DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	1/27/2026-2/4/2026* FEI NUMBER 3024304918

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Matthew D. Nagelbush, Center Manager

FIRM NAME	STREET ADDRESS
Biomat USA Inc	13700 N Dysart Rd, Suite 140
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Surprise, AZ 85379	Source Plasmapheresis Collection 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

Records fail to show test results so as to provide a complete history of the work performed.

Specifically,

During review of donor test records, serum protein electrophoresis records failed to include a quantitative Total Protein result to provide a complete history of the work performed. You fail to receive quantitative results from the contract laboratory for Total Protein and instead accept the interpretive value as your result. You currently receive these results as interpretations of results that are listed as N, ABN-L, and ABN-H.

Additionally, Center Medical Specialists do not review protein values that are reported. A review includes ensuring a hold is placed on the donor and 14-day medical screening is failed. Donor holds are reviewed to ensure the donor has not had (b) (4) consecutive unacceptable results.

These results are utilized in donor eligibility determination.

OBSERVATION 2

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

Specifically,

During observation of donor arm preparation and venipuncture, I observed three collections where your

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Emily S Mcgann, Investigator

X Emily S Mcgann
Investigator
Signed By: Emily S. Mcgann -S
Date Signed: 02-04-2026
13:50:30

DATE ISSUED
2/4/2026

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employees did not follow your standard operating procedure (SOP) titled, *Venipuncture and Plasma Collection* (PC-002), for donor arm preparation.

a. On 01/30/2026, I observed Phlebotomist (b)(6), (b)(7)(C) complete an arm scrub for collection number (b)(4), (b)(6), (b)(7)(C). The scrub observed did not meet your SOP's requirement of "scrubbing in a (b)(4) (b)(4) venipuncture site. Phlebotomist (b)(6), (b)(7)(C) scrubbed a space (b)(4) (b)(4) the venipuncture site for the (b)(4) scrub.

b. On 02/03/2026, I observed Plasma Processor (b)(6), (b)(7)(C) complete an arm scrub for collection number (b)(4), (b)(6), (b)(7)(C). The scrub observed did not meet your SOP's requirement of scrubbing venipuncture site for a (b)(4). PP (b)(6), (b)(7)(C) began (b)(4).

c. On 02/03/2026, I observed Donor Center Specialist (b)(6), (b)(7)(C) complete an arm scrub for collection number (b)(4), (b)(6), (b)(7)(C). The scrub observed did not meet your SOP's requirement of allowing the venipuncture site to dry for (b)(4). DCS (b)(6), (b)(7)(C) scrubbed for (b)(4) and (b)(4) (b)(4) (b)(4). DCS (b)(6), (b)(7)(C) (b)(4) (b)(4).

OBSERVATION 3

The standard operating procedure fails to include a written description of the procedures for investigating adverse donor and recipient reactions.

Specifically,

During review of Donor Adverse Event Reports, donor (b)(4), (b)(6), (b)(7)(C) had a donor adverse event (DAE) on 10/12/2025, which resulted in emergency services transporting the donor to the hospital. The DAE resulted from improper set up by Phlebotomist (b)(6), (b)(7)(C), which cause a centrifuge spill. The centrifuge spill resulted in a red blood cell loss for the donor. Deviation record 2711266 does not include discussion with employees involved, investigation into improper set-up, or immediate actions with the employees involved.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Emily S Mcgann, Investigator X Emily S Mcgann Investigator Signed By: Emily S. Mcgann -S Date Signed: 02-04-2026 13:50:30	2/4/2026

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*DATES OF INSPECTION

1/27/2026(Tue), 1/28/2026(Wed), 1/29/2026(Thu), 1/30/2026(Fri), 2/02/2026(Mon), 2/03/2026(Tue), 2/04/2026(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Emily S Mcgann, Investigator X Emily S Mcgann Investigator Signed By: Emily S. Mcgann -S Date Signed: 02-04-2026 13:50:30	2/4/2026

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."