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	1/20/2026-1/28/2026* FEI NUMBER 3023675901

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ferrin C. Crockett, Regional Operations Manager

FIRM NAME	STREET ADDRESS
Biomat USA Inc	15609 Lake Shore Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cleveland, OH 44110-1003	Plasmapheresis 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

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,

Your procedure entitled "Donor Adverse Events: Completing the Donor Adverse Events Report (DAER)" (Document #: (b) (4)) states to enter the Onset Time as reported by the first person to respond to the DAE. While reviewing (b) (4) Donor Adverse Events Reports, it was noted that on nine out of the (b) (4) records, the Onset Time does not match the time of collection and/or the DAER uploaded in the donor file, does not always match the DAER printed from the DAER program (b) (4). For example:

DAER Number	Donor Initials	Onset Time from DAER Program	Draw Time Start on Worksheet	Draw Time End on Worksheet	Onset Time from DAER in Donor File
DAER (b) (4)	(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C
DAER (b) (4)	(b) (6), (b) (7) (C)	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C
DAER (b) (4)	(b) (6), (b) (7) (C)	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C
DAER (b) (4)	(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Nancy L Neiger, Investigator

X Nancy L Neiger
Investigator
Signed By: Nancy L. Neiger -S
Date Signed: 01-28-2026
11:11:42

DATE ISSUED
1/28/2026

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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Cleveland, OH 44110-1003	Plasmapheresis Center

DAER (b) (4)	(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C
DAER (b) (4)	(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C	(b) (6), (b) (7	(b) (6), (b) (7)(C
DAER (b) (4)	(b) (6), (b) (7) (C)	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C
DAER (b) (4)	(b) (6), (b) (7) (C)	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C
DAER (b) (4)	(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C	(b) (6), (b) (7)(C

***DATES OF INSPECTION**
1/20/2026(Tue), 1/21/2026(Wed), 1/22/2026(Thu), 1/23/2026(Fri), 1/28/2026(Wed)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Nancy L Neiger, Investigator

X Nancy L Neiger
Investigator
Signed By: Nancy L. Neiger -S
Date Signed: 01-28-2026
11:11:42

DATE ISSUED
1/28/2026

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."