)	1.01 (0.97, 1.06)	-0.56 (-1.77, 0.65)	0.995	WD
Roche cobas® Integra 400 Plus	Lip (U/L)	1.01 (0.99, 1.02)	-0.22 (-0.6, 0.16)	0.998	WD
Beckman Coulter AU480	Mg (mg/dL)	1.01 (0.97, 1.04)	-0.01 (-0.08, 0.07)	0.987	D
Roche cobas® Integra 400 Plus	Mg (mg/dL)	1.04 (1, 1.08)	-0.14 (-0.23, -0.05)	0.959	D
Beckman Coulter AU480	Na (mmol/L)	0.98 (0.93, 1.02)	3.12 (-2.48, 8.72)	0.969	D
Roche cobas® Integra 400 Plus	Na (mmol/L)	0.98 (0.88, 1)	2.92 (-0.53, 16.49)	0.991	PB
Beckman Coulter AU480	Phos (mg/dL)	1 (1, 1.06)	-0.1 (-0.3, -0.1)	0.925	PB
Roche cobas® Integra 400 Plus	Phos (mg/dL)	1 (1, 1)	-0.1 (-0.1, 0)	0.97	PB
Beckman Coulter AU480	TBIL (mg/dL)	1.01 (1, 1.02)	-0.01 (-0.02, 0)	1	D
Roche cobas® Integra 400 Plus	TBIL (mg/dL)	1.02 (1, 1.05)	0 (-0.01, 0.02)	0.999	PB
Beckman Coulter AU480	TP (g/dL)	0.99 (0.89, 1.09)	0.09 (-0.61, 0.8)	0.892	WD
Roche cobas® Integra 400 Plus	TP (g/dL)	1 (0.94, 1.06)	0.01 (-0.41, 0.42)	0.958	WD
Beckman Coulter AU480	Trig (mg/dL)	1 (0.99, 1.02)	-0.04 (-1.91, 1.82)	0.998	WD
Roche cobas® Integra 400 Plus	Trig (mg/dL)	1 (0.99, 1.01)	0 (-1.06, 1.57)	0.995	PB
Beckman Coulter AU480	UA (mg/dL)	0.98 (0.96, 1)	0.04 (-0.04, 0.13)	0.991	WD
Roche cobas® Integra 400 Plus	UA (mg/dL)	1.02 (0.99, 1.04)	-0.09 (-0.19, 0.02)	0.992	WD

Regression Parameter Estimates: BD Vacutainer® RST™ vs. comparator tubes:

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
Beckman Coulter AU480	ALB (g/dL)	0.96 (0.91, 1)	0.16 (-0.02, 0.33)	0.957	WD
Roche cobas® Integra 400 Plus	ALB (g/dL)	0.99 (0.94, 1.05)	-0.01 (-0.24, 0.23)	0.926	WD
Beckman Coulter AU480	ALKP (U/L)	1 (0.99, 1.02)	-0.13 (-1.11, 0.85)	0.993	WD
Roche cobas® Integra 400 Plus	ALKP (U/L)	1.01 (0.98, 1.03)	-1.04 (-3.58, 1.5)	0.997	WD
Beckman Coulter AU480	ALT (U/L)	0.98 (0.94, 1.01)	0.07 (-0.65, 0.8)	0.998	WD
Roche cobas® Integra 400 Plus	ALT (U/L)	0.99 (0.97, 1.01)	0.05 (-0.38, 0.46)	0.997	PB
Beckman Coulter AU480	AMY (U/L)	1 (0.98, 1.03)	-0.96 (-1.94, 0.01)	0.99	WD
Roche cobas® Integra 400 Plus	AMY (U/L)	1 (0.99, 1.01)	-0.25 (-0.73, 0.23)	0.999	WD
Beckman Coulter AU480	AST (U/L)	1.05 (0.99, 1.11)	-0.99 (-1.78, -0.19)	0.999	WD
Roche cobas® Integra 400 Plus	AST (U/L)	0.99 (0.94, 1.03)	0.21 (-0.7, 1.13)	1	WD
Beckman Coulter AU480	BUN (mg/dL)	1 (0.99, 1.01)	0 (-0.11, 0.17)	0.999	PB
Roche cobas® Integra 400 Plus	BUN (mg/dL)	1.01 (1, 1.03)	0.04 (-0.32, 0.2)	0.999	PB
Beckman Coulter AU480	Ca (mg/dL)	0.99 (0.9, 1.09)	0.11 (-0.79, 1)	0.986	WD
Roche cobas® Integra 400 Plus	Ca (mg/dL)	0.95 (0.93, 0.98)	0.48 (0.23, 0.74)	0.97	WD

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
Beckman Coulter AU480	Chol (mg/dL)	1 (0.97, 1.03)	-0.28 (-6.41, 5.84)	0.988	D
Roche cobas® Integra 400 Plus	Chol (mg/dL)	1 (0.98, 1.02)	-1.01 (-5.06, 3.04)	0.994	D
Beckman Coulter AU480	CK (mg/dL)	1 (0.99, 1.01)	0.92 (0.05, 1.79)	0.999	WD
Roche cobas® Integra 400 Plus	CK (mg/dL)	0.99 (0.99, 1)	0.19 (-0.52, 0.91)	1	PB
Beckman Coulter AU480	CL (mmol/L)	1.01 (0.98, 1.03)	-0.31 (-3.13, 2.51)	0.961	D
Roche cobas® Integra 400 Plus	CL (mmol/L)	0.98 (0.9, 1.06)	2.73 (-5.06, 10.52)	0.936	D
Beckman Coulter AU480	CO ₂ (mmol/L)	0.98 (0.91, 1.06)	0.55 (-1.32, 2.43)	0.94	WD
Roche cobas® Integra 400 Plus	CO ₂ (mmol/L)	1.04 (0.98, 1.14)	-0.69 (-2.99, 0.72)	0.92	WD
Beckman Coulter AU480	Creat (mg/dL)	1 (0.98, 1)	0 (0, 0.02)	0.999	PB
Roche cobas® Integra 400 Plus	Creat (mg/dL)	1.01 (0.98, 1.03)	0 (-0.02, 0.02)	0.999	WD
Beckman Coulter AU480	DBIL (mg/dL)	1 (0.93, 1.07)	0 (-0.01, 0.01)	0.965	D
Roche cobas® Integra 400 Plus	DBIL (mg/dL)	0.98 (0.59, 1.38)	0 (-0.02, 0.03)	0.88	WD
Beckman Coulter AU480	Fe (µg/dL)	0.98 (0.96, 1)	0.08 (-1.2, 1.36)	0.997	WD
Roche cobas® Integra 400 Plus	Fe (µg/dL)	1.06 (1.02, 1.1)	-4.21 (-6.62, -1.81)	0.997	WD
Beckman Coulter AU480	GGT (U/L)	1 (0.98, 1.03)	-0.11 (-0.7, 0.47)	1	WD

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
Roche cobas® Integra 400 Plus	GGT (U/L)	0.99 (0.99, 1)	-0.17 (-0.4, 0.02)	1	PB
Beckman Coulter AU480	GLUC (mg/dL)	1.02 (0.97, 1.06)	0.55 (-3.46, 4.57)	0.991	WD
Roche cobas® Integra 400 Plus	GLUC (mg/dL)	1.03 (1.01, 1.06)	0.4 (-2.04, 2.84)	0.998	WD
Beckman Coulter AU480	HDL (mg/dL)	0.98 (0.95, 1.01)	0.27 (-1.05, 1.59)	0.995	WD
Roche cobas® Integra 400 Plus	HDL (mg/dL)	0.98 (0.95, 1.01)	0.18 (-0.96, 1.31)	0.983	WD
Beckman Coulter AU480	K (mmol/L)	1 (0.91, 1.09)	0.1 (-0.24, 0.45)	0.757	PB
Roche cobas® Integra 400 Plus	K (mmol/L)	0.99 (0.89, 1.09)	0.12 (-0.3, 0.54)	0.832	D
Beckman Coulter AU480	LDH (U/L)	1.06 (1.02, 1.1)	-10.5 (-17.55, -4.84)	0.954	PB
Roche cobas® Integra 400 Plus	LDH (U/L)	1 (0.96, 1.03)	-1.34 (-6.38, 3.69)	0.957	WD
Beckman Coulter AU480	LDL (mg/dL)	1.01 (0.98, 1.05)	-2.05 (-5.94, 1.83)	0.984	WD
Roche cobas® Integra 400 Plus	LDL (mg/dL)	1.01 (0.99, 1.03)	-1.29 (-3.79, 1.21)	0.995	WD
Beckman Coulter AU480	Lip (U/L)	0.99 (0.96, 1.01)	-0.09 (-0.57, 0.39)	0.991	WD
Roche cobas® Integra 400 Plus	Lip (U/L)	1 (0.99, 1.01)	-0.09 (-0.36, 0.18)	0.999	WD
Beckman Coulter AU480	Mg (mg/dL)	1 (0.98, 1.01)	-0.05 (-0.09, -0.02)	0.994	D
Roche cobas® Integra 400 Plus	Mg (mg/dL)	0.99 (0.93, 1.06)	-0.04 (-0.18, 0.09)	0.938	D

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
Beckman Coulter AU480	Na (mmol/L)	1 (0.98, 1.03)	-0.15 (-3.5, 3.2)	0.973	D
Roche cobas® Integra 400 Plus	Na (mmol/L)	0.98 (0.98, 0.99)	2.66 (1.2, 4.13)	0.991	D
Beckman Coulter AU480	Phos (mg/dL)	1.02 (0.97, 1.06)	-0.13 (-0.28, 0.03)	0.972	D
Roche cobas® Integra 400 Plus	Phos (mg/dL)	0.98 (0.96, 1.01)	0.11 (0.03, 0.2)	0.987	D
Beckman Coulter AU480	TBIL (mg/dL)	1.02 (1.01, 1.03)	-0.02 (-0.03, 0)	0.999	D
Roche cobas® Integra 400 Plus	TBIL (mg/dL)	1 (0.99, 1.03)	0 (-0.01, 0.01)	0.999	PB
Beckman Coulter AU480	TP (g/dL)	0.98 (0.9, 1.05)	0.23 (-0.32, 0.78)	0.933	WD
Roche cobas® Integra 400 Plus	TP (g/dL)	0.93 (0.89, 0.98)	0.49 (0.15, 0.84)	0.954	WD
Beckman Coulter AU480	Trig (mg/dL)	0.99 (0.98, 1)	0.91 (-0.66, 2.49)	0.999	WD
Roche cobas® Integra 400 Plus	Trig (mg/dL)	0.99 (0.98, 1.01)	0.66 (-1.34, 2.65)	0.998	WD
Beckman Coulter AU480	UA (mg/dL)	0.99 (0.98, 1.01)	0.03 (-0.02, 0.09)	0.996	WD
Roche cobas® Integra 400 Plus	UA (mg/dL)	1 (0.98, 1.02)	0.03 (-0.06, 0.12)	0.994	WD

Special Chemistry Analytes and Cardiac Markers

A multi-part study was conducted to evaluate equivalence between: a) BD Vacutainer® Serum Plastic tubes vs. cleared serum separator tubes; b) BD Vacutainer® Serum Glass tubes vs. cleared serum separator tubes and c) BD Vacutainer® RST™ Blood Collection Tubes vs. cleared serum separator tubes for testing special chemistry analytes and cardiac markers. 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 clinically relevant range for the tested analytes. Samples were tested on two different instrument platforms for each analyte.

For each analyte and tube comparison, data was analyzed using Passing Bablok regression, Deming or Weighted Deming regression. 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® Serum Plastic Tubes vs. comparator tubes:

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
Beckman DxC 700 AU	C3 (mg/dL)	0.97 (0.95, 1)	-0.37 (-3.82, 3.08)	0.99	WD
OCD Vitros 5600	C3 (mg/dL)	0.95 (0.92, 0.98)	2.88 (-0.45, 6.4)	0.984	PB
Beckman DxC 700 AU	CKMB (U/L)	1.04 (0.98, 1.11)	0.39 (-0.78, 1.56)	0.98	WD
Roche Cobas e411	CKMB (ng/mL)	1.03 (1.01, 1.05)	-0.04 (-0.08, 0.01)	0.999	WD
OCD Vitros 5600	CORT (nmol/L)	0.99 (0.98, 1)	0.73 (-0.23, 1.69)	0.998	WD
Roche Cobas e411	CORT (nmol/L)	0.99 (0.98, 1.01)	-1.12 (-3.02, 0.65)	0.997	PB
Beckman DxC 700 AU	CRP (mg/L)	1 (1, 1.01)	-0.01 (-0.03, 0.01)	0.997	PB
OCD Vitros 5600	CRP (mg/dL)	0.99 (0.98, 1)	-0.09 (-0.2, -0.08)	0.954	PB
OCD Vitros 3600/5600	E2 (pmol/L)	1.05 (1.03, 1.07)	1.64 (-0.98, 5.25)	0.999	PB
Siemens Dimension Vista 1500	E2 (pg/mL)	1.01 (0.99, 1.02)	-0.2 (-1.69, 1.3)	0.998	PB
OCD Vitros 3600/5600	FERR (ng/mL)	0.96 (0.95, 0.97)	0.13 (-0.05, 0.31)	0.999	WD
Siemens Dimension Vista 1500	FERR (ng/mL)	1 (0.99, 1.01)	0.03 (-0.2, 0.25)	0.999	WD
OCD Vitros 3600/5600	FOLATE (ng/mL)	0.97 (0.92, 1.03)	0.23 (-0.25, 0.7)	0.956	PB
Siemens Dimension Vista 1500	FOLATE (ng/mL)	1.01 (0.99, 1.04)	0.04 (-0.31, 0.38)	0.988	PB
OCD Vitros 3600/5600	FSH (mIU/mL)	0.96 (0.95, 0.97)	-0.04 (-0.08, 0.01)	0.999	WD
Siemens Dimension Vista 1500	FSH (mIU/mL)	1 (1, 1.01)	0.04 (0, 0.09)	1	WD

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
Integra 400 Plus	HAPTO (g/L)	1 (0.99, 1.02)	1.97 (-0.33, 4.28)	0.997	WD
OCD Vitros 5600	HAPTO (mg/dL)	1 (0.98, 1.02)	0.26 (-2.76, 3.27)	0.995	WD
OCD Vitros 3600/5600	HCG (mIU/mL)	1 (0.99, 1)	0.08 (0.01, 0.15)	1	WD
Siemens Dimension Vista 1500	HCG (mIU/mL)	1.01 (1, 1.01)	0.05 (-0.05, 0.14)	0.999	WD
Beckman DxC 700 AU	IgA (mg/dL)	0.99 (0.98, 1)	0.72 (-0.25, 1.7)	0.999	WD
OCD Vitros 5600	IgA (mg/dL)	0.98 (0.97, 0.99)	0.47 (-1.09, 2.03)	0.999	WD
Beckman DxC 700 AU	IgG (mg/dL)	0.97 (0.96, 0.99)	21.32 (8.38, 34.27)	0.996	WD
OCD Vitros 5600	IgG (mg/dL)	0.99 (0.96, 1.01)	9.13 (-12.35, 30.6)	0.994	WD
Beckman DxC 700 AU	IgM (mg/dL)	1 (0.98, 1.01)	-0.36 (-1.17, 0.46)	0.999	WD
OCD Vitros 5600	IgM (mg/dL)	1 (0.99, 1.01)	-1.22 (-2.3, -0.13)	1	WD
OCD Vitros 3600/5600	LH (mIU/mL)	0.96 (0.95, 0.97)	-0.02 (-0.07, 0.04)	0.999	PB
Siemens Dimension Vista 1500	LH (mIU/mL)	1 (1, 1.01)	0 (-0.04, 0.1)	0.999	PB
OCD Vitros 5600	NT-proBNP (pg/mL)	0.99 (0.97, 1.01)	0.46 (-0.82, 1.74)	0.999	WD
Roche Cobas e411	NT-proBNP (pg/mL)	1.01 (1, 1.02)	-0.14 (-2.93, 2.66)	1	WD
OCD Vitros 3600/5600	PROG (nmol/L)	1 (0.99, 1.02)	-0.06 (-0.1, -0.03)	1	PB
Siemens Dimension Vista 1500	PROG (ng/mL)	1.02 (1.01, 1.03)	-0.01 (-0.02, 0)	1	PB
OCD Vitros 5600	TPSA (ng/mL)	0.99 (0.98, 1)	0 (0, 0.01)	0.988	PB
Roche Cobas e411	TPSA (ng/mL)	1 (0.99, 1.01)	0 (0, 0.01)	1	PB
Beckman DxC 700 AU	RF (IU/mL)	1.02 (1, 1.04)	-0.41 (-0.76, -0.07)	0.998	WD
OCD Vitros 5600	RF (IU/mL)	0.99 (0.98, 1.01)	-0.14 (-0.66, 0.38)	0.999	WD

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
Beckman Access2	Total T3 (ng/mL)	1 (0.95, 1.06)	-0.01 (-0.04, 0.03)	0.978	WD
Roche Cobas e411	Total T3 (nmol/L)	0.99 (0.95, 1.02)	-0.02 (-0.06, 0.03)	0.965	WD
OCD Vitros 3600/5600	Free T3 (pmol/L)	0.98 (0.92, 1.04)	-0.07 (-0.38, 0.28)	0.942	PB
Siemens Dimension Vista 1500	Free T3 (pg/mL)	1.02 (0.98, 1.06)	-0.06 (-0.15, 0.04)	0.99	WD
OCD Vitros 3600/5600	Total T4 (nmol/L)	0.99 (0.97, 1.01)	1.05 (-1.29, 3.38)	0.992	WD
Siemens Dimension Vista 1500	Total T4 (µg/dL)	1 (0.97, 1.06)	-0.1 (-0.68, 0.11)	0.97	PB
Beckman Access2	Free T4 (ng/dL)	1 (0.96, 1.03)	-0.01 (-0.04, 0.02)	0.982	WD
Roche Cobas e411	Free T4 (ng/dL)	0.99 (0.97, 1.01)	0 (-0.02, 0.03)	0.995	WD
OCD Vitros 5600	TESTO (nmol/L)	1.06 (1.04, 1.07)	0.01 (-0.02, 0.02)	0.997	PB
Roche Cobas e411	TESTO (ng/mL)	1 (0.99, 1.01)	0 (-0.01, 0.01)	0.999	PB
Integra 400 Plus	TRF (mg/L)	1 (0.97, 1.04)	4.32 (-3.92, 12.55)	0.987	WD
OCD Vitros 5600	TRF (mg/dL)	1.02 (1, 1.04)	-3.62 (-8.27, 1.02)	0.997	WD
OCD Vitros 3600/5600	TSH (µIU/mL)	1 (0.98, 1.01)	0 (-0.01, 0.01)	1	PB
Siemens Dimension Vista 1500	TSH (µIU/mL)	1.01 (1, 1.02)	0 (-0.02, 0.01)	1	PB
Beckman Access2	TnI (ng/mL)	1.04 (1.01, 1.05)	0 (0, 0.01)	0.997	PB
Roche Cobas e411	TnI (ng/mL)	1.31 (1.18, 1.43)	-0.05 (-0.1, 0.01)	0.984	WD
Roche Cobas e411/e601	TnT (ng/mL)	1.05 (1.01, 1.08)	-0.29 (-1.03, 0.44)	0.998	WD
OCD Vitros 3600/5600	Vit B12 (pg/mL)	1.07 (1.02, 1.12)	-9.17 (-21.95, 3.61)	0.97	WD
Siemens Dimension Vista 1500	Vit B12 (pg/mL)	1 (0.98, 1.02)	3.61 (-4.17, 1.39)	0.998	WD
Beckman Access2	Vit D (ng/mL)	1.02 (0.99, 1.05)	-0.48 (-1.11, 0.16)	0.995	WD

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
Roche Cobas e411	Vit D (ng/mL)	0.98 (0.94, 1.01)	-0.28 (-0.96, 0.41)	0.99	WD
ADVIA Centaur XPT	hsTnI (pg/mL)	1.04 (1, 1.07)	-0.15 (-0.38, 0.08)	0.998	WD
Beckman Access2	hsTnI (pg/mL)	1.04 (1.01, 1.06)	-0.11 (-0.35, 0.13)	0.994	WD

Regression Parameter Estimates: BD Vacutainer® Serum Glass Tubes vs. comparator tubes:

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
Beckman DxC 700 AU	C3 (mg/dL)	0.98 (0.96, 0.99)	1.26 (-0.47, 2.99)	0.995	WD
OCD Vitros 5600	C3 (mg/dL)	0.95 (0.92, 0.97)	3.43 (0.44, 6.78)	0.981	PB
Beckman DxC 700 AU	CKMB (U/L)	0.99 (0.94, 1.04)	-0.03 (-0.8, 0.74)	0.987	WD
Roche Cobas e411	CKMB (U/L)	1.01 (1, 1.03)	-0.01 (-0.06, 0.03)	1	WD
OCD Vitros 5600	CORT (nmol/L)	0.99 (0.98, 1)	0.35 (-0.91, 1.61)	0.998	WD
Roche Cobas e411	CORT (nmol/L)	0.99 (0.98, 1.01)	0.27 (-1.15, 1.68)	0.998	WD
Beckman DxC 700 AU	CRP (mg/L)	1 (0.99, 1)	0 (-0.02, 0.02)	0.998	PB
OCD Vitros 5600	CRP (mg/dL)	0.99 (0.97, 1)	0.08 (-0.1, -0.04)	0.979	PB
OCD Vitros 3600/5600	E2 (pmol/L)	1.02 (1, 1.03)	3.07 (-0.06, 5.88)	0.999	PB
Siemens Dimension Vista 1500	E2 (pg/mL)	1.02 (1, 1.03)	0.27 (-0.74, 1.28)	0.999	PB
OCD Vitros 3600/5600	FERR (ng/mL)	0.98 (0.97, 0.99)	-0.07 (-0.21, 0.07)	0.999	WD
Siemens Dimension Vista 1500	FERR (ng/mL)	1 (0.99, 1)	-0.04 (-0.17, 0.1)	1	WD
OCD Vitros 3600/5600	FOLATE (ng/mL)	0.97 (0.92, 1.01)	0.31 (-0.07, 0.7)	0.966	PB
Siemens Dimension Vista 1500	FOLATE (ng/mL)	0.98 (0.97, 1.01)	0.18 (-0.1, 0.45)	0.992	PB
OCD Vitros 3600/5600	FSH (mIU/mL)	0.99 (0.98, 1)	0.01 (-0.03, 0.04)	1	WD

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
Siemens Dimension Vista 1500	FSH (mIU/mL)	1 (0.99, 1.01)	0.03 (-0.02, 0.07)	1	WD
Roche cobas® Integra 400 Plus	HAPTO (g/L)	0.99 (0.98, 1)	1.35 (-0.03, 2.74)	0.998	WD
OCD Vitros 5600	HAPTO (mg/dL)	0.98 (0.96, 1)	1.87 (-1.36, 5.11)	0.993	WD
OCD Vitros 3600/5600	HCG (mIU/mL)	1 (0.99, 1.01)	0.02 (-0.09, 0.12)	0.999	WD
Siemens Dimension Vista 1500	HCG (mIU/mL)	1 (1, 1.01)	-0.01 (-0.11, 0.1)	1	WD
Beckman DxC 700 AU	IgA (mg/dL)	0.99 (0.99, 1)	0.83 (-0.88, 2.53)	0.999	WD
OCD Vitros 5600	IgA (mg/dL)	0.97 (0.96, 0.98)	1.43 (-0.2, 3.06)	0.998	WD
Beckman DxC 700 AU	IgG (mg/dL)	1 (0.98, 1.01)	3.18 (-8.72, 15.09)	0.994	WD
OCD Vitros 5600	IgG (mg/dL)	0.98 (0.96, 1)	-1.13 (-15.65, 13.38)	0.996	WD
OCD Vitros 5600	IgM (mg/dL)	0.99 (0.98, 1.01)	-0.74 (-1.86, 0.38)	0.997	WD
OCD Vitros 3600/5600	LH (mIU/mL)	1 (0.98, 1.01)	0 (-0.05, 0.05)	0.999	PB
Siemens Dimension Vista 1500	LH (mIU/mL)	1 (1, 1.01)	0 (-0.06, 0.1)	0.999	PB
OCD Vitros 5600	NT-proBNP (pg/mL)	0.99 (0.99, 1)	0.1 (-0.86, 1.06)	0.998	WD
Roche Cobas e411	NT-proBNP (pg/mL)	1 (1, 1.01)	-0.69 (-2.26, 0.89)	1	WD
OCD Vitros 3600/5600	PROG (nmol/L)	1.04 (1.03, 1.05)	-0.01 (-0.05, 0.01)	1	PB
Siemens Dimension Vista 1500	PROG (ng/mL)	1.03 (1.01, 1.04)	0 (-0.01, 0.01)	1	PB
OCD Vitros 5600	TPSA (ng/mL)	1 (0.98, 1)	0 (0, 0.01)	0.987	PB
Roche Cobas e411	TPSA (ng/mL)	1 (0.99, 1.01)	0 (0, 0)	1	PB
Beckman DxC 700 AU	RF (IU/mL)	1.01 (0.98, 1.03)	-0.27 (-0.71, 0.17)	0.996	WD
OCD Vitros 5600	RF (IU/mL)	1 (0.98, 1.02)	-0.24 (-0.89, 0.42)	1	WD

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
Beckman Access 2	Total T3 (ng/mL)	1.09 (0.99, 1.19)	-0.07 (-0.13, 0)	0.974	WD
Roche Cobas e411	Total T3 (nmol/L)	1.01 (0.96, 1.06)	-0.02 (-0.09, 0.04)	0.975	WD
OCD Vitros 3600/5600	Free T3 (pmol/L)	0.98 (0.94, 1.02)	0.1 (-0.14, 0.36)	0.961	PB
Siemens Dimension Vista 1500	Free T3 (pg/mL)	1.01 (0.98, 1.03)	0.01 (-0.06, 0.08)	0.994	WD
OCD Vitros 3600/5600	Total T4 (nmol/L)	1.02 (1, 1.04)	-0.82 (-2.76, 1.12)	0.994	WD
Siemens Dimension Vista 1500	Total T4 (µg/dL)	1.01 (0.98, 1.07)	-0.09 (-0.57, 0.24)	0.978	PB
Beckman Access2	Free T4 (ng/dL)	0.99 (0.96, 1.02)	0 (-0.03, 0.03)	0.986	WD
Roche Cobas e411	Free T4 (ng/dL)	1 (0.98, 1.02)	0 (-0.02, 0.02)	0.994	WD
OCD Vitros 5600	TESTO (nmol/L)	1.01 (1, 1.03)	0 (-0.01, 0.01)	0.999	PB
Roche Cobas e411	TESTO (ng/mL)	1 (0.99, 1)	0.01 (0, 0.01)	0.999	PB
Roche cobas® Integra 400 Plus	TRF (mg/L)	1 (0.97, 1.02)	2.86 (-3.29, 9.01)	0.992	WD
OCD Vitros 5600	TRF (mg/dL)	1 (0.99, 1.02)	-3.64 (-6.31, -0.96)	0.997	WD
OCD Vitros 3600/5600	TSH (µIU/mL)	1 (0.99, 1.01)	0 (-0.01, 0.01)	1	PB
Siemens Dimension Vista 1500	TSH (µIU/mL)	1.01 (0.99, 1.02)	-0.01 (-0.02, 0.01)	1	PB
Beckman Access2	TnI (ng/mL)	1.03 (1, 1.04)	0 (0, 0.01)	0.997	PB
Roche Cobas e411	TnI (ng/mL)	1.25 (1.15, 1.35)	-0.03 (-0.07, 0.01)	0.99	WD
Roche Cobas e411/e601	TnT (ng/L)	1.02 (1, 1.05)	-0.22 (-0.77, 0.34)	1	WD
OCD Vitros 3600/5600	VIT B12 (pg/mL)	1.02 (0.98, 1.07)	-4.29 (-14.2, 5.63)	0.978	WD
Siemens Dimension Vista 1500	VIT B12 (pg/mL)	1 (0.98, 1.02)	-2.28 (-10.18, 5.62)	0.997	WD
Beckman Access2	VIT D (ng/mL)	1.01 (0.99, 1.03)	-0.23 (-0.63, 0.17)	0.997	WD

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
ADVIA Centaur XPT	hsTnI (pg/mL)	0.99 (0.95, 1.02)	-0.22 (-0.48, 0.44)	0.998	WD
Beckman Access2	hsTnI (pg/mL)	1 (0.98, 1.02)	-0.06 (-0.24, 0.13)	0.997	WD

Regression Parameter Estimates: BD Vacutainer® RST™ vs. comparator tubes:

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
Beckman Coulter DxC 700 AU	C3 (mg/dL)	1 (0.99, 1.01)	-0.95 (-2.56, 0.66)	0.998	WD
OCD Vitros 5600	C3 (mg/dL)	1 (0.97, 1.02)	0 (-2.06, 3.25)	0.987	PB
Beckman Coulter DxC 700 AU	CKMB (U/L)	1.01 (0.98, 1.04)	-0.56 (-1.16, 0.05)	0.994	WD
Roche cobas® e411	CKMB (U/L)	1.02 (0.99, 1.04)	-0.03 (-0.07, 0.02)	0.999	WD
OCD Vitros 5600	CORT (nmol/L)	1 (0.99, 1.01)	0.88 (-0.54, 2.3)	0.998	WD
Roche cobas® e411	CORT (nmol/L)	1 (0.99, 1.01)	-0.03 (-0.7, 0.65)	0.998	WD
Beckman Coulter DxC 700 AU	CRP (mg/L)	1 (0.99, 1.01)	-0.01 (-0.03, 0.01)	0.999	PB
OCD Vitros 5600	CRP (mg/dL)	1 (0.99, 1)	0 (-0.1, 0.01)	0.999	PB
OCD Vitros 3600/5600	E2 (pmol/L)	1.05 (1.03, 1.06)	7.8 (4.78, 10.87)	0.999	PB
Siemens Dimension Vista 1500	E2 (pg/mL)	1.01 (1, 1.02)	0.49 (-0.57, 1.45)	0.999	PB
OCD Vitros 3600/5600	FERR (ng/mL)	1.01 (1, 1.02)	0.03 (-0.09, 0.16)	0.999	WD
Siemens Dimension Vista 1500	FERR (ng/mL)	1 (0.99, 1.01)	0.13 (-0.06, 0.33)	1	WD
OCD Vitros 3600/5600	FOLATE (ng/mL)	0.97 (0.93, 1.01)	-0.14 (-0.48, 0.19)	0.98	PB
Siemens Dimension Vista 1500	FOLATE (ng/mL)	1 (0.98, 1.03)	-0.1 (-0.37, 0.21)	0.991	PB
OCD Vitros 3600/5600	FSH (mIU/mL)	0.97 (0.96, 0.98)	-0.04 (-0.07, -0.01)	1	WD

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
Siemens Dimension Vista 1500	FSH (mIU/mL)	0.9 (0.99, 1)	0.05 (0.01, 0.09)	1	WD
Roche cobas® Integra 400 Plus	HAPTO (g/L)	0.99 (0.95, 1.02)	1.15 (-3.48, 5.78)	0.999	WD
OCD Vitros 5600	HAPTO (mg/dL)	1.01 (0.99, 1.02)	-0.86 (-3.13, 1.4)	0.997	WD
OCD Vitros 3600/5600	β-hCG (mIU/mL)	1 (0.99, 1)	-0.11 (-0.23, 0.01)	1	WD
Siemens Dimension Vista 1500	β-hCG (mIU/mL)	1 (0.99, 1.01)	0.05 (-0.04, 0.14)	0.999	WD
Beckman Coulter DxC 700 AU	IgA (mg/dL)	0.99 (0.99, 1)	0.49 (-0.19, 1.17)	0.999	WD
OCD Vitros 5600	IgA (mg/dL)	1.01 (0.99, 1.02)	-0.38 (-1.89, 1.12)	0.998	WD
Beckman Coulter DxC 700 AU	IgG (mg/dL)	0.98 (0.96, 0.99)	16.39 (-1.04, 33.82)	0.995	WD
OCD Vitros 5600	IgG (mg/dL)	1.01 (0.99, 1.02)	-3.3 (-17.28, 10.69)	0.996	WD
Beckman Coulter DxC 700 AU	IgM (mg/dL)	1 (0.99, 1.01)	0.21 (-0.61, 1.03)	1	WD
OCD Vitros 5600	IgM (mg/dL)	1.01 (1, 1.03)	-0.63 (-1.82, 0.56)	1	WD
OCD Vitros 3600/5600	LH (mIU/mL)	0.96 (0.95, 0.96)	-0.04 (-0.09, -0.02)	1	PB
Siemens Dimension Vista 1500	LH (mIU/mL)	1 (0.99, 1)	0.01 (-0.06, 0.04)	1	PB
OCD Vitros 5600	NT-proBNP (pg/mL)	1.01 (1, 1.01)	-0.49 (-1.34, 0.35)	1	WD
Roche cobas® e411	NT-proBNP (pg/mL)	1.01 (1, 1.02)	-0.04 (-2.05, 1.97)	0.998	WD
OCD Vitros 3600/5600	PROG (nmol/L)	1.04 (1.03, 1.05)	0.05 (0.02, 0.08)	1	PB
Siemens Dimension Vista 1500	PROG (ng/mL)	1 (0.99, 1.01)	-0.01 (-0.03, 0)	1	PB
OCD Vitros 5600	TPSA (ng/mL)	1 (0.99, 1.02)	0.03 (0.01, 0.04)	1	PB

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
Roche cobas® e411	TPSA (ng/mL)	1 (0.99, 1)	0 (0, 0.01)	1	PB
Beckman Coulter DxC 700 AU	RF (IU/mL)	1.02 (1, 1.04)	-0.3 (-0.7, 0.11)	0.997	WD
OCD Vitros 5600	RF (IU/mL)	1.01 (0.99, 1.03)	-0.18 (-0.7, 0.34)	0.998	WD
Beckman Coulter Access 2	Total T3 (ng/mL)	1.02 (0.99, 1.05)	0.01 (-0.01, 0.03)	0.979	WD
Roche cobas® e411	Total T3 (nmol/L)	0.97 (0.91, 1.02)	0.03 (-0.05, 0.11)	0.973	WD
OCD Vitros 3600/5600	Free T3 (pmol/L)	0.97 (0.93, 1.01)	0.23 (-0.03, 0.46)	0.958	PB
Siemens Dimension Vista 1500	Free T3 (pg/mL)	1 (0.97, 1.03)	-0.02 (-0.1, 0.05)	0.995	WD
OCD Vitros 3600/5600	Total T4 (nmol/L)	1.01 (0.99, 1.03)	-1.9 (-4.21, 0.41)	0.994	WD
Siemens Dimension Vista 1500	Total T4 (µg/dL)	1.04 (1, 1.08)	-0.38 (-0.74, 0)	0.984	PB
Beckman Coulter Access 2	Free T4 (ng/dL)	0.99 (0.95, 1.04)	-0.01 (-0.05, 0.04)	0.982	WD
Roche cobas® e411	Free T4 (ng/dL)	0.99 (0.97, 1.02)	0.01 (-0.02, 0.03)	0.992	WD
OCD Vitros 5600	TESTO (nmol/L)	1.09 (1.07, 1.1)	0.04 (0.01, 0.06)	0.998	PB
Roche cobas® e411	TESTO (ng/mL)	1 (0.99, 1.01)	-0.01 (-0.02, 0)	0.999	PB
Roche cobas® Integra 400 Plus	TRF (mg/L)	0.97 (0.94, 0.99)	8.08 (0.86, 15.3)	0.994	WD
OCD Vitros 5600	TRF (mg/dL)	1.02 (1, 1.04)	-3.73 (-7.09, -0.37)	0.995	WD
OCD Vitros 3600/5600	TSH (µIU/mL)	1.01 (1, 1.02)	0 (0, 0.01)	1	PB
Siemens Dimension Vista 1500	TSH (µIU/mL)	0.99 (0.99, 1)	0 (-0.01, 0.01)	1	PB
Beckman Coulter Access 2	TnI (ng/mL)	1 (0.98, 1)	0 (0, 0)	0.998	PB

Instrument	Analyte (unit)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient	Regression
Roche cobas® e411	TnI (ng/mL)	1.11 (1.03, 1.2)	-0.02 (-0.07, 0.02)	0.996	WD
Roche cobas® e411/e601	TnT (ng/L)	1.01 (0.98, 1.04)	-0.11 (-0.95, 0.74)	0.999	WD
OCD Vitros 3600/5600	VIT B12 (pg/mL)	1.02 (1.01, 1.03)	-3 (-5.96, -0.04)	0.999	WD
Siemens Dimension Vista 1500	VIT B12 (pg/mL)	1 (0.98, 1.02)	-1.41 (-11, 8.18)	0.998	WD
Beckman Coulter Access 2	VIT D (ng/mL)	1.01 (0.99, 1.04)	-0.21 (-0.67, 0.25)	0.996	WD
Roche cobas® e411	VIT D (ng/mL)	1.02 (0.99, 1.06)	-0.48 (-1.28, 0.32)	0.991	WD
Siemens ADVIA Centaur XPT	hsTnI (pg/mL)	0.99 (0.97, 1.01)	-0.15 (-0.32, 0.01)	0.999	WD
Beckman Coulter Access 2	hsTnI (pg/mL)	1.01 (0.99, 1.03)	-0.01 (-0.16, 0.13)	0.997	WD

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.