DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	4/23/2026-4/24/2026
	FEI NUMBER 3008533766

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Theresa M. Baldwin, Director of Laboratory Services

FIRM NAME	STREET ADDRESS
University of Vermont Health Network - Adirondack Blood Center	85 Plaza Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Plattsburgh, NY 12901-6438	Blood Donor Center

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

The phlebotomy site is not prepared by a method that gives maximum assurance of a sterile container of Whole Blood.

Specifically,

On 04/23/2026, I observed a blood bank registered nurse prepare venipuncture sites for whole blood collection of units (b) (4), (b) (6), (b) (7)(C) and (b) (4), (b) (6), (b) (7)(C). (b) (4) sterilization of the venipuncture sites for each of the units, the staff member (b) (4) placed a sterile gauze on the site without allowing the area to air dry. The gauze that was placed on the venipuncture site was then used to wipe the area (b) (4) to needle insertion and collection of the units. These actions are not in accordance with your firm's written procedure "Preparation of Donor Venipuncture Site" (version 1.2, effective date: 02/20/2026) and the manufacturer's instructions, which both require the venipuncture site to air dry for (b) (4) (b) (4) after sterilization and (b) (4) wiping the sterilized area.

OBSERVATION 2

Failure to use supplies and reagents in a manner consistent with instructions provided by the manufacturer.

Specifically,

The storage room containing your firm's (b) (4) supplies is not equipped with (b) (4) temperature

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Chanel E Crawford, Investigator	X Chanel E Crawford Investigator Signed By: CHANEL E. CRAWFORD -S Date Signed: 04-24-2026 12:41:55	4/24/2026

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monitoring, which is necessary to ensure product integrity. (b) (4) supplies stored in the storage room include but are not limited to the following:

- (b) (4)
-
-

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Chanel E Crawford, Investigator	DATE ISSUED 4/24/2026

X Chanel E Crawford Investigator Signed By: CHANEL E. CRAWFORD -S Date Signed: 04-24-2026 12:41:55

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."