DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969	5/15/2017-7/6/2017* FEI NUMBER 2243072

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ms. Elizabeth Gaipa , WW VP Quality Management

FIRM NAME	STREET ADDRESS
Becton Dickinson & Company	1 Becton Dr
CITY, STATE, ZIP CODE, COUNTRY Franklin Lakes, NJ 07417-1815	TYPE ESTABLISHMENT INSPECTED Specification Developer/Complaint File Establishment

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Design validation did not ensure the device conforms to defined user needs and intended uses.

A. Specifically, your firm failed to validate [redacted (b) (4)]" testing that is used to support design changes, in lieu of performing clinical studies/assessments. Such design changes include those made to [redacted (b) (4)] associated with stoppers, and [redacted (b) (4)] and [redacted (b) (4)] The following are examples of design changes that occurred to tubes or the rubber stoppers used for K2EDTA where [redacted (b) (4)] testing, which has not been proven accurate and reliable, was conducted to approve/support design changes in lieu of performing clinical studies/assessments:

[redacted (b) (4)]

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Melissa A Freeman, Investigator Dave M Deroche, Investigator Yung W Chan, Investigator	7/6/2017 X Melissa A Freeman Melissa A Freeman Investigator Signed by: Melissa A. Freeman -S	DATE ISSUED 7/6/2017

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(b) (4)

B. Design validation did not ensure the device conforms to defined user needs and intended uses. Specifically, validation studies used to support changes that occurred from a period of (b) (4) (b) (4) for K2EDTA tubes (including both lavender stopper top and tan stopper top) are inadequate. (b) (4) testing was used to support your firm's claim that various project changes did not impact the performance of the K2EDTA tubes. However, the (b) (4) studies conducted did not utilize/collect patient blood into the tubes, and the studies did not demonstrate any clinical measurements associated with the tubes. The impact on the clinical performance of the tubes was not adequately evaluated for the following projects/changes:

Project Number	Type of Change	Project Start Date
(b) (4)		(b) (4)

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C. The final process validation report associated with (b) (4), dated (b) (4) concerned (b) (4) changes for multiple rubber stopper compounds. The validation report identified several rubber stopper (b) (4) batches that failed the (b) (4) specifications. The conditions were outside the control limits that your firm pre-determined. The validation report noted that an interim Quality Alert would be attached to the holding cage of the rubber (b) (4) batch, and that this would alert (b) (4) that process variations maybe required for the stoppers during the (b) (4) phases. However, there is no further information included for how the failures may effect/impact the overall performance and acceptance criteria of the rubber stoppers over time, with respect to the (b) (4) changes.

OBSERVATION 2

Design input requirements were not adequately documented.

Specifically, your firm does not adequately define and document the acceptance criteria for design input. There is no assurance that design input requirements for changes to (b) (4) for Stoppers, were appropriate. For example, documents included in file (b) (4) note a Design Input Requirements and Traceability (DIR) Matrix Rev 02 dated 11/20/2013. One of the requirements for Line 4 of the DIR states (b) (4)". The verification or validation method is "(b) (4) (b) (4)", and the acceptance criteria include (b) different types; (b) (4) (b) (4)", the (b) (4) (b) (4) (b) (4) Another requirement for Line 6 of the DIR states (b) (4)". The verification or validation method is "(b) (4)". The (b) (4) acceptance criterion is (b) (4)", the (b) (4)" acceptance criterion (b) (4) (b) (4) However, BD CPD (Clinical Affairs) did not define the acceptance criteria anywhere in the DIR or in the clinical memo. In addition, according to the SOP "Design Input

Requirements Management and Traceability" V08-832 Rev 6 section 4.14, (b) (4) (b) (4). Section 6.3.1 indicates that each design input requirement, verifiable acceptance criteria must be established. Acceptance criteria must be identified and documented prior to Design Verification/Validation.

OBSERVATION 3

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

A. Specifically, your firm's complaint procedure 1501-092-000-SWI; "Global Complaints Management"; Revision 3; Version C; Section 5.1.2 fails to identify (b) (4) call log as a possible area of complaint information. Your firm failed to adequately review entries recorded by the technical service department, within the (b) (4) call log as complaint data, prior to closure. Additionally, (b) (4) audits of the call log performed by the technical service department failed to further evaluate and identify entries with product complaint information and determination for MDR reportability. The following are examples, not limited to, those entries that were logged into (b) (4) (b) (4) but failed to be identified by your firm as product complaints:

Description	Action Type	Date Received	Inquiry Number
Lab reported K+ results greater than 10	Troubleshooting	01/16/2017	(b) (4)
CBCs showing degenerated neutrophils	General Inquiry	02/13/2015	(b) (4)
Caps coming off when centrifuging	General Inquiry	08/04/2015	(b) (4)
Pediatric samples are clotting in tubes	General Inquiry	03/26/2014	(b) (4)
Lab samples are	General Inquiry	05/08/2015	(b) (4)

gelatinous in tubes			
Blood would not go in the tube	General Inquiry	10/14/2016	(b) (4)
Specimens are clotting in tubes	General Inquiry and Troubleshooting	10/02/2014	(b) (4)

There have been approximately 424 inquiries that your firm has now retrospectively deemed to be "complaints" which were not previously reviewed, evaluated, or processed within your complaint handling system, nor were they evaluated for MDR reportability.

B. Information received by your firm in May 2015, identifying potential complaint information for K2EDTA tubes possibly contributing to the suppressing of lead values in blood, was not investigated, evaluated, and documented formally into your complaint handling database. To date, the information has not been translated into your complaint system. Furthermore, your firm's "Quality System Policy Manual"; Document Number FL-01PL; Rev. 36; Ver. J, Section 5.2 explains that data can be gathered informally or formally from many sources.

C. "BD Technical Service Call Log (b) (4) "; Document number CTS-003; Revision 2; serves as work instructions for the initial receipt of complaint information. This document fails to provide instruction or guidance for determining if an inquiry should be handled as a complaint and forwarded to the designated complaint handling unit. Furthermore, Section 6.1; Step 13, references "Complaint Processing Procedure"; VO8-706; which was obsoleted on 12/13/2011 despite CTS-003 having been last revised on 03/10/2014.

D. Your firm utilizes procedure VO8-878; "Quality Data Analysis" to track and trend complaint data for management review. This procedure fails to include the requirement for tracking and trending complaint data located in the firm's Inquiry Call Logs. This data includes numerous trouble shooting inquires and other information alerting your firm of product failures and potential malfunctions. Since January 2013 the call logs contain approximately 23,000 inquires.

E. Specifically, there are no written procedures or user instructions for (b) (4). Your firm's sales representatives used this system to intake and report information for potential device complaints, malfunctions and MDR reportable events. This software has been used to document and report complaints or PIRs (product incident reports) to the designated complaint handling unit since 12/2014. Furthermore, your firm has not established a written procedure for verifying or validating this software.

OBSERVATION 4

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically, the following complaint files containing reports of malfunctions were not reported as MDRs to the agency within 30 days of becoming aware of a device malfunction:

Complaint Number	Aware Date	Date of MDR	Complaint Description
66750	10/11/2016	06/14/2017	Nurse's finger stuck by burr on bottom of EDTA tube. Nurse's blood leaked.
71551	11/21/2016	06/02/2017	Stopper pulled out of EDTA tube and blood spilled down nurse's uniform.
78514	02/21/2017	06/14/2017	Stopper creep-out and EDTA tube spilled blood all over the floor.
69006	10/31/2016	06/14/2017	The lip of the EDTA blood collection tube was cracked and blood leaked out during mixing.
73958	01/03/2017	06/14/2017	Blood shed after stopper popping off EDTA tube when withdrawing needle from tube.

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OBSERVATION 5

The written MDR Procedure does not include an internal system which provides for the timely and effective identification, communication and evaluation of events that may be subject to medical device reporting requirements.

Specifically, your firm's utilizes procedures CPR-051, CPR-119, NASSC-AEG-001, and position paper 07-05 to review, evaluate and submit MDR's to the agency. These procedures are deficient in the following areas:

A. Procedure NASSC-AEG-001; "Medical Device Reporting (MDR) review and reporting for (b) (4) "; section 4.1.2. states, (b) (4) (b) (4) " This procedure does not require a thorough collection of information in order to perform the appropriate evaluation and investigation for MDR reportability of malfunction complaints.

B. The decision tree to determine MDR reportability included per procedure CPR-119, notes a step within the decision tree that asks, " (b) (4) (b) (4) (b) (4) ?" However, there is no further criteria established for how to interpret, define, and standardize this step in order to assure review and outcome for MDR reportability decisions are adequate.

C. Procedures CPR-051, CPR-119, NASSC-AEG-001, and position paper 07-05 fail to require review of complaint files for additional supplemental MDR information prior to final complaint closure. Specifically, your firm failed to report all information known when submitting a supplemental MDR to the agency for complaint file # 77167 which explained

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blood entered a phlebotomist's mouth as a result of blood pooling on the outside of the tube. The supplemental MDR submitted on 05/04/2017 failed to inform the agency that a CAPA for the failure mode of '(b) (4)' was opened on 03/17/2017. Subsequently, your firm closed the complaint file without further evaluation that all information reasonably known was submitted to the agency. Your firm filed an additional supplemental MDR after complaint closure on 06/05/2017 to report/clarify conflicting information.

OBSERVATION 6

Complaints involving the possible failure of a device to meet any of its specifications were not reviewed, evaluated and investigated where necessary.

Specifically, complaint # 000029473A was received on 07/02/2013 and reported that cartridge errors occurred when using BD Vacutainer tube #366664, Lot #3032032 with an i-STAT portable clinical analyzer, which is used to screen for troponin levels in blood in order to detect potential cardiac distress. The complainant also explained there was a strong sulfurous smell coming from the tube. These cartridge errors delayed critical test results. Your firm failed to investigate the sulfurous smell reported by the complainant. Additionally, the testing conducted as part of your investigation did not reproduce the clinical conditions by using fresh whole blood specimens. Frozen blood specimens collected from a donor (with no troponin levels present) were used as part of the investigation. Further, it is not documented whether an i-STAT analyzer was utilized to test the frozen blood specimens.

OBSERVATION 7

Personnel do not have the necessary training to perform their jobs.

A. Specifically, personnel have not received adequate training to identify, document, and report product complaints to your designated complaint handling unit. Specifically,

troubleshooting/complaint information related to technical issues with your firm's K2EDTA tubes in the detection of lead poisoning was relayed from another manufacturer to your firm via email in 2015. This information was not forwarded for review and evaluation by your designated complaint handling unit, nor was it documented within your formal complaint handling software.

B. Not all personnel had been trained prior to execution of testing associated with validation protocol (b) (4) The validation study was associated with a (b) (4) change with respect to stopper material. Specifically, 4 of your firm's lab technicians conducting testing for the (b) (4) testing, and other (b) (4) and (b) (4), were not trained on the protocol/testing prior to the initiation of the study.

Annotations to Observations

Observation 1:	Not annotated
Observation 2:	Not annotated
Observation 3:	Not annotated
Observation 4:	Not annotated
Observation 5:	Not annotated
Observation 6:	Not annotated
Observation 7:	Not annotated

***DATES OF INSPECTION**

5/15/2017(Mon),5/16/2017(Tue),5/17/2017(Wed),5/18/2017(Thu),5/22/2017(Mon),5/23/2017(Tue),5/24/2017(Wed),5/25/2017(Thu),5/31/2017(Wed),6/05/2017(Mon),6/15/2017(Thu),7/06/2017(Thu)

7/6/2017

X Dave M Deroche
Dave M Deroche
Investigator
Signed by: Dave M. Deroche -5

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."