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

A. 510(k) Number:

k160657

B. Purpose for Submission:

New Device

C. Measurand:

Not applicable – blood collection system

D. Type of Test:

Not applicable

E. Applicant:

Becton, Dickinson and Company

F. Proprietary and Established Names:

BD Vacutainer® Barricor™ Lithium Heparin Plasma Blood Collection Tube

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1675 (Blood specimen collection devices)

2. Classification:

   Class II

3. Product code:

   JKA

4. Panel:

   75 (Chemistry)

H. Intended Use:

1. Intended use(s):

   See Indication for use below

2. Indication(s) for use:

   The BD Vacutainer® Barricor™ Lithium Heparin^{N} Plasma Blood Collection Tubes (BD Barricor™ Tubes) are used to collect, separate, process, transport and store venous blood samples for use in chemistry determinations, therapeutic drug monitoring (TDM), and zinc testing in plasma for in vitro diagnostic use. It is used in settings where a venous blood sample is collected by a trained healthcare worker.

3. Special conditions for use statement(s):

   Prescription use only.

   The BD Barricor™ Tube is not designed for use with fixed angle centrifuges. If spun in a fixed angle centrifuge, a barrier between the plasma and the cellular material will not be formed. The BD Barricor™ Tube is designed for use with swing bucket centrifuges.

   These blood collection tubes are not intended to be used to collect blood specimens for blood banking, immunohematology test, infectious disease, lithium, and Di (2-ethylhexyl) phthalate determination.

   The BD Barricor™ Tube is not designed for use with open blood collection systems (manual filling of tube with the BD Hemogard™ removed) due to the increased risk of exposure to blood borne pathogens. Blood should be collected directly into the tube or transfer devices should be used if blood is collected in a syringe.

4. Special instrument requirements:

   Specific analyzers used to evaluate the device are listed in the labeling and below in section M. 2. a. Method Comparison.

I. Device Description:

The BD Vacutainer® Barricor™ Lithium Heparin Plasma Blood Collection Tubes (BD Barricor™ Tube) are sterile (interior), single-use, evacuated blood collection tubes. The tubes are comprised of a plastic tube containing a mechanical separator (in place of gel), a low-zinc stopper and a plastic BD Hemogard™ color-coded lime green safety-engineered shield. The interior of the BD Barricor™ Tube is spray coated with lithium heparin anticoagulant. The tube stopper and mechanical separator are lubricated with silicone based surfactant. The tubes are available in 13 x 75mm and 13 x 100mm configurations with draw volumes from 3.0 to 5.5 mL. The BD Barricor™ Tube is designed to be compatible with current phlebotomy and clinical laboratory practice. It employs a novel separation technology, a mechanical separator, which remains stable in its initial position, to enable the

blood to be filled via current methods and subsequently creates a stable, robust barrier during processing. The mechanical separator is comprised of two materials of different densities - an elastomer and a higher density base material. In its resting position, the diameter of the mechanical separator is greater than that of the tube. The resulting friction from this interface allows the separator to maintain its position and orientation prior to blood collection and permits filling of the tube. Under centrifugation, the force applied on the separator will correctly orient the separator and allows it to move within the tube. While immersed in the collected sample, the differential buoyancy of the two materials will stretch the separator enabling the passage of cellular content and appropriate positioning of the separator between the cell column and plasma sample. When centrifugation stops, the mechanical separator returns to its original shape to form a barrier between the plasma sample (at the top), which is subsequently available for analysis, and the sedimented cells below.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   BD Vacutainer® Brand PST™ Plasma Separation Tube

2. Predicate 510(k) number(s):

   k954592

3. Comparison with predicate:

Similarities / Differences		
Item	BD Vacutainer® Barricor™ Tube (Candidate Device) k160657	BD Vacutainer® PST™ Tube (Predicate Device) k954592
Intended Use	The BD Vacutainer® Barricor™ Lithium Heparin Plasma Blood Collection Tubes (BD Barricor™ Tubes) are used to collect, separate, process, transport and store venous blood samples in a closed tube system for clinical laboratory testing. It is used in settings where a venous blood sample is collected by a trained healthcare worker.	Same
Clinical testing use for	Clinical chemistry, therapeutic drugs, and zinc testing	Clinical chemistry assays
TUBE COMPARISON:		
Tube Dimension	13 x 75 mm and 13 x 100 mm	Same
Draw Volume	3.0 – 5.5 mL	4.0mL – 9.5 mL
Closure	Hemogard™ safety closure	Same
Tube Stopper	Halobutyl rubber – low zinc	Compression Molded Rubber

Similarities / Differences		
Item	BD Vacutainer® Barricor™ Tube (Candidate Device) k160657	BD Vacutainer® PST™ Tube (Predicate Device) k954592
Lubricant	Silicone-based (Tube Stopper and Separator)	Silicone-based (Tube Stopper)
Tube Material	Polyethylene Teraphthalate (PET)	Glass
Barrier	Mechanical separator	Gel
Clot Activator	None	None
Anticoagulant	Lithium Heparin	Same
Sterility	Sterile	Sterile
Tube Shelf Life	18 months at 4 – 25°C	12 months at 4 – 25°C
Shelf	Shrink-wrapped polystyrene tray	Printed shelf carton
Case Level	Corrugated cardboard	Same

K. Standard/Guidance Document Referenced (if applicable):

1. CLSI GP34-A Validation and Verification of Tubes for Venous and Capillary Blood Specimens Collection
2. ISO 11137-1 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
3. ISO 11137-2 Sterilization of health care products - Radiation - Part 2:Establishing the sterilization dose
4. ASTM D4169-14 Standard Practice for Performance Testing of Shipping Containers and Systems

L. Test Principle:

The BD Vacutainer® Barricor™ Lithium Heparin Plasma Blood Collection Tube is intended to be placed inside any BD Vacutainer® Needle Holders of the standard size or an adapter of a blood collection system. Once the vein of the patient has been penetrated using a standard needle, center the collection tube in the holder and push the tube fully onto the needle, puncturing the stopper of the tube. Hold the tube in place to ensure complete vacuum draw. The tube uses a controlled vacuum to pull a specific volume of blood into the sterile interior of the tube. Once the pressure is equalized, the blood flow ceases and the tube is removed from the needle holder or needle. Immediately after the blood has been drawn, the tube is gently inverted 8 times to mix the blood with the anticoagulant. The BD Barricor™ Tubes are centrifuged at 4000 RCF (relative centrifuge force or g's) for 3 minutes in a swing bucket centrifuge within 2 hours of collection. Once a complete barrier formed between the plasma (at the top of the tube) and the cellular components (at the bottom of the tube), the plasma portion of the sample is removed for various clinical laboratory testing.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Two studies were conducted to assess the repeatability (within tube), lot-to-lot variation (between lots), and tube-to-tube (between tube) variation in BD Barricor™ Tubes. The study designs included subjects from the clinical settings. Three lots of each of BD Barricor™ Tubes (candidate device), BD PST™ Plasma Tubes, and BD Serum Tubes were tested and evaluated.

The first study was performed using samples collected from 35 subjects and evaluated the BD Barricor™ Tube performance for 15 representative routine and special chemistry analytes: Alanine Aminotransferase (ALT), Total Bilirubin (T Bili), Calcium (Ca), Chloride (Cl), Cortisol, Complement C3 (C3), Glucose, Lactate Dehydrogenase (LDH), Phosphorus (Phos), Potassium (K), Total Protein, Thyroxine (T4), Testosterone (Testo), Immunoglobulin G (IgG) and Prostate Specific Antigen (PSA).

The second study assessed performance for 5 representative therapeutic drugs: Carbamazepine (CBZ), Acetaminophen (ACET), Digoxin (DIG), Phenytoin (PHT), and Vancomycin (VANCO).

All samples were run in duplicate on the two instrument platforms, Roche cobas® 6000 and the Beckman UniCel DxC 680i. Both instrument platforms yielded similar results. One representative platform with precision results is summarized in the tables below (one table with %CV, one table with SD).

Table 1. Precision Summary (%CV) on Roche cobas® 6000 for representative routine and special chemistry analytes

Analyte/ Unit	Mean	Variance Component	CV (%)	95% Lower Confidence Limit	95% Upper Confidence Limit
ALT U/L	27.4	Between Lots	0.54%	<0.01%	1.76%
		Between Tubes	1.58%	0.54%	2.20%
		Within Tubes	2.45%	2.15%	2.78%
		Total	2.97%	2.67%	3.28%
C3 mg/dL	114.1	Between Lots	<0.01%	<0.01%	0.94%
		Between Tubes	1.35%	0.96%	1.67%
		Within Tubes	1.24%	1.09%	1.40%
		Total	1.83%	1.69%	1.97%
Ca mg/dL	9.37	Between Lots	<0.01%	<0.01%	0.58%
		Between Tubes	0.83%	0.54%	1.01%
		Within Tubes	0.84%	0.72%	0.95%
		Total	1.18%	1.06%	1.31%

Analyte/ Unit	Mean	Variance Component	CV (%)	95% Lower Confidence Limit	95% Upper Confidence Limit
Cl mmol/L	100.4	Between Lots	<0.01%	<0.01%	0.68%
		Between Tubes	0.70%	0.36%	0.94%
		Within Tubes	0.65%	0.57%	0.74%
		Total	0.95%	0.82%	1.09%
Cortisol µg/dL	11.529	Between Lots	<0.01%	<0.01%	2.22%
		Between Tubes	3.02%	2.15%	3.68%
		Within Tubes	2.73%	2.39%	3.07%
		Total	4.08%	3.78%	4.37%
Glucose mg/dL	97.3	Between Lots	<0.01%	<0.01%	0.99%
		Between Tubes	1.49%	1.02%	1.80%
		Within Tubes	1.11%	0.97%	1.24%
		Total	1.86%	1.63%	2.05%
IgG mg/dL	951.1	Between Lots	<0.01%	<0.01%	0.94%
		Between Tubes	1.48%	1.13%	1.77%
		Within Tubes	1.00%	0.88%	1.12%
		Total	1.79%	1.62%	1.96%
K mmol/L	4.07	Between Lots	3.76%	2.67%	5.02%
		Between Tubes	2.34%	1.78%	2.95%
		Within Tubes	0.84%	0.74%	0.95%
		Total	4.51%	3.96%	5.11%
LDH U/L	158.6	Between Lots	0.46%	<0.01%	1.78%
		Between Tubes	2.42%	1.89%	2.84%
		Within Tubes	1.06%	0.93%	1.20%
		Total	2.68%	2.45%	2.93%
Phos mg/dL	3.13	Between Lots	<0.01%	<0.01%	0.93%
		Between Tubes	1.35%	0.97%	1.61%
		Within Tubes	1.11%	0.97%	1.24%
		Total	1.75%	1.62%	1.87%
Testo ≥1 ng/mL	3.458	Between Lots	<0.01%	<0.01%	3.88%
		Between Tubes	3.99%	2.07%	5.49%
		Within Tubes	2.20%	1.79%	2.56%
		Total	4.55%	4.05%	5.10%
Total Protein g/dL	7.34	Between Lots	<0.01%	<0.01%	0.97%
		Between Tubes	1.48%	1.11%	1.76%
		Within Tubes	1.19%	1.04%	1.34%
		Total	1.90%	1.65%	2.15%
PSA ≥ 3 ng/mL	6.951	Between Lots	0.08%	<0.01%	0.39%
		Between Tubes	0.01%	<0.01%	0.42%
		Within Tubes	0.64%	0.48%	0.74%
		Total	0.64%	0.50%	0.78%

Analyte/ Unit	Mean	Variance Component	CV (%)	95% Lower Confidence Limit	95% Upper Confidence Limit
Total T4 µg/dL	6.807	Between Lots	<0.01%	<0.01%	0.96%
		Between Tubes	0.83%	<0.01%	1.30%
		Within Tubes	1.97%	1.73%	2.21%
		Total	2.13%	1.93%	2.34%

Table 2. Precision Summary (SD) on Roche cobas® 6000 for representative routine and special chemistry analytes

Analyte/ Unit	Mean	Variance Component	SD	95% Lower Confidence Limit	95% Upper Confidence Limit
T Bili mg/dL	0.51	Between Lots	<0.0001	<0.0001	0.01
		Between Tubes	0.02	0.01	0.02
		Within Tubes	0.03	0.02	0.03
		Total	0.03	0.03	0.03
Testo <1 ng/mL	0.167	Between Lots	<0.0001	<0.0001	0.0054
		Between Tubes	<0.0001	<0.0001	0.0059
		Within Tubes	0.013	0.0112	0.0140
		Total	0.013	0.0119	0.0142
PSA < 3 ng/mL	0.5387	Between Lots	0.0018	<0.0001	0.0093
		Between Tubes	0.0115	0.0081	0.0141
		Within Tubes	0.0057	0.0048	0.0067
		Total	0.0130	0.0112	0.0144

Results of the comparator tube type, BD Vacutainer® PST™ Tube, were very similar to the candidate tube type, BD Vacutainer® Barricor™ Tube. Calculated SD for the BD Vacutainer® PST™ Tube was <0.05 mg/dL for Total Bilirubin, Testosterone and PSA and % CVs for all other analytes were <10%.

Table 3. Precision Summary (%CV) on Roche cobas® 6000 for 5 representative therapeutic drugs

Analyte/ Unit	Mean	Variance Component	CV (%)	95% Lower Confidence Limit	95% Upper Confidence Limit
CBZ µg/mL	5.514	Between Lots	<0.005%	<0.005%	1.21%
		Between Tubes	<0.005%	<0.005%	1.43%
		Within Tubes	3.24%	2.84%	3.52%
		Total	3.24%	2.81%	3.72%

Analyte/ Unit	Mean	Variance Component	CV (%)	95% Lower Confidence Limit	95% Upper Confidence Limit
ACET µg/mL	7.59	Between Lots	0.16%	<0.005%	1.37%
		Between Tubes	1.03%	<0.005%	1.77%
		Within Tubes	2.91%	2.51%	3.24%
		Total	3.09%	2.72%	3.40%
DIG ng/mL	1.418	Between Lots	0.63%	<0.005%	1.26%
		Between Tubes	0.78%	<0.005%	1.33%
		Within Tubes	1.75%	1.53%	1.94%
		Total	2.01%	1.81%	2.21%
PHT µg/mL	13.45	Between Lots	0.34%	<0.005%	1.12%
		Between Tubes	0.20%	<0.005%	1.19%
		Within Tubes	2.65%	2.31%	2.90%
		Total	2.68%	2.44%	2.92%
VANCO µg/mL	16.05	Between Lots	0.47%	<0.005%	1.21%
		Between Tubes	0.08%	<0.005%	0.99%
		Within Tubes	2.11%	1.83%	2.28%
		Total	2.16%	1.94%	2.39%

Results of the comparator tube type, BD Serum Tube, were very similar to the candidate tube type, BD Vacutainer® Barricor™ Tube.

b. Linearity/assay reportable range:

Not applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

i. Shelf-life stability:
Real Time stability testing of the BD Vacutainer® Barricor™ Tube showed that the tube is stable for 18 months when stored at 4 to 25 °C. Stability study protocol and acceptance criteria has been reviewed and found to be acceptable.

ii. Analyte stability:
Multiple analyte stability studies were conducted to assess the analyte within tube stability for representative routine and special chemistry analytes and therapeutic drugs in BD Barricor™ Tubes. Stability studies were assessed for representative analytes at initial time (Time 0) and 24hrs or 48hrs with room temperature storage, followed by refrigerated storage for 3 days and 7 days post centrifugation. Please see the analytes assessed in the summary table below.

Table 4. Within Tube Stability in the BD Barricor™ Tube: Study, Analyte, and Time points

Study	Analyte	Time points tested
#1	Routine Chemistry: Albumin (ALB), Alkaline Phosphatase (ALKP), Alanine Aminotransferase (ALT), Amylase (AMY), Aspartate Aminotransferase (AST), Bilirubin –Total (TBIL),Blood Urea Nitrogen (BUN), Calcium (Ca), Carbon Dioxide (CO_2), Chloride (Cl), Cholesterol (Chol), Creatine Kinase (CK), Creatinine (Creat), Gamma-glutamyltransferase (GGT), Glucose (GLU), High-Density Lipoprotein (HDL), Iron (Fe), Lactate Dehydrogenase (LDH), Lipase (Lip), Low-Density Lipoprotein(LDL), Magnesium (Mg), Phosphorus (Phos), Potassium (K), Sodium (Na), Total Protein (TP), Triglycerides (Trig), Uric Acid (UA) Special Chemistry: Complement C3 (C3), Cortisol (CORT), Ferritin (FERR), Folate, Follicle Stimulating Hormone (FSH), Free Triiodothyronine (Free T3), Free Thyroxine (Free T4), Haptoglobin (HPT), Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM),Luteinizing Hormone (LH), Testosterone, Thyroid Stimulating Hormone (TSH), Total Triiodothyronine (Total T3), Total Thyroxine (Total T4), Transferrin, Vitamin B12 (Vit B12)	0hr, 24hrs, 3 days and 7 days 0hr, 24hrs, 3 days and 7 days
#2	Glucose (GLU) Carbon Dioxide (CO_2)	0 hr, 6 hrs and 12 hrs; 0 and 18 hrs
#3	C-Reactive Protein (CRP)	0 hr, 24 hrs, 3 days and 7 days
#4	β Human Chorionic Gonadotropin (βhCG), Prostate Specific Antigen (PSA)	0 hr and 24 hrs
#5	Creatine Kinase MB Fraction (CKMB) Troponin I(TnI) Troponin T(TnT)	0 hr and 24 hrs
#6	Therapeutic Drugs: Acetaminophen (ACET), Carbamazepine (CBZ), Digoxin (DIG), Phenytoin (PHT), Salicylate (ASA), Valproic Acid (VPA), and Vancomycin (VANCO)	0 hr, 48 hrs and 7 days

The results of the study support the sponsor's claim the within-tube stability was demonstrated in the BD Barricor™ Tube for up to 24 hrs with room temperature storage and up to 7 days of refrigerated storage for all routine and special chemistry analytes except Folate, Glucose and CO_2.

For Folate, stability was established for 24 hours, while Glucose and CO_2 demonstrated stability for 18 hrs with room temperature storage. Within tube analyte stability was demonstrated for CRP for up to 24 hrs with room temperature storage and up to 7 days of refrigerated storage.

βhCG, PSA, CKMB, TnI, and TnT were only tested for 24 hrs at room temperature and demonstrated stability at that time point.

Within tube analyte stability was demonstrated for all therapeutic drugs for up to 48 hours of storage at room temperature and up to 7 days of refrigerated storage.

iii. Additional bench testing evaluated on the candidate device:

Clinical and benchtop studies were conducted to evaluate the effect of various centrifugation conditions on sample quality and analyte stability in the BD Barricor™ Tubes at multiple time points. The study protocols were reviewed and performance was considered acceptable at the recommended centrifugation range.

Additional studies were conducted to assess draw volume, Zinc testing, stopper closure assembly stability, stopper pull out force, and simulated ship testing, including both pre-use shipping testing and post-centrifugation (after blood collection and centrifugation) ship testing. Study protocols, acceptance criteria and results for these studies were provided and found to be acceptable.

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

To demonstrate comparable performance with the comparator device, apparently healthy subjects and patients admitted into hospitals with various diseases were used. Testing was performed at seven different clinical and hospital sites. All subjects in the comparative studies have blood samples collected into the BD Barricor^{TM} tubes (candidate device) and the comparator tubes (BD PST^{TM} (k945952) for chemistry and BD Serum tube (k960250) for TDM) at the same time. The specimens collected in

BD Serum tube (for TDM) were allowed to clot, and the serum was removed for testing immediately after centrifugation according to the instructions provided in the labeling. Evaluations were performed on a selective common general chemistry analytes, immunology analytes, special chemistry analytes, cardiac markers, and therapeutic drug monitoring analytes on multiple instrument platforms. A total of 62 analytes (55 chemistry and 7 TDM) were evaluated and demonstrated comparable results between the candidate tube and the comparator tubes. A small number of spiked samples were also prepared to obtain abnormal low or high values for selected analytes. Summary of the results (Deming or Passing-Bablok regressions correlations with 95% confidence intervals) on one representative platform with the analytes and instruments evaluated are provided in the tables below:

Table 5. Deming regressions correlations with 95% confidence intervals from one representative platform/study

Analyte	Instrument(s)	Intercept (95% CI)	Slope (95% CI)
Acetaminophen	4, 15	-0.76 (-1.47, -0.06)	0.98 (0.91, 1.05)
Alanine Aminotransferase	6, 12	-0.5 (-0.9, -0.2)	1.0 (1.0, 1.0)
Albumin	6, 12	0.02 (-0.19, 0.23)	0.99 (0.93, 1.05)
Alkaline Phosphatase	6, 12	-0.1 (-1.2, 1.0)	1.0 (1.0, 1.0)
Amylase	6, 12	0.2 (-0.6, 1.0)	1.0 (1.0, 1.0)
Aspartate Aminotransferase	6, 12	0.0 (-0.5, 0.6)	1.0 (1.0, 1.0)
Bilirubin, Direct	6, 12	0.01 (-0.02, 0.05)	0.99 (0.97, 1)
Bilirubin, Total	6, 12	-0.26 (-1.05, 0.53)	1.00 (0.98, 1.01)
Blood Urea Nitrogen	6, 12	-0.3 (-0.5, 0.0)	1.0 (1.0, 1.0)
Calcium	6, 12	-0.08 (-0.34, 0.19)	1.00 (0.97, 1.02)
Carbamazepine	4, 15	0.414 (0.127, 0.700)	0.935 (0.898, 0.972)
Carbon Dioxide, Total	6, 12	-0.41 (-1.62, 0.80)	1.04 (0.99, 1.08)
Chloride	6, 12	0.5 (-1.5, 2.6)	1.0 (1.0, 1.0)
Cholesterol	6, 12	1.3 (-1.9, 4.4)	1.0 (1.0, 1.0)
Complement C3	1, 7	1.1 (-1.0, 3.2)	1.0 (1.0, 1.0)
Cortisol	3, 11	-0.083 (-0.212, 0.047)	1.006 (0.992, 1.021)
C-Reactive Protein	2, 7	-0.011 (-0.171, 0.149)	0.988 (0.958, 1.017)
Creatine Kinase, MB fraction	5, 13	-0.19 (-0.63, 0.25)	1.03 (0.99, 1.07)
Creatine Kinase, Total	6, 14	-3.5 (-11.3, 4.2)	1.0 (1.0, 1.1)
Creatinine	6, 12	0.00 (-0.03, 0.03)	1.00 (0.98, 1.02)
Digoxin	4, 15	-0.039 (-0.090, 0.013)	1.039 (0.992, 1.086)
Ferritin	8, 13	-12.75 (-37.11, 11.61)	1.06 (0.94, 1.19)
Folate	5, 8	-0.284 (-0.981, 0.414)	1.020 (0.975, 1.066)
Free Thyroxine	3, 15	0.0564 (0.0096, 0.1032)	0.9333 (0.8859, 0.9807)
Free Triiodothyronine	3, 15	0.131 (0.035, 0.228)	0.961 (0.927, 0.995)
Gamma-glutamyltransferase	6, 12	-0.4 (-1.2, 0.4)	1.0 (1.0, 1.0)
Glucose	6, 12	-2.3 (-4.3, -0.4)	1.0 (1.0, 1.0)
Haptoglobin	1, 7	0.3 (-0.7, 1.4)	1.0 (1.0, 1.0)
High Density Lipoprotein	6, 12	-0.1 (-0.4, 0.2)	1.0 (1.0, 1.0)
Immunoglobulin A	1, 7	1.2 (-1.9, 4.3)	1.0 (1.0, 1.0)
Immunoglobulin G	1, 7	-16.7 (-44.8, 11.4)	1.0 (1.0, 1.0)
Immunoglobulin M	1, 7	0.6 (-3.6, 4.8)	1.0 (1.0, 1.0)
Iron	6, 12	1.9 (-2.0, 5.8)	1.0 (0.9, 1.0)

Analyte	Instrument(s)	Intercept (95% CI)	Slope (95% CI)
Lactate Dehydrogenase	6, 12	14.8 (10.4, 19.1)	1.0 (1.0, 1.0)
Lipase	6, 12	-0.6 (-1.6, 0.5)	1.0 (1.0, 1.0)
Low Density Lipoprotein	6, 12	1.0 (-1.6, 3.7)	1.0 (1.0, 1.0)
Magnesium	6, 12	0.01 (-0.03, 0.05)	1.00 (0.98, 1.01)
Phenytoin	4, 15	0.136 (-0.290, 0.562)	0.988 (0.939, 1.038)
Phosphorus	6, 12	0.03 (-0.01, 0.07)	0.99 (0.98, 1.00)
Potassium	6, 12	0.033 (-0.087, 0.153)	0.993 (0.961, 1.024)
Rheumatoid Factor	6, 12	0.17 (-0.77, 1.10)	1.01 (0.99, 1.02)
Salicylate	4, 9	0.073 (-0.309, 0.456)	0.969 (0.945, 0.994)
Sodium	6, 12	1.1 (-1.6, 3.8)	1.0 (1.0, 1.0)
Thyroid Stimulating Hormone	3, 15	0.1134 (0.0539, 0.1730)	0.9580 (0.9380, 0.9781)
Total Protein	6, 12	-0.25 (-0.68, 0.19)	1.04 (0.98, 1.10)
Total Thyroxine	3, 15	0.25 (-0.21, 0.70)	0.97 (0.93, 1.02)
Total Triiodothyronine	3, 5	-1.6 (-5.7, 2.6)	1.0 (1.0, 1.1)
Transferrin	2, 7	-4.35 (-23.47, 14.77)	1.02 (0.94, 1.09)
Triglycerides	6, 12	1.6 (-0.5, 3.8)	1.0 (1.0, 1.0)
Uric Acid	6, 12	0.02 (-0.02, 0.05)	1.00 (0.99, 1.00)
Valproic Acid	4, 15	-2.84 (-6.43, 0.75)	1.01 (0.95, 1.07)
Vancomycin	4, 15	1.56 (0.93, 2.19)	0.99 (0.95, 1.02)
Vitamin B12	8, 13	10.8 (-13.7, 35.2)	1.0 (0.9, 1.0)

Table 6. Passing-Bablok regressions correlations with 95% confidence intervals from one representative platform/study

Analyte	Instrument(s)	Intercept (95% CI)	Slope (95% CI)
Estradiol	3, 15	0.76 (-0.97, 1.56)	1.05 (1.03, 1.07)
Follicle Stimulating Hormone	3, 15	-0.01 (-0.06, 0.03)	1.0 (0.98, 1.01)
Human Chorionic Gonadotropin	3, 11	0.13 (-0.04, 1.02)	1.0 (0.99, 1.01)
Luteinizing Hormone	3, 15	0.01 (0, 0.01)	0.99 (0.98, 1.0)
Progesterone	3, 11	-0.07 (-0.08, -0.03)	1.03 (1, 1.06)
Prostate Specific Antigen	10, 11	-0.01 (-0.02, 0.0)	1.0 (0.99, 1.02)
Testosterone	3, 11	-0.74 (-1.65, 0.03)	1.04 (1.02, 1.06)
Troponin I	5, 13	0.0 (0.0, 0.0)	1.01 (1, 1.03)
Troponin T	11	0.0 (0.0, 0.0)	0.97 (0.93, 1.0)

Instruments:

1. Abbott ARCHITECT C4000
2. Abbott ARCHITECT C8000
3. Abbott ARCHITECT i1000SR
4. Abbott ARCHITECT® ci4100
5. Beckman Coulter Access® 2
6. Beckman Coulter AU680
7. Beckman Coulter UniCel® DxC 660i
8. Beckman Coulter UniCel® DxI 800
9. Ortho Clinical Diagnostics Vitros® 5600

10. Ortho Clinical Diagnostics Vitros® ECi
11. Roche cobas® e411
12. Roche MODULAR® Analytics
13. Siemens ADVIA Centaur® XP
14. Siemens Dimension RxL
15. Siemens Dimension Vista® 1500

The sponsor stated the following: "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 storage conditions 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 specific instrument/reagent system. Based on such information, the laboratory can then decide if changes are appropriate."

Summary of all the studies:

Study 1: A total of 90 adult subjects participated in a study from a hospital site (site A) to compare BD Barricor™ with the BD PST™ tubes. Chemistry results were generated for 27 general chemistry analytes on the Roche Modular® Analytics.

Study 2: A total of 85 adult subjects participated in a study from a hospital site (site B). Chemistry results were generated for 29 routine chemistry on the Beckman Coulter AU680 and 3 special chemistry analytes on the Beckman Coulter Unicel® DxI instruments.

Study 3: A total of 103 adult subjects participated in a study from a clinical site (site C). Chemistry results were generated for 5 special chemistry analytes on the Abbott ARCHITECT C4000, 2 special chemistry analytes on the Abbott ARCHITECT C8000 and 7 special chemistry analytes on the Beckman Coulter DxC 660i.

Study 4: A total of 96 adult subjects participated in a study from a hospital site (site D). Chemistry results were generated for 12 special chemistry analytes on the Abbott ARCHITECT i1000SR, 1 special chemistry analyte on the Roche cobas e411 and 1 special chemistry analyte on the Roche Modular® Analyzer.

Study 5: A total of 121 adult subjects participated in a study from a clinical site (site E). Chemistry results were generated for 7 special chemistry analytes on the Siemens Dimension Vista® 1500.

Study 6: A total of 88 adult subjects participated in a study from a clinical site (site F). Chemistry results were generated for 1 special chemistry analyte on the Siemens Dimension RxL, Ortho Clinical Diagnostics Vitros® ECi and Roche cobas e411; and 4 special chemistry analytes on the Beckman Coulter Access® 2 and the Siemens ADVIA Centaur® XP.

Study 7: A total of 722 adult subjects participated in a study from a hospital site (site G, recruitment was also performed at 7 additional sites). Chemistry results were generated for 7 representative therapeutic drugs on the Abbott ARCHITECT and the Siemens Dimension Vista®, in addition one therapeutic drug was tested on the Ortho Clinical Diagnostics Vitros® 5600.

The sponsor performed a meta-analysis to evaluate plasma quality in the BD Barricor™ Tube compared to the BD PST™ Tube based on visual observations for barrier formation, hemolysis, fibrin mass, fibrin strand, and stopper fibrin ring. Study protocols, acceptance criteria and results for these studies were provided and found to be acceptable.

b. Matrix comparison:

Not applicable. These tubes are for plasma only.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.