DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	12/10/2024-12/13/2024
	FEI NUMBER 3006811800

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Justin M. Mackey, Center Manager

FIRM NAME	STREET ADDRESS
Biomat USA, Inc.	1132 Locust St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Terre Haute, IN 47807-1642	Source Plasma 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 WE OBSERVED:

OBSERVATION 1

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,

1. On 12/13/2024, phlebotomist (b) (6), (b) . failed to identify plasmapheresis donors prior to venipuncture per your SOP Document#: PC-001 titled "Preparation for Plasmapheresis" Revision 26.0, Effective: 15-Oct-2024. During observation of donors (b) (6), (b) (7)(C) phlebotomist (b) (6), (b) (7 scanned the barcode associated with the donors' donation but failed to verbally ask the donors' full name and last (b) (4) digits of their donor number.

2. On 12/10/2024, operations supervisor (b) (6), (b) (7)(and quality systems manager (b) (6), (b) (7) . failed to properly obtain proof of address for applicant donor (b) (6), (b) (7)(C) per your SOP, Document #: DE-014 titled "Verifying the Donor Address and Determining Cohabitants" Revision 17.0, effective 15-Oct-2024. On the first day of donation for applicant donor (b) (6), (b) (7)(C) she stated to operations supervisor (b) (6), (b) (7 that she currently does not have proof of residency of her new address. Quality systems manager (b) (6), (b) (7) . directed operations supervisor (b) (6), (b) (7)(C to mail a post card to the applicant donor's address so that the applicant donor may bring the post card to the center at their next donation as evidence of their new address.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Lesley Mae P Lutao, Investigator
David A Moore, Investigator

X Lesley Mae P Lutao
Investigator
Signed By: Lesley Mae P. Lutao - S
Date Signed: 12-13-2024 14:54:11

DATE ISSUED
12/13/2024

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X David A Moore
Investigator
Signed By: 2002807636
Date Signed: 12-13-2024 14:54:47

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Lesley Mae P Lutao, Investigator
David A Moore, Investigator

X Lesley Mae P Lutao
Investigator
Signed By: Lesley Mae P. Lutao - S
Date Signed: 12-13-2024 14:54:11

DATE ISSUED
12/13/2024

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."