DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	4/24/2025-4/24/2025
	FEI NUMBER 1070630

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Amanda L. Wagoner, Vice Presdient, Operations

FIRM NAME	STREET ADDRESS
Baptist Health Deaconess Madisonville Inc	900 Hospital Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Madisonville, KY 42431-1644	Blood Bank

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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Failure to perform a thorough investigation of an unexplained discrepancy.

Specifically,

a) On (b) (4), (b) (6), (b) (7)(C) an ABO blood type and antibody screen was conducted on a patient. The ABO type result was O positive. Your firm's computer system had the patient's historical (b) (4), (b) (6), (b) (7)(C)) ABO type as A positive.
b) On (b) (4), (b) (6), (b) (7)(C), an ABO blood type and antibody screen was conducted on a patient requiring an emergency release of a blood component for transfusion. The ABO type result was A negative. Your firm's computer system had the patient's historical ((b) (6), (b) (7)() ABO blood type as B positive.

Your firm failed to conduct and identify a root cause analysis. Your firm failed to identify if other computer system historical ABO types were incorrect. Your firm failed to take actions and follow-up to prevent these issues from reoccurring.

OBSERVATION 2

Written standard operating procedures including all steps to be followed in the collection and processing of blood and blood components for allogeneic transfusion and further manufacturing purposes were not always established and followed.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Cody D Rickman, Investigator	X Cody D Rickman Investigator Signed By: Cody D. Rickman -S Date Signed: 04-24-2025 15:42:00	4/24/2025

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Your firm's standard operating procedure B-900, titled Donor Phlebotomy Procedure – Link and Bleed, effective 01/14/2020, page 2 of 6, instructs employees to "***Mix all tubes (b) (4) times after collection.". According to the (b) (4), Evacuated Blood Collection System package insert: (b) (4)

Your firm's standard operating procedure B-900, titled Donor Phlebotomy Procedure – Link and Bleed, effective 01/14/2020 fails to instruct employees to invert sample test tubes (b) (4) times after blood is collected in the sample tubes according to package insert instructions.

On 04/24/2025, I observed your donor collection technician collect blood in (b) (4), Evacuated Blood Collection System test tubes. The donor collection technician "mixed" the test tubes but failed to invert the tubes (b) (4) times according to package insert instructions.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Cody D Rickman, Investigator

X Cody D Rickman
Investigator
Signed By: Cody D. Rickman -S
Date Signed: 04-24-2025
15:42:00

DATE ISSUED
4/24/2025

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."