510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K231237

B Applicant

Becton, Dickinson and Company

C Proprietary and Established Names

BD Vacutainer® Fluoride Blood Collection 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
GIM	Class II	21 CFR 862.1675 - Blood Specimen Collection Device	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Not applicable. Blood Collection Tube

C Type of Test:

Not applicable

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

BD Vacutainer® Fluoride Blood Collection Tubes are evacuated, sterile, single use, in vitro diagnostic medical devices available with Sodium Fluoride/Potassium Oxalate or Sodium Fluoride/Na2EDTA. They are intended to be used by trained healthcare professionals for the collection, containment, preservation, transportation, and centrifugation of venous blood specimens as required for in vitro diagnostic testing. Plastic BD Vacutainer® Fluoride Blood Collection Tubes are used to collect whole blood for the generation of plasma samples.

Blood collected in BD Vacutainer® Fluoride Blood Collection Tubes containing Sodium Fluoride/Potassium Oxalate are used for glucose and lactate determinations. Blood collected in BD Vacutainer® Fluoride Blood Collection Tubes containing Sodium Fluoride/Na2EDTA are used for glucose determinations.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

Do not use if foreign matter is present or if tube is damaged.

Fluoride powdered additives may be white to pale pink. Do not use if it is any other color.

Follow your facility's procedures if clots or other visible obstructions are present in the sample as this could lead to the inability to test the sample.

Any change in blood collection tube type, size, handling, processing, or storage condition for a particular laboratory assay should be evaluated by the laboratory for each instrument/reagent system per the laboratory's standard procedures.

BD Vacutainer® Fluoride Blood Collection Tubes may contain trace levels of tert-butanol, ethylbenzene, formate, hexane, 2-methylpentane, 3-methylpentane, and xylene. It has not been determined if the presence of trace levels of these compounds will affect test results in chromatography-based assays.

D Special Instrument Requirements:

Not applicable. Specific analyzers used to evaluate the device are listed in the labeling and in section VII.B.1. Method Comparison, below.

IV Device/System Characteristics:

A Device Description:

The BD Vacutainer® Fluoride Blood Collection Tubes are evacuated, sterile, single use tubes intended to be used in settings where venous blood samples would be collected by trained healthcare professionals for the collection, containment, preservation, transportation, and centrifugation of blood in a closed tube.

BD Vacutainer® Fluoride Blood Collection Tubes are available in plastic13 x 75mm and 13 x 100mm configurations with draw volumes from 2.0 to 6 mL. The configurations contain various additive combinations in a blended powder mixture, including the additives Potassium Oxalate (kOx) and Na_2-EDTA which provide an anticoagulated specimen when used according to the instructions for use. The tubes containing Na_2-EDTA can be used to produce plasma samples to measure glucose. The tubes containing kOx can be used to produce plasma samples to measure glucose or lactate. The blended powder mixture contains sodium fluoride (NaF), which acts as an antiglycolytic agent. Tubes include a gray color-coded BD Hemogard™ Closure indicative of the NaF additive. Tube stoppers are lubricated with silicone to facilitate stopper insertion.

B Principle of Operation:

The BD Vacutainer® Fluoride Blood Collection Tubes are intended to be placed inside any BD Vacutainer® Needle Holder 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. 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 and antiglycolytic. The BD Vacutainer® Fluoride Blood Collection Tubes are centrifuged at 2000 RCF (relative centrifuge force or g's). The whole blood is then processed to plasma for various clinical laboratory testing.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Vacutainer Plus With Hemogard Closure

B Predicate 510(k) Number(s):
K901449

C Comparison with Predicate(s):

Device & Predicate Device(s):	K231237	K901449
Device Trade Name	BD Vacutainer® Fluoride Blood Collection Tubes	Vacutainer Plus with Hemogard Closure
General Device Characteristic Similarities		
Intended Use/Indications For Use	The BD Vacutainer® Fluoride Blood Collection Tubes are	Same

	used for the collection, containment, transportation, and processing of blood in a closed tube. It is used in settings where a venous blood sample is collected by a trained healthcare worker.	
Tube Material	Plastic	Same
Closure	Hemogard™ safety closure	Same
General Device Characteristic Differences		
Tube Dimensions and Draw Volume	BD Vacutainer® Sodium Fluoride / Potassium Oxalate tubes: 13x75 mm – 2.0 mL 13x75 mm – 4.0 mL 13x100 mm – 6.0 mL BD Vacutainer® Sodium Fluoride / Na2EDTA tubes: 13x75 mm – 2.0 mL	BD Vacutainer® Sodium Fluoride / Potassium Oxalate tubes: 13x75 mm – 2.0 mL
Shelf-Life	15 – 16 months	12 months
Anticoagulant	Sodium Fluoride /Potassium Oxalate, Sodium Fluoride /Disodium EDTA	Sodium Fluoride /Potassium Oxalate
Sample Type	Plasma	Serum, Plasma, Whole Blood
Intended Use Analytes	Glucose and Lactate	Glucose

VI Standards/Guidance Documents Referenced:

CLSI GP39-A6, Tubes and Additives for Venous Blood Specimen Collection: Approved Standard-Sixth Edition
CLSI EP25-A, Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline
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
ISO 11137-2, Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

ISO 14971:2019 Medical Devices – Application of risk management to medical devices- Third Edition

ANSI/AAMI/ISO 11137-3:2017 Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control

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

14-540 ANSI/AAMI/ISO 11737-2:2019 Sterilization of BD 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"

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Two studies were conducted to evaluate the repeatability (within-tube), lot-to-lot (between lots), and tube-to-tube (between tube) variation in the BD Vacutainer® Fluoride Blood Collection Tubes. Sodium Fluoride/ Potassium Oxalate (NaF/KOx) tubes were tested and evaluated using glucose and lactate, and Sodium Fluoride EDTA (NaF/Na_2EDTA) tubes were tested and evaluated using glucose. The study designs included subjects from the clinical settings. Three lots of each of the BD Vacutainer® Fluoride Blood Collection Tubes (candidate device) were used in the study. The study was performed using samples collected from 25 subjects for glucose and 40 subjects for lactate, and all samples were run in duplicate on two instrument platforms. One representative platform with precision results is summarized in the tables below:

Table 1. Precision Summary for BD Sodium Fluoride/Potassium Oxalate (NaF/KOx)

Analyte (mg/dL)	Mean	Variance Component	CV%	SD	CV 95% CI	SD 95% CI
Glucose	202.4	Total Precision	1.4	2.8	0.5,1.17	0.5,1.17
		Within-Tubes	1.2	2.4	1.1, 1.3	2.1, 2.7
		Between-Tubes	0.7	1.5	0.4, 0.9	0.8, 1.9
		Between Lots	0.0	0.0	0.0	0.0
Lactate	2.044	Total Precision	6.7	0.137	5.6, 8.5	0.114, 0.173
		Within-Tubes	6.7	0.137	6.3, 7.1	0.129, 0.146
		Between-Tubes	0.6	0.009	0.0,1.2	0.0,0.022
		Between Lots	0.0	0.0	0.0	0.0

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

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

4. Assay Reportable Range:

   Not applicable.

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

   A. Within-Tube Stability (sample stability):
   Glucose (GLU) and lactate stability studies were conducted to assess within-tube stability for BD Vacutainer® Fluoride Blood Collection tubes using NaF/ Na_2EDTA 13x75 2mL tubes for glucose determinations and NaF/KOx 13x75 4mL for glucose and lactate determinations. Stability studies were assessed for glucose up to 24hr. Lactate studies were assessed up to 45 minutes while the samples were stored in tubes on ice, followed by refrigerated storage and centrifugation. Analyte stability was tested on a minimum of two instrument platforms. The study protocols and acceptance criteria have been reviewed and found to be acceptable. These studies support the storage of samples for measurement of lactate up to 45 minutes when held on ice and glucose up to 4 hours at room temperature or 24 hours when refrigerated.

   B. Shelf-Life
   Real Time stability testing of the BD Vacutainer® Fluoride Blood Collection tubes showed that the candidate device is stable for 15-16 months when stored at 4 to 25°C. The stability study protocol and acceptance criteria has been reviewed and found to be acceptable. The claimed shelf-life of each tube is shown below:

Fluoride Blood Tube	Claimed Shelf-life	Volume
NaF/Na_2EDTA	16 months	2 mL
NaF/KOx	15 months	2 mL
NaF/KOx	16 months	4 mL
NaF/KOx	15 months	6 mL

   C. Additional bench testing on the candidate device
   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, barrier formation and packaging performance during shipping and handling. 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:

   Not applicable.

2. Matrix Comparison:

   Not applicable. These tubes are for venous whole blood or plasma only.

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 study was conducted to evaluate equivalence between the BD Vacutainer® Fluoride Blood Collection Tubes (6 mL BD Vacutainer® Sodium Fluoride / Potassium Oxalate and 2 mL BD Vacutainer® Sodium Fluoride / Na2EDTA) and a cleared comparator tube (NaF/K Oxalate Blood Collection Tubes, 2 mL) for testing glucose and lactate. All samples were collected by routine venipuncture using standard phlebotomy techniques. In addition, contrived samples were prepared to obtain results that spanned the analytical measurement range for the tested analytes. Glucose and Lactate were evaluated on two instrument platforms each and demonstrated comparable results between the candidate tubes and the comparator tubes.

   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. Biases between tube types were estimated with 95% confidence intervals. Regression analyses for a representative tube using each instrument platform are provided in the tables below:

   Comparison results: BD NaF/K-Ox vs Comparator Tube NaF/K-Ox

Analyte	Instrument	N	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
Glucose	1	119	0.53 (-0.12, 1.17)	0.99 (0.99, 1.0)	1.0
	2		-1.0 (-1.0, 0.42)	1.0 (0.99, 1.0)	0.99

Comparison results: BD NaF/Na2EDTA (Plasma) vs Comparator Tube NaF/K-Ox

Analyte	Instrument	N	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
Glucose	1	137	2 (0.13, 2)	1 (1, 1.01)	0.999
	2		0.62 (-1.01, 1)	1 (1, 1.02)	0.999

Comparison results: BD NaF/KOx vs Comparator Tube NaF/KOx

Analyte	Instrument	N	Intercept (95% CI)	Slope (95% CI)	Correlation Coefficient
Lactate	1	83	0 (-0.03, 0.1)	1 (1, 1.03)	0.993
	2		-0.01 (-0.07, 0.04)	1 (0.96, 1.04)	0.992

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.