510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K213953

B Applicant

Becton Dickinson and Company

C Proprietary and Established Names

BD Vacutainer® Trace Element K_2EDTA Tubes, BD Vacutainer® Trace Element Serum Tubes

D Regulatory Information

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

II Submission/Device Overview:

A Purpose for Submission:

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® Trace Element Serum Tubes and BD Vacutainer® Trace Element K_2EDTA Tubes are plastic, evacuated, sterile, single use, in vitro diagnostic medical devices. They are intended to be used in settings where venous blood specimens are collected by trained healthcare professionals for the collection, transportation, and processing of blood in a closed tube. Blood collected in the BD Vacutainer® Trace Element Serum Tubes and BD Vacutainer® Trace Element K_2EDTA Tubes are used for trace element testing (e.g., Arsenic, Cadmium, Chromium, Copper, Lead, Manganese, Mercury, Selenium, and Zinc).

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

BD Vacutainer® Trace Element Tubes have not been evaluated for other testing applications which use serum or EDTA anticoagulated blood.

BD Vacutainer® Trace Element tubes are controlled only for the trace elements listed within their respective upper limits. Other trace elements may be present, however, these levels have not been evaluated and are not controlled. Users should assess whether the use of these tubes is appropriate for their intended testing purposes.

D Special Instrument Requirements:

Not applicable.

IV Device/System Characteristics:

A Device Description:

The BD Vacutainer® Trace Element K_2EDTA Tube is a sterile, plastic, evacuated plastic blood collection tube. It consists of closure assembly, a plastic tube, and K_2EDTA coating and is available in two draw sizes, 6 mL (13 x 100 mm) and 3 mL (13 x 75 mm). The plastic tube is manufactured from PET (polyethylene terephthalate) plastic. The K_2EDTA anticoagulant coating is spray-dried on the walls of the tube.

The BD Vacutainer® Trace Element Serum Tube is a sterile, plastic, evacuated plastic blood collection tube consisting of a closure assembly, a plastic tube and contains a silica clot activator additive which is spray-dried on the interior walls of the tube. It is available in one draw size, 6 mL (13 x 100 mm). The plastic tube is manufactured from PET.

Both types of tubes are closed with a BD Hemogard™ Closure, which consists of a rubber stopper and protective plastic shield to help reduce user exposure to blood. The stopper/closures

are color coded in royal blue to reflect that the tubes are intended to collect samples for trace element.

B Principle of Operation:

The BD Vacutainer® Trace Element K_2EDTA and BD Vacutainer® Trace Element Serum tubes use controlled vacuum to pull a specific volume of blood into the sterile interior of the tube. Within the serum tube, silica clot activator serves to enhance clot activation of the blood, thus rendering serum samples for trace element testing. The other tube contains K_2EDTA, which prevents blood coagulation, thus rendering whole blood or plasma samples for trace element testing.

The tubes are compatible with BD Vacutainer® Blood Collection Needles, Blood Collection Sets, Transfer Devices, Holders and Adapters. Once the vein of the patient has been penetrated using a standard needle, the collection tube is centered in the holder and pushed onto the needle, puncturing the stopper of the tube. Immediately after the blood has been drawn, the tube is gently inverted 8-10 times for K_2EDTA and 8 times for serum to mix the blood with the additive. For the serum tubes, blood should be allowed to clot for a minimum of 60 minutes before centrifugation, The recommended centrifugation conditions are 1300 RCF (relative centrifuge force or g) for 10 minutes.

V Substantial Equivalence Information:

A Predicate Device Name(s):

BD Vacutainer® Trace Element Serum Plus Tube and BD Vacutainer® Trace Element K2EDTA Plus Tube

B Predicate 510(k) Number(s):

K041071

C Comparison with Predicate(s):

Due to an administrative error, the shelf life of the candidate device in the table below was listed incorrectly and is now updated:

Device & Predicate Device(s):	K213953	K041071
Device Trade Name	BD Vacutainer® Trace Element K_2EDTA Tubes, BD Vacutainer® Trace Element Serum Tubes	BD Vacutainer® Trace Element Serum Plus Tubes and BD Vacutainer® Trace Element K_2EDTA Tubes
General Device Characteristic Similarities		
Intended Use/Indications for Use	Plastic evacuated blood collection tubes that provide a means of collecting,	Same

Device & Predicate Device(s):	K213953	K041071
	transporting, separating, and processing venous whole blood in a closed tube for trace element testing.	
Evacuated Blood Collection Tube	Yes	Same
Additive Type	BD Vacutainer® Trace Element Serum Tube: Serum Clot Activator BD Vacutainer® Trace Element K_2EDTA Tube: K_2EDTA	Same
Additive Application/Quantity	Spray dried	Same
Tube Material	PET (polyethylene terephthalate) plastic	Same
Tube Closure	BD Hemogard™/Royal Blue	Same
Sterilization Method	Gamma irradiation	Same
Sterility Assurance Level	10^{-6}	Same
General Device Characteristic Differences		
Tube Dimensions and Draw Volume	BD Vacutainer® Trace Element Serum Tube: 13 x 100 mm, 6 mL BD Vacutainer® Trace Element K_2EDTA Tube: 13 x 100 mm, 6 mL and 13 x 75 mm, 3 mL	BD Vacutainer® Trace Element Serum Plus Tube: 13 x 100 mm, 6 mL BD Vacutainer® Trace Element K_2EDTA Tube: 13 x 100mm, 6 mL
Shelf Life	13 x 100 mm, 6 mL BD Vacutainer® Trace Element Serum Tube and BD Vacutainer® Trace Element K_2EDTA Tube: 12 months 13 x 75 mm, 3 mL BD Vacutainer® Trace Element K_2EDTA Tube:10 months	12 months
Elements Tested	Arsenic, Cadmium, Chromium, Copper, Lead, Manganese, Mercury, Selenium, and Zinc	Arsenic, Cadmium, Calcium, Chromium, Copper, Iron, Lead, Magnesium, Manganese, Mercury, Selenium, and Zinc

VI Standards/Guidance Documents Referenced:

CLSI GP34-A: 2010 Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guideline

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:

A study was conducted to evaluate BD Vacutainer® Trace Element K_2EDTA Tubes (6 mL) and BD Vacutainer® Trace Element Serum Tubes (6 mL) for repeatability (within tube) and reproducibility (lot to lot and tube to tube) performance using lead and zinc as representative trace elements for testing. Two sample matrices, including serum (for zinc testing) and anticoagulated whole blood (for lead testing), were evaluated on two instrument platforms for Zinc and one platform for Lead to confirm tube performance. Three lots of each of the evaluation tubes (BD Vacutainer® Trace Element K_2EDTA Tubes and BD Vacutainer® Trace Element Serum Tubes) were evaluated.

The first study (whole blood lead testing) was performed using samples collected from 35 subjects. The second study (serum zinc testing) was performed using samples collected from 43 subjects.

The samples were tested for trace elements using atomizing methods, i.e., inductively coupled plasma mass spectrometry (ICP-MS).

Variance Components and Confidence Intervals (CI): ICP-MS Platform 1

Analyte/Unit	Tube Type	Mean	Variance Component	CV (%)	95% CI
Lead (µg/L)	BD Trace Element K_2EDTA	5.4056	Between Lots	0	0, 0
			Between Tubes	3.6	3.1, 4.1
			Within Tube	1.2	1.1, 1.4
			Total	3.8	3.0, 5.4
Zinc (µg/L)	BD Trace Element Serum	74.5167	Between Lots	3.3	1.9, 4.3
			Between Tubes	4.3	3.6, 4.9
			Within Tube	1.5	1.4, 1.6
			Total	5.6	4.6, 7.2

Variance Components and Confidence Intervals (CI): ICP-MS Platform 2

Analyte/Unit	Tube Type	Mean	Variance Component	CV (%)	95% CI
Zinc (µg/L)	BD Trace Element Serum	751.5803	Between Lots	0	0, 3.5
			Between Tubes	5.6	3.8, 6.9
			Within Tube	7.3	6.6, 8
			Total	9.1	7.7, 11.3

2. Linearity:

   Not applicable.

3. Analytical Specificity/Interference:

   Benchtop studies were conducted to evaluate interference from stopper materials over the sample storage time and over the shelf life of the tube. Study protocols, acceptance criteria and results for these studies were provided and found to be acceptable.

4. Assay Reportable Range:

   Not applicable.

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

   a) Shelf-life stability:

   Real Time stability testing of the BD Vacutainer® Trace Element K_2EDTA Tubes and BD Vacutainer® Trace Element Serum Tubes showed that the 6 mL BD Vacutainer® Trace Element K_2EDTA Tubes and 6 mL BD Vacutainer® Trace Element Serum Tubes are stable for 12 months (6 mL tubes) and the 3 mL BD Vacutainer® Trace Element

K_2EDTA Tubes are stable for 10 months, when stored at 4°C to 25 °C. Stability study protocol and acceptance criteria has been reviewed and found to be acceptable.

b) Analyte stability:

Multiple analyte stability studies were conducted to assess the analyte within tube stability for As, Cd, Cr, Cu, Hg, Pb, Mn, Se and Zn in BD Vacutainer® Trace Element K_2EDTA Tubes and BD Vacutainer® Trace Element Serum Tubes. Stability studies were assessed at initial time (Time 0) and 24 hrs at room temperature storage (for As, Cd, Cr, Cu, Hg, Pb, Mn, Se) and 4 hrs at room temperature storage (Zn).

The results of the study support the sponsor's claim, the within-tube stability was demonstrated in the BD Vacutainer® Trace Element K_2EDTA Tubes and BD Vacutainer® Trace Element Serum Tubes for up to 24 hrs at room temperature storage for As, Cd, Cr, Cu, Hg, Pb, Mn, Se and up to 4 hrs at room temperature storage for Zn.

c) Clinical Transportation Study:

A study was conducted to assess the analyte within tube stability for As, Cd, Cr, Cu, Hg, Pb, Mn, Se and Zn when exposed to simulated transportation conditions and worst-case room temperature. Conditions evaluated included:

- Exposure to vibration and impact simulations that replicate the vibratory and impact loadings which a small parcel (e.g., small box) is expected to experience when shipped via a parcel carrier.
- Exposure to the upper limit of the labeled temperature of 25°C.

The results of the study support that the tubes can be used to transport venous blood sample when subjected to the drop, vibration, temperature and humidity conditions used in this test method. Study protocols and acceptance criteria have been reviewed, and performance was considered acceptable.

d) Additional Bench Testing on the Candidate Device:

Due to an administrative error, the packaging performance study in the section below was previously redacted and is now included:

Benchtop studies were conducted to assess draw volume, X-value, 2nd stopper pullout, stopper/shield separation, stopper leakage, tube leakage, breakage resistance during drop testing, breakage resistance during centrifugation testing, packaging performance 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:

A study was conducted to evaluate the Clinical Equivalence of BD Vacutainer® Trace Element Blood Collection Tubes (BD Vacutainer® Trace Element Serum and K_2EDTA) in comparison with Greiner Bio-One Vacuette® Trace Element Blood Collection Tubes (Greiner Bio-One Vacuette® Trace Element Serum and Sodium Heparin) for testing trace elements.

A total of 159 subjects were enrolled in the study across several study parts. All samples were collected by routine venipuncture into the corresponding candidate tube and also in no additive tubes that were used for the preparation of the contrived samples to obtain results for high levels of trace elements that spanned the analytical measurement range.

Immediately after collection and prior to centrifugation, tubes were inspected for complete fill, clot formation and stopper leakage. After centrifugation, additional visual assessments were performed. Tubes were then handled and processed according to manufacturer's recommended handling conditions for tube inversions and centrifugation time and force.

The following tube comparisons were performed for clinical equivalence:
- 6 mL BD Trace Element K_2EDTA vs 6 mL Greiner Trace Element NaHep
- 6 mL BD Trace Element Serum vs 6 mL Greiner Trace Element Serum
- 3 mL BD Trace Element K_2EDTA vs 6 mL Greiner Trace Element NaHep
- 3 mL BD Trace Element K_2EDTA vs 6 mL BD Trace Element K_2EDTA

Samples collected in the BD Trace Element K_2EDTA were analyzed on one ICP-MS instrument platform for testing As, Cd, Cr, Pb, Mn, Hg and Se in anticoagulated whole blood and samples collected in the BD Trace Element Serum were tested for Cr, Cu, Mn, Se and Zn in serum. Biases between tube types at pre-determined medical decision points were estimated with 95% intervals. The mean biases and 95% limit were compared to the clinically acceptable limit (CAL). Data was analyzed using Passing Bablok regression .

Summary of the Passing-Bablok regressions analyses is provided in the table below:

Analyte	Comparison	N	Range Tested (µg/mL)	Slope	Intercept	r
Arsenic	BD Trace Element K_2EDTA 3 mL vs Greiner Trace Element NaHep	121	0.340-676.800	0.99	-0.02	0.986
	BD Trace Element K_2EDTA 6 mL vs Greiner Trace Element NaHep	121	0.340-676.800	1.01	-0.02	0.988
Cadmium	BD Trace Element K_2EDTA 3 mL vs Greiner Trace Element NaHep	121	0.140-33.580	0.97	0.01	0.997
	BD Trace Element K_2EDTA 6 mL vs Greiner Trace Element NaHep	121	0.140-33.580	1	0	0.997

Analyte	Comparison	N	Range Tested (µg/mL)	Slope	Intercept	r
Chromium	BD Trace Element K_2EDTA 3 mL vs Greiner Trace Element NaHep	122	0.040-5.210	1	0.1	0.949
	BD Trace Element K_2EDTA 6 mL vs Greiner Trace Element NaHep	121	0.040-5.210	1.03	0.1	0.929
	BD Trace Element Serum vs Greiner Trace Element Serum	110	0.060-8.560	1	0	0.987
Copper	BD Trace Element Serum vs Greiner Trace Element Serum	108	17.132-415.634	1	0.51	0.996
Lead	BD Trace Element K_2EDTA 3 mL vs Greiner Trace Element NaHep	121	0.180-88.766	0.97	0.02	0.997
	BD Trace Element K_2EDTA 6 mL vs Greiner Trace Element NaHep	121	0.180-88.766	0.99	-0.01	0.997
Manganese	BD Trace Element K_2EDTA 3 mL vs Greiner Trace Element NaHep	120	3.690-93.656	1	0.19	0.979
	BD Trace Element K_2EDTA 6 mL vs Greiner Trace Element NaHep	120	3.690-93.656	1.03	-0.39	0.981
	BD Trace Element Serum vs Greiner Trace Element Serum	106	0.128-169.554	0.99	0.07	0.995
Mercury	BD Trace Element K_2EDTA 3 mL vs Greiner Trace Element NaHep	120	0.250-73.637	1.04	-0.18	0.979
	BD Trace Element K_2EDTA 6 mL vs Greiner Trace Element NaHep	119	0.250-73.637	1.06	-0.15	0.978
Selenium	BD Trace Element K_2EDTA 3 mL vs Greiner Trace Element NaHep	110	134.053-711.770	0.99	2.74	0.976
	BD Trace Element K_2EDTA 6 mL vs Greiner Trace Element NaHep	110	91.547-711.770	0.99	2.67	0.976
	BD Trace Element Serum vs Greiner Trace Element Serum	108	53.862-569.510	1.01	-0.73	0.977
Zinc	BD Trace Element Serum vs Greiner Trace Element Serum	108	34.560-259.571	1.01	-1.25	0.994

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):

   Not applicable.

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.