



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

I Background Information:

A 510(k) Number

K240455

B Applicant

Becton Dickinson and Company

C Proprietary and Established Names

BD Vacutainer Citrate 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 tubes

B Measurand:

Not applicable to blood collection tube

C Type of Test:

Not applicable

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The BD Vacutainer Citrate Blood Collection Tube (0.109M buffered sodium citrate) is a sterile, single use tube used for the collection, containment, transport, and centrifugation of venous blood specimens to obtain plasma for in vitro diagnostic testing. It is used in settings where a venous blood sample is collected by a trained healthcare worker. The BD Vacutainer Citrate Blood Collection Tube is used for clinical laboratory testing in coagulation.

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 Citrate Blood Collection Tubes (BD Citrate Tubes) are for collection, containment, transport, and centrifugation of venous blood. The blood collection tube consists of a closure assembly (BD Hemogard Closure), a plastic configuration and a liquid additive (0.109 M buffered sodium citrate). The BD Citrate tubes are available with Hemogard Closure Assembly which consists of a rubber stopper and protective plastic shield to reduce user exposure to blood. The buffered sodium citrate solution prevents specimen coagulation. The tubes are compatible with the BD Vacutainer Blood Collection Needles, Blood Collection Sets, Transfer Devices, Holders, and Adaptors.

BD Citrate Tubes Configurations

SKU #	Product Family	Tube Material	Tube Size (mm)	Draw Volume (mL)	Tube Closure
363080	3.2% (0.109 M) Sodium Citrate	Plastic	13x75	1.8	Hemogard translucent shield with blue stopper
363083	3.2% (0.109 M) Sodium Citrate	Plastic	13x75	2.7	Hemogard light blue shield with blue stopper
366560	3.2% (0.109 M) Sodium Citrate	Plastic	13x75	2.7	Hemogard light blue shield with blue stopper

B Principle of Operation:

The BD Vacutainer Citrate Tubes are plastic, evacuated, and sterile (1.8 mL or 2.7 mL) tubes. The tubes contain a buffered sodium citrate used to anti-coagulate whole blood for hematological investigations. It acts as an extracorporeal anticoagulant by binding free calcium in the blood which is a necessary co-factor to several steps in the clotting/coagulation cascade. Anticoagulation with buffered sodium citrate is reversible with the addition of excess calcium.

The blood collected into the BD Vacutainer Citrate Tube are centrifuged and the plasma portion (containing the specimen) is analyzed for coagulation parameters.

V Substantial Equivalence Information:

A Predicate Device Name(s):

BD Vacutainer Safety Coagulation Tube

B Predicate 510(k) Number(s):

K013971

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K240455</u>	<u>K013971</u>
Device Trade Name	BD Vacutainer Citrate Blood Collection Tubes	BD Vacutainer Safety Coagulation Tube
General Device Characteristic Similarities		
Indications For Use	<p>The BD Vacutainer Citrate Blood Collection Tube (0.109M buffered sodium citrate) is a sterile, single use tube used for the collection, containment, transport, and centrifugation of venous blood specimens to obtain plasma for in vitro diagnostic testing. It is used in settings where a venous blood sample is collected by a trained healthcare worker. The BD Vacutainer Citrate Blood Collection Tube is used for clinical laboratory testing in coagulation.</p>	<p>BD Vacutainer Safety Coagulation tube is a plastic evacuated blood collection tube that provides a means of collecting, transporting and processing blood in a closed tube. The buffered sodium citrate additive provides an anticoagulated specimen that may be used for clinical laboratory coagulation assays. The benefits of a safety plastic coagulation tube with Hemogard Safety Closure Assembly are:</p> <ul style="list-style-type: none"> • Reduced risk of specimen tube breakage • Reduced exposure to blood by laboratory personnel and to minimize blood splatter during stopper removal. <p>These benefits lead to increased safety of laboratory personnel and reduced necessity of repeat</p>

Device & Predicate Device(s):	<u>K240455</u>	<u>K013971</u>
		specimen collection.
Evacuated Blood Collection Tube	Yes	Same
Test Type	Coagulation	Same
Tube Material	Inner Tube: Polypropylene Outer Tube: Polypropylene terephthalate	Same
Tube Size	13 x 75mm	Same
Draw Volume	1.8 mL or 2.7 mL	Same
Additive Type and Concentration	0.109 M (3.2%) Sodium Citrate (liquid) in 2.7 mL and 1.8 mL	2.7mL 0.109M (3.2%) Sodium Citrate (liquid), 1.8 mL 0.129M (3.2%) Sodium Citrate (liquid)
Closure Type/Color	2.7mL: Hemogard light blue cap and blue stopper 1.8mL: Hemogard Translucent cap and blue stopper	Same
Sterilization Method	Gamma Irradiation	Same
Sterility Assurance Level (SAL)	10 ⁻³	Same
Shelf-life	2.7 mL: 9 months 1.8 mL: 6 months	Same
General Device Characteristic Differences		
Tube Type of Material	Plastic	Plastic and Glass

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; Approved Guideline – Third Edition
- CLSI EP25, Evaluation of Stability of In Vitro Medical Laboratory Test Reagents, 2nd Edition.
- ANSI AAMI ISO 11137-1:2006/(R)2015 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013) and Amendment 2 (2019)].
- ANSI AAMI ISO 11137-2:2013/(R)2019 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".
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems.
- EN ISO 14971:2019 Medical Devices – Application of risk management to medical devices.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

The study was conducted to evaluate the clinical performance of BD Vacutainer Citrate Tubes (2.7 mL) for repeatability (within-tube), lot-to-lot and tube-to-tube variation in comparison with Greiner Bio-One Vacuette Citrate Tubes (2.7 mL) for selected coagulation parameters (PT, INR, aPTT, D-Dimer, and Anti-Factor Xa). Blood from sixty-five subjects was collected into the study tubes, which consisted of three lots of each tube type. Samples were tested for the coagulation parameters within 4 hours of collection at room temperature on the STA Compact Max, Sysmex CS-2500 and Instrumentation Laboratory ACL TOP 750. Performance of the BD Vacutainer Citrate Tubes for between-lot variation and between-tube variation showed non inferiority for all tube comparisons for the coagulation parameters tested on instrument platforms when compared with the comparator device.

Variance Components and Confidence Intervals (CI)

Instrument	Analyte	Tube Type	Source	Mean	SD (95% CI)	CV% (95% CI)
Stago STA Compact Max	D-Dimer (µg/mL FEU)	BD Citrate	Between-Lot	1.592	0.004 (0.000, 0.028)	0.0% (0.0%, 0.0%)
			Between-Tube	1.592	0.006 (0.000, 0.031)	0.0% (0.0%, 0.0%)
			Within-Tube	1.592	0.138 (0.127, 0.152)	8.4% (7.7%, 9.3%)
			Total	1.592	0.138 (0.107, 0.197)	8.4% (6.5%, 12.0%)
Stago STA Compact Max	D-Dimer (µg/mL FEU)	Greiner Citrate	Between-Lot	1.580	0.000 (0.000, 0.000)	0.0% (0.0%, 0.0%)
			Between- Tube	1.580	0.000 (0.000, 0.000)	0.0% (0.0%, 0.0%)
			Within-Tube	1.580	0.168 (0.154, 0.184)	8.9% (8.1%, 9.7%)
			Total	1.580	0.168 (0.129, 0.239)	8.9% (6.8%, 12.6%)
Sysmex CS-2500	D-Dimer (µg/mL FEU)	BD Citrate	Between-Lot	1.656	0.000 (0.000, 0.000)	1.6% (1.0%, 4.3%)
			Between- Tube	1.656	0.014 (0.000, 0.028)	1.5% (0.0%, 2.3%)
			Within-Tube	1.656	0.107 (0.098, 0.117)	3.6% (3.2%, 4.1%)
			Total	1.656	0.108 (0.083, 0.152)	4.2% (3.2%, 5.9%)
Sysmex CS-2500	D-Dimer (µg/mL FEU)	Greiner Citrate	Between-Lot	1.681	0.000 (0.000, 0.000)	0.0% (0.0%, 0.0%)
			Between- Tube	1.681	0.014 (0.000, 0.038)	0.6% (0.0%, 1.2%)
			Within-Tube	1.681	0.172 (0.158, 0.188)	4.3% (4.0%, 4.7%)
			Total	1.681	0.172 (0.133, 0.243)	4.4% (3.4%, 6.2%)

Instrument	Analyte	Tube Type	Source	Mean	SD (95% CI)	CV% (95% CI)
Stago STA Compact Max	INR	BD Citrate	Between-Lot	1.268	0.024 (0.021,0.031)	0.0% (0.0%, 0.0%)
			Between- Tube	1.268	0.022 (0.010, 0.029)	0.0% (0.0%, 0.0%)
			Within-Tube	1.268	0.034 (0.030, 0.038)	2.8% (2.6%, 3.1%)
			Total	1.268	0.047 (0.036, 0.065)	2.8% (2.2%, 4.0%)
Stago STA Compact Max	INR	Greiner Citrate	Between-Lot	1.260	0.012 (0.011, 0.016)	1.1% (0.7%, 2.0%)
			Between- Tube	1.260	0.015 (0.006, 0.020)	0.2% (0.0%, 1.0%)
			Within-Tube	1.260	0.024 (0.022, 0.027)	2.1% (1.9%, 2.4%)
			Total	1.260	0.031 (0.024, 0.043)	2.4% (1.9%, 3.4%)
Sysmex CS-2500	INR	BD Citrate	Between-Lot	1.309	0.007 (0.000, 0.019)	1.4% (1.0%, 2.4%)
			Between- Tube	1.309	0.000 (0.000, 0.000)	2.0% (1.6%, 2.3%)
			Within-Tube	1.309	0.089 (0.082, 0.098)	0.5% (0.4%, 0.5%)
			Total	1.309	0.089 (0.070, 0.125)	2.4% (1.9%, 3.4%)
Sysmex CS-2500	INR	Greiner Citrate	Between-Lot	1.298	0.021 (0.000, 0.035)	1.7% (1.3%, 2.3%)
			Between- Tube	1.298	0.000 (0.000, 0.000)	1.1% (0.9%, 1.3%)
			Within-Tube	1.298	0.069 (0.064, 0.076)	0.5% (0.5%, 0.6%)
			Total	1.298	0.072 (0.056, 0.101)	2.1% (1.6%, 2.9%)
Stago STA Compact Max	PT (sec)	BD Citrate	Between-Lot	15.73	0.00 (0.00, 0.00)	0.0% (0.0%, 0.0%)
			Between- Tube	15.73	0.01 (0.00, 0.07)	0.0% (0.0%, 0.0%)
			Within-Tube	15.73	0.39 (0.36, 0.43)	2.2% (2.0%, 2.4%)
			Total	15.73	0.39 (0.310.55)	2.2% (1.7%, 3.1%)
Stago STA Compact Max	PT (sec)	Greiner Citrate	Between-Lot	15.65	0.03 (0.00, 0.06)	0.8% (0.6%, 1.5%)
			Between- Tube	15.65	0.00 (0.00, 0.00)	0.1% (0.0%, 0.7%)
			Within-Tube	15.65	0.27 (0.25, 0.30)	1.6% (1.5%, 1.9%)
			Total	15.65	0.28 (0.21, 0.39)	1.8% (1.4%, 2.6%)
Sysmex CS-2500	PT (sec)	BD Citrate	Between-Lot	13.43	0.57 (0.50, 0.70)	0.2% (0.0%, 0.5%)
			Between- Tube	13.43	0.69 (0.57, 0.80)	0.1% (0.0%, 0.5%)
			Within-Tube	13.43	0.07 (0.06, 0.08)	2.1% (2.0%, 2.3%)
			Total	13.43	0.90 (0.70, 1.26)	2.1% (1.7%, 3.0%)
Sysmex CS-2500	PT (sec)	Greiner Citrate	Between-Lot	13.33	0.66 (0.53, 0.87)	1.6% (1.3%, 2.2%)
			Between- Tube	13.33	0.36 (0.29, 0.42)	1.0% (0.8%, 1.2%)
			Within-Tube	13.33	0.07 (0.07, 0.08)	0.5% (0.5%, 0.6%)
			Total	13.33	0.76 (0.59, 1.06)	2.0% (1.5%, 2.7%)
Stago STA Compact Max	aPTT (sec)	BD Citrate	Between-Lot	43.09	1.60 (0.99, 4.14)	0.1% (0.0%, 0.9%)
			Between- Tube	43.09	2.57 (1.93, 3.08)	0.5% (0.0%, 1.1%)
			Within-Tube	43.09	1.82 (1.62, 2.07)	4.1% (3.7%, 4.5%)
			Total	43.09	3.53 (2.72, 5.02)	4.1% (3.2%, 5.8%)
Stago STA Compact Max	aPTT (sec)	Greiner Citrate	Between-Lot	43.95	0.36 (0.00, 1.33)	0.0% (0.0%, 0.0%)
			Between- Tube	43.95	0.95 (0.00, 1.67)	1.3% (0.0%, 2.1%)
			Within-Tube	43.95	3.86 (3.54, 4.25)	5.0% (4.6%, 5.6%)
			Total	43.95	4.00 (3.09, 5.67)	5.2% (4.0%, 7.4%)
Sysmex CS-2500	aPTT (sec)	BD Citrate	Between-Lot	40.84	0.00 (0.00, 0.00)	0.0% (0.0%, 0.0%)
			Between- Tube	40.84	0.13 (0.00, 0.59)	0.0% (0.0%, 0.0%)
			Within-Tube	40.84	3.01 (2.77, 3.31)	3.9% (3.6%, 4.2%)
			Total	40.84	3.02 (2.34, 4.25)	3.9% (3.0%, 5.5%)
Sysmex CS-2500	aPTT (sec)	Greiner Citrate	Between-Lot	40.88	2.20 (1.64, 3.36)	1.0% (0.4%, NA)
			Between- Tube	40.88	2.27 (1.83, 2.63)	4.8% (3.9%, 5.5%)
			Within-Tube	40.88	0.50 (0.44, 0.56)	0.8% (0.7%, 0.9%)
			Total	40.88	3.20 (2.48, 4.51)	4.9% (3.8%, 7.0%)
IL TOP 750	Anti-Factor Xa (IU/mL)	BD Citrate	Between-Lot	0.474	0.000 (0.000, 0.000)	0.0% (0.0%, 0.0%)
			Between Tube	0.474	0.000 (0.000, 0.000)	0.3% (0.0%, 1.1%)
			Within-tube	0.474	0.021 (0.020, 0.023)	6.8% (6.3%, 7.4%)
			Total	0.474	0.021 (0.017, 0.028)	6.8% (5.5%, 8.9%)
			Between-Lot	0.471	0.000 (0.000, 0.000)	0.0% (0.0%, 0.0%)

Instrument	Analyte	Tube Type	Source	Mean	SD (95% CI)	CV% (95% CI)
IL TOP 750	Anti-Factor Xa (IU/mL)	Greiner Citrate	Between Tube	0.471	0.000 (0.000, 0.000)	0.0% (0.0%, 0.0%)
			Within-tube	0.471	0.023 (0.022, 0.025)	9.6% (9.0%, 10.4%)
			Total	0.471	0.023 (0.019, 0.030)	9.6% (7.8%, 12.7%)
Stago STA Compact Max	Anti-Factor Xa (IU/mL)	BD Citrate	Between-Lot	0.944	0.001 (0.000, 0.007)	0.1% (0.1%, 0.2%)
			Between Tube	0.944	0.000 (0.000, 0.000)	0.1% (0.0%, 1.7%)
			Within-tube	0.944	0.035 (0.032, 0.039)	3.7% (3.2%, 4.3%)
			Total	0.944	0.035 (0.026, 0.054)	3.7% (2.7%, 5.7%)
Stago STA Compact Max	Anti-Factor Xa (IU/mL)	Greiner Citrate	Between-Lot	0.936	0.011 (0.006, 0.036)	2.2% (1.5%, 4.1%)
			Between Tube	0.936	0.000 (0.000, 0.000)	0.0% (0.0%, 0.0%)
			Within-tube	0.936	0.027 (0.024, 0.03)	3.7% (3.4%, 4.2%)
			Total	0.936	0.029 (0.021, 0.044)	4.3% (3.2%, 6.7%)

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 Citrate Tubes at 7 months for 1.8 mL BD Citrate Tubes and at 10 months for 2.7 mL BD Citrate Tubes, respectively, comparing with BD Vacutainer Citrate Tubes that were near manufacture date (<30 days). The studies were conducted by testing selected routine coagulation parameters. Sixty-nine normal and abnormal samples (on anticoagulants) were included in this study. The results showed that the shelf-life for BD Citrate Tubes is 6 months (1.8 mL) and 9 months (2.7 mL) when stored at 4–25 °C.

Within-Tube Stability

Within-tube stability was evaluated by using BD Vacutainer Citrate Tubes stored at room temperature for routine coagulation parameters PT/INR, aPTT, Anti-Factor Xa and D-Dimer. Sixty normal and abnormal (on anticoagulants) samples were tested at time zero (t0), 4 hours, 8 hours measuring Anti-Factor Xa, D-Dimer, PT/INR, and aPTT; Sixty-eight normal and abnormal (on anticoagulants) samples were tested at 0, 16, and 24 hours measuring D-Dimer, INR, and PT. The BD Vacutainer Citrate Tubes results showed clinical equivalence of within-tube stability for PT/INR at 24 hours, D-Dimer at 16 hours, and aPTT, Anti-Factor Xa at 8 hours. All analytes tested at every time point were tested at room temperature (15-25 °C).

Additional Bench Testing on the Candidate Device

Benchtop studies were conducted to assess draw volume, X-value, stopper/shield separation, second stopper pullout, stopper leakage, tube leakage, drop testing, centrifugation, moisture loss, ship testing, 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 with Predicate Device:

The method comparison study was conducted at five clinical sites including 219 participants with 18 years of age or older. Fresh venous whole blood was collected into BD Vacutainer Citrate Tubes (BD Citrate) and Greiner Bio-One Vacuette Citrated Tubes (Greiner Citrate). Samples were tested for representative tests including, Prothrombin Time with International Normalized Ratio (PT/INR), Activated Partial Thromboplastin Time (aPTT), D-Dimer, and Anti-Factor Xa. An additional tube (Greiner K2EDTA) for hematocrit was drawn for study eligibility. Participant populations included healthy/normal participants, patients on oral anticoagulant therapy, and patients on unfractionated heparin. The study was tested on two platforms (Diagnostica Stago STA Compact Max and Instrumentation Laboratory ACL TOP). For each analyte on each platform, Deming or Passing-Bablok regression was used to estimate average differences between the evaluation tube (BD Citrate) and comparator (Greiner Citrate) tubes at the medically relevant points for each analyte on each platform. The results are summarized in the following table:

Regression Parameter Estimates: BD Citrate (2.7 mL) vs Greiner Citrate

Instrument	Analyte	Number of Pairs	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
IL TOP	Anti-Factor Xa	89	0 (0, 0)	1 (1, 1.03)	0.992
Stago	Anti-Factor Xa	82	0 (-0.01, 0.02)	1.02 (1, 1.03)	0.996
IL TOP	D-Dimer	78	-4.93 (-15.48, 5.63)	1.02 (0.98, 1.05)	0.999
Stago	D-Dimer	136	-0.01 (-0.04, 0.01)	1.04 (0.99, 1.09)	0.959
IL TOP	INR	193	-0.01 (-0.03, 0.01)	1.03 (1.01, 1.04)	0.996
Stago	INR	210	-0.03 (-0.05, -0.02)	1.03 (1.02, 1.04)	0.997
IL TOP	PT	193	-0.23 (-0.42, -0.04)	1.03 (1.02, 1.05)	0.997

Instrument	Analyte	Number of Pairs	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
Stago	PT	210	-0.5 (-0.68, -0.34)	1.03 (1.02, 1.04)	0.998
IL TOP	aPTT	193	0.69 (-0.2, 1.82)	0.97 (0.94, 1)	0.875
Stago	aPTT	208	0.23 (-0.29, 0.77)	0.97 (0.96, 0.99)	0.929

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 Citrate tube products to confirm retention of vacuum by comparing the results from the control at time zero (t0) to time points over the claimed 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 Citrate Tubes (2.7 mL and 1.8 mL) met the draw volume acceptance criteria for all intervals of accelerated aging to support a shelf life of 6 months (1.8 mL) and 9 months (2.7 mL).

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 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 three (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 (3) product lots, was collected at each test interval for each sterilization dose and storage condition.

The results showed that the BD Vacutainer Citrate Blood Collection tubes (1.8 mL and 2.7 mL) met the drop and centrifugation breakage acceptance criteria to support the current claimed shelf life of 9 months for the BD Vacutainer 2.7 mL Citrate Blood Collection and 6 months for the BD Vacutainer 1.8 mL Citrate Blood Collection tube.

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. The tests confirmed the acceptance criteria was met.

D. Ship Testing

Ship testing 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 (3) product lots, was collected. The result demonstrated that all tubes (1.8 mL and 2.7 mL) 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.