

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 1201 Main Street, Suite 7200 Dallas, TX 75202 (214) 253-5200 Fax: (214) 253-5314	DATE(S) OF INSPECTION 4/8/2026-4/14/2026*
	FEI NUMBER 3014028128

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ruby A. Guevara, Regional Quality Manager

FIRM NAME Biomat USA Inc	STREET ADDRESS 2950 S John Redditt Dr Ste 105
CITY, STATE, ZIP CODE, COUNTRY Lufkin, TX 75904-5687	TYPE ESTABLISHMENT INSPECTED Source Plasma 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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Failure to present educational material to the donor in an appropriate form and in a manner designed to be understood by the donor.

Specifically, on 4/8/26, your donor center technician administered the donor history questionnaire to an (b) (6), (b) (7)(C) donor (b) (6), (b) (7)(C). The donor's profile in the blood establishment system notifies your employee that the donor must be (b) (6), (b) (7)(C) since (b) (6), (b) (7)(C). Your employee failed to (b) (6), (b) (7)(C) to the donor education materials relating to risk factors associated with relevant transfusion-transmitted infections and risks and hazards associated with donating. Your employee asked the donor if they read the educational materials and medication deferral list and marked (b) (6), (b) (7)(C) on the questionnaire. The SOP "Accommodating Donors with Disabilities" states, for (b) (4) donors, "A staff member will ask all screening questions ... All Job Aids will be displayed in (b) (4). The staff member will (b) (4) (b) (4) " "... all documents normally presented to be read by a prospective or repeat donor and understood by them as a part of the initial and subsequent screening process must be read in their entirety to the donor by a center employee."

This donor has been donating since (b) (6), (b) (7)(C) and has made (b) (6), (b) (7)(C) donations.

OBSERVATION 2

Failure to perform a thorough investigation and make a record of the conclusions and follow-up of an unexplained discrepancy.

Specifically, your firm opened a deviation 2196858 on 11/19/22 which identified a donor with multiple

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accounts under (b) (6), (b) (7)(C). This issue was discussed during the previous inspection. This incident was reported to the FDA (BPD 851423) and (b) (4) products were identified as effected. The donor's profiles were merged on 12/23/22 after the donor provided proof of identification. Your Regional Quality Manager and Quality Systems Manager were unable to provide documentation related to the root cause of the incident and additional corrective action related to prevention of reoccurrence.

Additionally, in the report to FDA, it was stated the donor was permanently deferred. However, records indicate the donor was temporarily deferred until they could provide proof of identification. The donor continued to donate until (b) (6), (b) (7)(C) and has a total of (b) (6), (b) (7)(C) donations.

OBSERVATION 3

Failure to maintain donor, processing and general records.

Specifically, you failed to maintain accurate records during the eligibility process and when treating donor adverse events.

1. When documenting adverse events, your employees fail to document treatment given to donors. On 4/9/26, your donor center specialist performed a venipuncture where blood spilled and resulted in a (b) (6), (b) (7)(C) (unit ID (b) (4), (b) (6), (b) (7)(C)). Your firm classified this as a minor donor adverse event. The documentation of the event did not include the treatment given to the donor. The SOP "Event Types and Information to Record" states, for a (b) (4) Uncomplicated "Document symptoms, actions taken to resolve the adverse event, and if symptoms resolved." The following are four examples of minor donor adverse event records where your employees failed to include treatment given to the donor. Donor ID: (b) (6), (b) (7)(C), donation on (b) (6), (b) (7)(C); donor ID: (b) (6), (b) (7)(C), donation on (b) (6), (b) (7)(C) and donor ID: (b) (6), (b) (7)(C) on (b) (6), (b) (7)(C).
2. On 4/9/26 your donor screening technician failed to document a consultation with your center medical specialist regarding a donor's (b) (6), (b) (7)(C) pulse (ID (b) (6), (b) (7)(C)). After consultation with the

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center medical specialist, the donor was cleared to donate. The SOP "Donor Requirement – Blood Pressure and Pulse" states, "If the medical staff determines that the donor does not have (b) (4) pulse, then documentation of this evaluation must be included in the donor's record. (b) (4)." ."

- When drawing blood during the screening process, (b) (4) capillary tubes were filled from the (b) (4) finger, and it was not documented. Your donor screening technician filled (b) (4) capillary tubes from (b) (4) finger stick (donor ID: (b) (6), (b) (7)(C)). Furthermore, your SOP does not instruct employees to document when (b) (4) capillary tubes are filled from the (b) (4) finger stick, and it only instructs your employees to document when (b) (4) finger sticks are performed.

You collected (b) (4) units of plasma in 2026 and (b) (4) units of plasma in 2025.

OBSERVATION 4

Written standard operating procedures including all steps to be followed in the collection and storage of blood and blood components for were not always followed.

Specifically, the following are examples where your employees did not follow standard operating procedures (SOPs).

- Your employees filled the capillary tubes, used to determine hematocrit and total protein, (b) (4) (b) (4). The SOP "Donor Requirement – Hematocrit" states, "(b) (4) (b) (4)." The operator's manual for the (b) (4) states, "Fill a capillary tube (b) (4)." For (b) (4) out of (b) (4) donor screenings observed, donor screening technicians filled the capillary tubes (b) (4) : (b) (6), (b) (7)(C) (b) (6), (b) (7)(C).

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2. Your donor screening technician failed to clean the (b) (4) during performance of (b) (4) quality control on 4/9/26. The SOP "Vital Sign Equipment Standardization" states, "Follow the below steps to complete the (b) (4) quality control:" "Clean the unit per instructions in the Operator's manual using (b) (4) (b) (4) "

3. Your employees are not ensuring source plasma products in the freezers are set up according to your procedures. Your procedures state products should be (b) (4) and (b) (4). In freezer (b) (4) I observed product was stored (b) (4) (b) (4) and (b) (4). In freezer (b) (4) I observed product was stored (b) (4). Freezer (b) (4) holds (b) (4) (b) (4) products and (b) (4), and freezer (b) (4) holds product that are (b) (4) (b) (4) products and (b) (4).

You collected (b) (4) units of plasma in 2026 and (b) (4) units of plasma in 2025.

***DATES OF INSPECTION**

4/08/2026(Wed), 4/09/2026(Thu), 4/10/2026(Fri), 4/13/2026(Mon), 4/14/2026(Tue)

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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."