

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

I Background Information:

A 510(k) Number

K213670

B Applicant

Becton Dickinson and Company

C Proprietary and Established Names

BD Vacutainer K2EDTA Blood Collection Tubes, BD Vacutainer K3EDTA Blood Collection Tubes

D Regulatory Information

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

II Submission/Device Overview:

A Purpose for Submission:

Modifications to existing blood collection devices

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 EDTA 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, preservation, and transport of human venous blood specimens used for in vitro diagnostic testing.

BD Vacutainer K2EDTA and K3EDTA Blood Collection Tubes are used for testing in hematology including white blood cells (WBC), red blood cells (RBC), red blood cell distribution width (RDW), hemoglobin (Hgb), hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), platelets, and 5-part white blood cell (WBC) differential counts (neutrophils, lymphocytes, monocytes, eosinophils, basophils).

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

Not applicable.

IV Device/System Characteristics:

A Device Description:

BD Vacutainer K₂EDTA Blood Collection Tubes and BD Vacutainer K₃EDTA Blood Collection Tubes are for collecting, transporting, and centrifuging blood. The blood collection tube consists of a closure assembly (Vacutainer Hemogard Closure), a plastic (for BD Vacutainer K₂EDTA) or glass tube (for BD Vacutainer K₃EDTA) and EDTA additive (dipotassium or tri-potassium). The EDTA anticoagulant is either spray coated in the dipotassium (K₂) form or added as a liquid in the tri-potassium (K₃) form. The EDTA additive prevents specimen coagulation.

SKU #	Product Family	Tube Material	Tube Size (mm)	Draw Volume (mL)	Closure Type
367841	K2EDTA	Plastic	13x75	2	Hemogard
367856	K2EDTA	Plastic	13x75	3	Hemogard
367861	K2EDTA	Plastic	13x75	4	Hemogard
367862	K2EDTA	Plastic	13x75	4	Hemogard
367863	K2EDTA	Plastic	13x100	6	Hemogard
366643	K2EDTA	Plastic	16x100	10	Hemogard
366450	K3EDTA	Glass	13x100	7	Conventional

The tube is manufactured from either plastic (Polyethylene terephthalate, PET) or glass. The standard closure assembly is a basic rubber stopper. The tube is also available with the Vacutainer Hemogard Closure Assembly which consists of a rubber stopper and protective plastic shield to reduce user exposure to blood. All stopper/closures are color coded to reflect additive type. The closures included in this submission are either pink or lavender to indicate the presence of EDTA additive.

B Principle of Operation:

The BD Vacutainer K2EDTA Blood Collection Tubes are plastic, evacuated, and sterile (2 to 10 mL) tubes. The interior of the tube wall is spray coated with K2EDTA which binds calcium ions thus blocking the coagulation cascade.

The BD Vacutainer K3EDTA Blood Collection Tubes are glass, evacuated, sterile with large sample volume (7 mL) tubes. The interior of the tube wall is coated with liquid K3EDTA which binds calcium ions thus blocking the coagulation cascade.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Vacutainer Brand Plus Tube with EDTA Anticoagulant

B Predicate 510(k) Number(s):

K981013

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K213670</u>	<u>K981013</u>	<u>Reference Device Pre-Amendment Device</u>
Device Trade Name	BD Vacutainer K2EDTA and K3EDTA Blood Collection Tubes	Vacutainer Brand Plus Tube with EDTA Anticoagulant	BD Vacutainer K3EDTA Blood Collection Tube
General Device Characteristic Similarities			
Indications For Use	BD Vacutainer EDTA 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, preservation, and transport of human venous blood specimens	Blood collected in PLUS EDTA and PLUS Serum tubes can be used for immunohematology testing including ABO grouping, Rh grouping, and antibody screening which requires red cells and plasma or serum	BD Vacutainer K3EDTA Blood Collection Tubes are intended for the collection of a plasma specimen in a closed evacuated system, The tube may be used for in vitro diagnostic testing for chemistry and hematology determinations in plasma or whole blood.

	used for in vitro diagnostic testing. BD Vacutainer K2EDTA and K3EDTA Blood Collection Tubes are used for testing in hematology such as white blood cells (WBC), red blood cells (RBC), red bloodcell distribution width (RDW), hemoglobin (Hgb), hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), platelets, and 5-part white blood cell (WBC) differential counts (neutrophils, lymphocytes, monocytes, eosinophils, basophils).		
Evacuated Blood Collection Tube	Yes	Yes	Yes
Additive Type	K2EDTA, K3EDTA	K2EDTA	K3EDTA
Stopper Fabrication	Compression Molded Rubber	Same	Same
Hemogard Shield Fabrication	Injection Molded Plastic	Same	N/A
Tube Evacuation	Vacuum Chamber	Same	Same
Unit Labeling	Printer paper label	Printer paper label or printed on tube	Printer paper label
Sterilization Method	Gamma Irradiation	Same	Same
Sterility Assurance Level (SAL)	$\leq 10^{-3}$	Same	Same
General Device Characteristic Differences			
Intended Use	Blood Collection for hematology	Blood Collection for hematology and Immunohematology	Blood Collection for Chemistry and hematology
Additive Concentration	1.8 mg/mL(K2EDTA), 1.7 mg/mL (K3EDTA)	1.8 mg/mL	1.2–4 mg/mL
Tube Dimensions (mm)	13x75, 13x100, 16x100	13x75	13x100

Draw Volume	2, 3, 4, 6, 7, 10 mL	6 mL	2, 3, 5, 7, 10, 20 mL
Tube Material	Plastic (K2EDTA), Glass (K3EDTA)	Plastic	Glass
Tube Closure	Vacutainer Hemogard Closure	Conventional or Vacutainer Hemogard Closure	Conventional
Shelf Life	10 months depending on the tube volume	15–24 months	12 months
Additive Dispense	Spray Dry (K2EDTA), Liquid Fill (K3EDTA)	Spray Dry (K2EDTA)	Liquid Fill (K3EDTA)

VI Standards/Guidance Documents Referenced:

- CLSI GP34-A, Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guidance.
- CLSI GP39-A6, Tubes and Additives for Venous Blood Specimen Collection; Approved Standard – Sixth Edition.
- CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems
- ANSI/AAMI/ISO 11137-1:2006, A1: 2013, A2 2018 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ANSI/AAMI/ISO 11137-2: 2013 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"
- EN ISO 14971:2012 Medical Devices – Application of risk management to medical devices

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

This study was conducted to evaluate the performance of BD Vacutainer K2EDTA Blood Collection Tubes (6 mL) with Hemogard closure (Evaluation) compared to Greiner Bio-One Vacuette K2EDTA (6 mL) (Comparator) and to BD Vacutainer Royal Blue K2EDTA Tubes (6 mL) with Hemogard closure (without thiuram curing agent) for repeatability, lot-to-lot and

tube-to-tube variation using selected hematology parameters (white blood cells (WBC), red blood cells (RBC), red blood cell distribution width (RDW), hemoglobin (Hgb), hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), and platelets). This study was conducted at one single site. Blood from twenty subjects was collected into the study tubes, which consisted of three lots of each tube type. Samples were tested for the hematology parameters within 4 hours of collection at room temperature on the Beckman Coulter LH750 and Sysmex XE 2100. Performance of the BD Vacutainer K2EDTA Blood Collection Tubes with Hemogard closure for between-lot variation and between-tube variation showed non-inferiority for all tube comparisons for the hematology parameters tested on two instrument platforms when compared with the comparator device.

Variance Components and Confidence Intervals (CI): Beckman Coulter LH750

Analyte	Mean	Variance Component	SD (95% CI)	CV (95% CI)
HCT (%)	42.331	Between-Lot	0.084 (0, 0.154)	0.2% (0.0%, 0.5%)
		Between-Tube	0.13 (0, 0.255)	0.3% (0.0%, 0.6%)
		Within-Tube	0.296 (0.254, 0.326)	0.7% (0.6%, 0.8%)
		Total	0.335 (0.254, 0.441)	0.8% (0.6%, 1.1%)
HGB (g/dL)	14.086	Between-Lot	0.055 (0.032, 0.08)	0.4% (0.2%, 0.5%)
		Between-Tube	0.039 (0, 0.064)	0.3% (0.0%, 0.5%)
		Within-Tube	0.076 (0.066, 0.085)	0.5% (0.5%, 0.6%)
		Total	0.102 (0.073, 0.133)	0.7% (0.5%, 0.9%)
MCH (pg)	28.984	Between-Lot	0.022 (0, 0.099)	0.0% (0.0%, 0.3%)
		Between-Tube	0.065 (0, 0.117)	0.2% (0.0%, 0.4%)
		Within-Tube	0.199 (0.175, 0.221)	0.7% (0.6%, 0.8%)
		Total	0.21 (0.175, 0.268)	0.7% (0.6%, 0.9%)
MCHC (g/dL)	33.269	Between-Lot	0.047 (0, 0.13)	0.1% (0.0%, 0.4%)
		Between-Tube	0.037 (0, 0.147)	0.1% (0.0%, 0.4%)
		Within-Tube	0.277 (0.24, 0.301)	0.8% (0.7%, 0.9%)
		Total	0.284 (0.24, 0.36)	0.8% (0.7%, 1.1%)
MCV (fL)	87.047	Between-Lot	0 (0, 0.168)	0.0% (0.0%, 0.1%)
		Between-Tube	0.066 (0, 0.206)	0.1% (0.0%, 0.2%)
		Within-Tube	0.376 (0.322, 0.404)	0.4% (0.4%, 0.5%)
		Total	0.382 (0.322, 0.484)	0.4% (0.4%, 0.5%)
MPV (fL)	8.97	Between-Lot	0.02 (0, 0.069)	0.2% (0.0%, 0.7%)
		Between-Tube	0.063 (0, 0.103)	0.7% (0.0%, 1.1%)
		Within-Tube	0.118 (0.103, 0.132)	1.2% (1.1%, 1.4%)
		Total	0.135 (0.103, 0.181)	1.4% (1.1%, 1.9%)
PLT (10 ³ /μL)	246.58	Between-Lot	1.75 (0, 3.45)	0.2% (0.0%, 1.1%)
		Between-Tube	3.16 (1.72, 4.3)	1.2% (0.5%, 1.7%)
		Within-Tube	4.25 (3.69, 4.85)	1.9% (1.6%, 2.1%)
		Total	5.58 (4.07, 7.35)	2.3% (1.7%, 2.9%)
RBC (10 ⁶ /μL)	4.8866	Between-Lot	0.011 (0, 0.0179)	0.3% (0.0%, 0.4%)
		Between-Tube	0.0128 (0, 0.0222)	0.3% (0.0%, 0.4%)
		Within-Tube	0.0256 (0.0222, 0.0287)	0.5% (0.4%, 0.6%)
		Total	0.0307 (0.0222, 0.0404)	0.6% (0.4%, 0.8%)

RDW (%)	13.288	Between-Lot	0 (0, 0.057)	0.0% (0.0%, 0.5%)
		Between-Tube	0 (0, 0.073)	0.0% (0.0%, 0.6%)
		Within-Tube	0.168 (0.144, 0.182)	1.3% (1.1%, 1.4%)
		Total	0.168 (0.144, 0.204)	1.3% (1.1%, 1.6%)
WBC (10 ³ /μL)	6.306	Between-Lot	0.084 (0.041, 0.123)	1.6% (0.9%, 2.1%)
		Between-Tube	0.092 (0.071, 0.114)	1.2% (0.9%, 1.5%)
		Within-Tube	0.059 (0.051, 0.066)	1.0% (0.8%, 1.1%)
		Total	0.138 (0.096, 0.18)	2.2% (1.5%, 2.8%)

Variance Components and Confidence Intervals (CI): Sysmex XE 2100

Analyte	Mean	Variance Component	SD (95% CI)	CV (95% CI)
HCT (%)	42.34	Between-Lot	0.19 (0.11, 0.28)	0.5% (0.3%, 0.7%)
		Between-Tube	0 (0, 0.15)	0.0% (0.0%, 0.2%)
		Within-Tube	0.28 (0.25, 0.31)	0.7% (0.6%, 0.7%)
		Total	0.34 (0.27, 0.44)	0.8% (0.6%, 1.0%)
HGB (g/dL)	14.11	Between-Lot	0.05 (0.03, 0.07)	0.4% (0.2%, 0.5%)
		Between-Tube	0.03 (0.01, 0.05)	0.2% (0.0%, 0.3%)
		Within-Tube	0.06 (0.05, 0.07)	0.4% (0.4%, 0.5%)
		Total	0.08 (0.06, 0.11)	0.6% (0.4%, 0.8%)
MCH (pg)	29.23	Between-Lot	0.01 (0, 0.09)	0.0% (0.0%, 0.3%)
		Between-Tube	0 (0, 0.05)	0.0% (0.0%, 0.1%)
		Within-Tube	0.22 (0.19, 0.23)	0.7% (0.7%, 0.8%)
		Total	0.22 (0.19, 0.25)	0.7% (0.7%, 0.9%)
MCHC (g/dL)	33.32	Between-Lot	0.07 (0, 0.13)	0.2% (0.0%, 0.3%)
		Between-Tube	0 (0, 0.05)	0.0% (0.0%, 0.4%)
		Within-Tube	0.24 (0.21, 0.26)	0.7% (0.6%, 0.8%)
		Total	0.25 (0.21, 0.3)	0.7% (0.6%, 0.9%)
MCV (fL)	87.65	Between-Lot	0.13 (0.08, 0.17)	0.1% (0.1%, 0.2%)
		Between-Tube	0.04 (0, 0.08)	0.0% (0.0%, 0.1%)
		Within-Tube	0.12 (0.11, 0.14)	0.1% (0.1%, 0.2%)
		Total	0.18 (0.14, 0.24)	0.2% (0.2%, 0.3%)
MPV (fL)	10.88	Between-Lot	0.04 (0, 0.08)	0.4% (0.0%, 0.7%)
		Between-Tube	0.04 (0, 0.08)	0.3% (0.0%, 0.6%)
		Within-Tube	0.12 (0.1, 0.13)	1.1% (1.0%, 1.2%)
		Total	0.13 (0.1, 0.17)	1.2% (1.0%, 1.5%)
PLT (10 ³ /μL)	237.6	Between-Lot	3.3 (1.9, 4.6)	1.4% (0.7%, 2.0%)
		Between-Tube	0 (0, 0)	0.0% (0.0%, 1.2%)
		Within-Tube	5.3 (4.7, 5.7)	2.3% (2.0%, 2.5%)
		Total	6.2 (5.1, 7.3)	2.7% (2.1%, 3.4%)
RBC (10 ⁶ /μL)	4.856	Between-Lot	0.019 (0.007, 0.025)	0.4% (0.2%, 0.6%)
		Between-Tube	0 (0, 0.018)	0.0% (0.0%, 0.4%)
		Within-Tube	0.034 (0.029, 0.037)	0.7% (0.6%, 0.7%)
		Total	0.039 (0.03, 0.048)	0.8% (0.6%, 1.0%)
RDW (%)	13.16	Between-Lot	0.01 (0, 0.03)	0.1% (0.0%, 0.2%)
		Between-Tube	0 (0, 0.01)	0.0% (0.0%, 0.2%)
		Within-Tube	0.06 (0.05, 0.06)	0.5% (0.4%, 0.5%)

		Total	0.06 (0.05, 0.07)	0.5% (0.4%, 0.6%)
RDWSD	42.03	Between-Lot	0.07 (0, 0.12)	0.2% (0.0%, 0.3%)
		Between-Tube	0 (0, 0)	0.0% (0.0%, 0.2%)
		Within-Tube	0.2 (0.18, 0.22)	0.5% (0.4%, 0.5%)
		Total	0.21 (0.18, 0.25)	0.5% (0.4%, 0.6%)
WBC (10 ³ /μL)	5.889	Between-Lot	0.109 (0.06, 0.171)	1.9% (1.0%, 2.9%)
		Between-Tube	0.062 (0.009, 0.095)	0.8% (0.0%, 1.4%)
		Within-Tube	0.108 (0.093, 0.121)	2.0% (1.7%, 2.2%)
		Total	0.166 (0.111, 0.23)	2.8% (2.0%, 3.9%)

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

Not applicable.

4. Assay Reportable Range:

Not applicable.

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

Shelf-Life Stability

Shelf-life stability studies were conducted by using BD Vacutainer K2EDTA and K3EDTA Blood Collection Tubes at 12 months and 11 months from date of manufacture, respectively, comparing with BD Vacutainer K2EDTA and K3EDTA Blood Collection tubes that were recently manufactured. The studies were conducted by testing selected routine hematology parameters. Forty-eight apparently healthy subjects with 18 years of age or older were enrolled in this study. The results showed that the shelf-life for the BD Vacutainer K2EDTA and K3EDTA Blood Collection Tubes is 10 months when stored at 4–25 °C.

Within-Tube Stability

Within-tube stability was evaluated by using BD Vacutainer K2EDTA and K3EDTA Blood Collection Tubes for the routine hematology test parameters. Storage conditions included: 12 and 24 hours at room temperature (15–25°C), 24 and 48 hours stored refrigerated (2–8°C), and 48 hours storage at mixed temperatures (i.e., first 24 hours at room temperature and then refrigerated for an additional 24 hours). Fifty-seven apparently healthy subjects 18 years of age or older, were enrolled in this study. The within-tube stability showed that the samples are stable at 12 and 24 hours when stored at room temperature, 24 hours when stored refrigerated at 2–8°C, and 48 hours storage at mixed temperatures (i.e., first 24 hours at room temperature and then refrigerated at 2–8°C for an additional 24 hours).

Additional Bench Testing on the Candidate Device

Benchtop studies were conducted to assess X-value, stopper/shield separation, stopper leakage, tube leakage, and the trace metal content prior to blood draw. 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 Study:

The method comparison study was conducted at one clinical site including 101 subjects 18 years of age or older. Nine study tubes (three BD Vacutainer K2EDTA Blood Collection tubes, one BD Vacutainer K3DTA Blood Collection tube, three Greiner Bio One Vacuette K2EDTA tubes, one Greiner Bio-One Vacuette K3EDTA tube) were collected from each subject. Samples were tested for the routine hematology parameters (White Blood Cell Count, Red Blood Cell Count Hemoglobin, Hematocrit, Platelet count, Neutrophil%, Lymphocyte%, Monocyte %, Eosinophil% and Basophil %) on two platforms (Abbott-Cell Dyn Ruby and Sysmex XN 9100)). For each analyte on each platform, Deming or Passing Bablok Regression was used to estimate average differences between the evaluation tube (BD Vacutainer K2EDTA Blood Collection Tubes, BD Vacutainer K3EDTA Blood Collection Tubes) and the comparator tube (Greiner K2EDTA, Greiner K3EDTA) at medically relevant points for each analyte on each platform. The results are summarized in the following tables:

The following tube comparisons were performed for clinical equivalence:

- BD Vacutainer K2EDTA 2 mL vs 2 mL Greiner K2EDTA
- BD Vacutainer K2EDTA 6 mL vs 6 mL Greiner K2EDTA
- BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA

Regression Parameter Estimates – Abbott Cell-Dyn Ruby

Parameter	Comparison	N	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
WBC	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	94	0.06 (-0.08, 0.17)	0.99 (0.98, 1.02)	0.989
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	99	-0.1 (-0.23, 0.02)	1.02 (1, 1.04)	0.99
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	99	0.12 (-0.04, 0.26)	0.97 (0.95, 1)	0.987
RBC	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	95	-0.03 (-0.1, 0.05)	1.01 (0.99, 1.03)	0.87

Parameter	Comparison	N	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	99	0 (-0.05, 0.11)	1 (0.98, 1.02)	0.768
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	99	-0.12 (-0.29, -0.01)	1.03 (1, 1.07)	0.81
HGB	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	96	0 (-0.08, 0.25)	1 (0.98, 1.01)	0.903
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	100	0.14 (-0.02, 0.44)	0.99 (0.97, 1.01)	0.8
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	100	-0.21 (-0.74, -0.04)	1.01 (0.99, 1.06)	0.782
Hct	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	95	-0.3 (-1.22, 0.87)	1 (0.97, 1.03)	0.863
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	99	0.01 (-0.7, 1.13)	0.99 (0.97, 1.01)	0.747
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	99	-1.55 (-3.35, 0)	1.04 (0.99, 1.09)	0.8
PLT	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	96	3.32 (-2.89, 8.86)	0.99 (0.94, 1.01)	0.958
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	101	-2 (-7.06, 3)	1 (0.98, 1.03)	0.984
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	101	1.37 (-3.27, 6.55)	0.99 (0.97, 1.01)	0.977
NE %	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	89	0.82 (-0.43, 1.89)	0.99 (0.97, 1.01)	0.995
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	95	-0.29 (-1.4, 0.98)	1 (0.99, 1.02)	0.984
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	94	0 (-1.36, 1.26)	1 (0.98, 1.02)	0.994
LY %	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	95	0.59 (0.09, 1.05)	0.97 (0.95, 1)	0.988
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	99	-0.39 (-0.95, 0.08)	1.03 (1, 1.06)	0.973
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	99	0.14 (-0.2, 0.72)	0.99 (0.97, 1.01)	0.988
MO %	2 mL BD Vacutainer K2EDTA vs 2 mL	95	-0.03 (-0.41, 0.25)	1 (0.96, 1.06)	0.96

Parameter	Comparison	N	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
	Greiner K2EDTA				
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	97	-0.14 (-0.5, 0.15)	1.03 (0.99, 1.09)	0.965
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	96	0.11 (-0.27, 0.4)	1 (0.95, 1.05)	0.951
EO %	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	95	0.03 (-0.04, 0.07)	0.98 (0.94, 1.03)	0.991
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	100	-0.02 (-0.12, 0.06)	1.02 (0.97, 1.07)	0.984
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	100	0.01 (-0.05, 0.1)	1.01 (0.97, 1.04)	0.995
BA %	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	95	-0.04 (-0.14, 0.04)	1.03 (0.92, 1.15)	0.88
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	100	-0.05 (-0.18, 0.06)	1.07 (0.91, 1.22)	0.766
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	100	-0.02 (-0.11, 0.07)	0.92 (0.83, 1.01)	0.789
MCH	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	95	-0.56 (-1.73, 0.2)	1.02 (1, 1.06)	0.989
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	99	-0.34 (-1.01, 0.1)	1.01 (1, 1.04)	0.993
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	99	-0.1 (-1.03, 0.53)	1 (0.98, 1.03)	0.992
MCHC	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	95	0.2 (-2.41, 2.23)	1 (0.94, 1.08)	0.944
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	99	-1.36 (-3.57, 0.4)	1.05 (1, 1.12)	0.961
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	99	-0.1 (-1.97, 1.43)	1 (0.95, 1.06)	0.97
MCV	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	96	1.47 (-0.75, 4.37)	0.98 (0.95, 1)	0.994
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	101	1.25 (-0.5, 3.18)	0.98 (0.96, 1)	0.996
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	101	0 (-2.13, 1.19)	1 (0.99, 1.02)	0.996

Parameter	Comparison	N	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
MPV	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	96	0.52 (0.06, 0.97)	0.92 (0.85, 1)	0.944
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	101	-0.05 (-0.55, 0.48)	1 (0.93, 1.08)	0.924
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	101	-0.51 (-1.25, 0.17)	1.06 (0.97, 1.18)	0.832
RDW	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	96	-0.2 (-0.2, 0.35)	1 (0.96, 1)	0.995
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	101	0.15 (-0.1, 0.5)	0.98 (0.96, 1)	0.995
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	101	0 (-0.19, 0.42)	1 (0.97, 1.02)	0.993

Regression Parameter Estimates – Sysmex XN 9100™

Parameter	Comparison	Number of Pairs	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
WBC	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	95	-0.02 (-0.12, 0.06)	1 (0.99, 1.02)	0.99
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	101	-0.04 (-0.18, 0.05)	1.01 (1, 1.02)	0.999
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	101	0.03 (-0.07, 0.12)	0.98 (0.97, 1)	0.998
RBC	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	95	0 (-0.04, 0.05)	1 (0.99, 1.01)	0.992
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	101	0.03 (-0.03, 0.1)	1 (0.98, 1.01)	0.987
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	101	-0.03 (-0.09, 0.06)	1 (0.98, 1.02)	0.987
HGB	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	95	0.16 (-0.19, 0.51)	0.99 (0.96, 1.02)	0.992
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	101	0.3 (-0.1, 0.7)	0.97 (0.93, 1.01)	0.987
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	101	-0.1 (-0.3, 0.16)	1 (0.98, 1.03)	0.987
HCT	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	95	-0.2 (-0.73, 0.4)	1 (0.98, 1.01)	0.988

Parameter	Comparison	Number of Pairs	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	101	0.15 (-0.51, 0.77)	0.99 (0.97, 1.01)	0.985
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	101	-0.37 (-1.14, 0.41)	1 (0.98, 1.03)	0.987
PLT	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	95	0.16 (-4.39, 5.77)	1 (0.97, 1.02)	0.984
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	101	-2 (-7.95, 1.12)	1.01 (0.99, 1.04)	0.992
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	101	-0.76 (-5.24, 4.04)	0.99 (0.97, 1.01)	0.993
NE %	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	89	0.82 (-0.43, 1.89)	0.99 (0.97, 1.01)	0.996
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	95	-0.29 (-1.4, 0.98)	1 (0.99, 1.02)	0.997
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	94	0 (-1.36, 1.26)	1 (0.98, 1.02)	0.997
LY %	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	89	0.15 (-0.32, 0.62)	1 (0.98, 1.01)	0.995
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	95	-0.12 (-0.43, 0.18)	1 (0.99, 1.02)	0.998
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	94	-0.04 (-0.46, 0.38)	1 (0.98, 1.02)	0.996
MO %	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	89	-0.06 (-0.65, 0.54)	0.99 (0.93, 1.06)	0.967
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	94	-0.27 (-0.91, 0.38)	1.04 (0.96, 1.12)	0.976
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	93	-0.02 (-0.62, 0.59)	1.02 (0.95, 1.09)	0.972
EO %	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	88	0.05 (-0.13, 0.22)	0.97 (0.9, 1.05)	0.992
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	92	-0.03 (-0.16, 0.1)	1 (0.94, 1.06)	0.99
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	92	-0.05 (-0.16, 0.06)	1.03 (1, 1.07)	0.992
BA %	2 mL BD Vacutainer K2EDTA vs 2 mL	89	0.03 (-0.06, 0.13)	1 (0.83, 1.16)	0.859

Parameter	Comparison	Number of Pairs	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
	Greiner K2EDTA				
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	95	0.05 (-0.03, 0.12)	0.88 (0.73, 1.03)	0.87
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	95	-0.05 (-0.13, 0.04)	1.08 (0.91, 1.24)	0.85
MCH	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	95	-0.5 (-1.05, 0.04)	1.02 (1, 1.04)	0.993
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	101	0.08 (-0.43, 0.59)	1 (0.98, 1.01)	0.995
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	101	0.44 (-0.5, 1.39)	0.98 (0.95, 1.02)	0.993
MCHC	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	95	-0.68 (-1.92, 0.56)	1.03 (0.99, 1.07)	0.978
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	101	1.83 (0.25, 3.4)	0.95 (0.9, 1)	0.98
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	101	0.88 (-2.84, 4.59)	0.97 (0.86, 1.08)	0.97
MCV	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	95	0.75 (-0.71, 2.43)	0.98 (0.97, 1)	0.997
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	101	0.92 (-0.7, 2.34)	0.98 (0.97, 1)	0.997
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	101	-0.6 (-2.25, 0.2)	1.01 (1, 1.03)	0.997
MPV	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	91	0 (-0.45, 0.27)	1 (0.97, 1.05)	0.94
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	96	0 (-0.38, 0.06)	1 (1, 1.03)	0.952
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	97	0 (-0.68, 0.42)	1 (0.96, 1.06)	0.926
RDW	2 mL BD Vacutainer K2EDTA vs 2 mL Greiner K2EDTA	94	0.06 (-0.1, 0.23)	0.99 (0.98, 1.01)	0.998
	6 mL BD Vacutainer K2EDTA vs 6 mL Greiner K2EDTA	100	0.12 (-0.07, 0.3)	0.99 (0.98, 1)	0.999
	7 mL BD Vacutainer K3EDTA vs 6 mL Greiner K3EDTA	100	0 (-0.17, 0.16)	1 (0.99, 1.01)	0.998

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

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

A. Draw Volume Performance

The draw volume study is conducted to demonstrate functional draw volume performance of BD Vacutainer Blood Collection tube products to confirm retention of vacuum at time-zero and over shelf life. A sample size of n=90, evenly divided between each of the three product lots was collected at each test interval for each sterilization dose and storage condition. The results showed that the BD Vacutainer 2 mL, 3 mL, 4 mL, 6mL and 10 mL K2EDTA Blood Collection tube met the draw volume acceptance criteria for all intervals over 13 months of accelerated aging to support a shelf life of 11 months and the BD Vacutainer 7 mL K3EDTA Blood Collection tube met the draw volume acceptance criteria for all intervals over 13 months of accelerated aging to support a shelf life of 10 months.

B. Breakage Resistance During Drop and Centrifugation Testing

This study is conducted to demonstrate functional breakage resistance performance during drop testing for plastic tubes and during centrifugation for plastic and glass tubes.

Drop Breakage Resistance: The test article is filled, centrifuged, stored at frozen and refrigerated temperatures, and then dropped from a set height. Samples are subsequently inspected for breakage and leakage. A sample size of n=183, evenly divided between each of the 3 product lots, was collected at each test interval for each sterilization dose and storage condition.

Centrifugation Breakage Resistance: The test article is filled, centrifuged, and subsequently inspected for breakage and leakage. a sample size of n=300, evenly divided between each of the three products lots, was collected at each test interval for each sterilization dose and storage condition.

The results showed that the BD Vacutainer 2 mL, 3 mL, 4 mL, 6mL and 10 mL K2EDTA Blood Collection tube met the drop and centrifugation breakage acceptance criteria for all intervals over 13 months in real time to support the current claimed shelf life of 11 months and the BD Vacutainer 7 mL K3EDTA Blood Collection tube met the drop and

centrifugation breakage acceptance criteria for all intervals over 13 months in real time to support the current claimed shelf life of 10 months.

C. Stopper Pullout

Stopper Pullout testing is to demonstrate functional stopper performance in the event that the stopper is removed from the tube to access the sample and then reinserted. 90 samples were measured for First Stopper Pullout Force, and n=90 samples were measured for Needle Withdrawal Force. Results demonstrate that the force holding the stopper in the tube is greater than the force required to remove the collection needle from the stopper during sample collection. Second Stopper Pullout testing is to demonstrate functional stopper performance in the event that the stopper is removed from the tube to access the sample and then reinserted.

D. Ship Testing

This study was performed to evaluate packaging efficacy and safety during simulated shipping and handling conditions. Shipping and handling were simulated for temperature fluctuations, vibrations during shipping, and dropping. A sample size of at least n=30 shelf packs, evenly divided between each of the three products lots, was collected. The results showed that the BD Vacutainer 2 mL, 3 mL, 4 mL, 6mL and 10 mL K2EDTA Blood Collection tube and BD Vacutainer 7 mL K3EDTA Blood Collection tube met the Ship testing acceptance criteria. Results indicated no occurrence of damage from ship testing.

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.