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	1/5/2026-1/12/2026* FEI NUMBER 3022988848

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Priscilla A. Tisdale, Regional Quality Manager

FIRM NAME	STREET ADDRESS
Biomat USA Inc	1009 Park Ave W
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mansfield, OH 44906-2809	Source Plasma 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

Records are not concurrently maintained with the performance of each significant step in the processing of each unit of blood and blood components so that all steps can be clearly traced.

Specifically,

During the inspection on 01/09/2026, Plasma Processor (b) (6), (b) (7)(C) was observed with a plasma bottle rack containing processed plasma bottles that had not been placed into the freezer for initial freezing. Review of the bottles in the rack showed that five plasma bottles had exceeded your (b) (4) processing window between collection machine removal and freezer placement, yet the (b) (4) labels documented compliant freezer placement times. Labels affixed to four bottles indicated a freezer placement time of (b) (4) and one bottle of (b) (4); however, the time of observation was (b) (4). The remaining plasma bottles in the rack were within your established (b) (4) processing window.

The five plasma bottles affected:

(b) (4), documented removal at (b) (4). Documented placement into the freezer at (b) (4).
(b) (4), documented removal at (b) (4). Documented placement into the freezer at (b) (4).
(b) (4), documented removal at (b) (4). Documented placement into the freezer at (b) (4).
(b) (4), documented removal at (b) (4). Documented placement into the freezer at (b) (4).
(b) (4), documented removal at (b) (4). Documented placement into the freezer at (b) (4).

Upon discovery, the bottles were segregated but had not yet been relabeled as (b) (4) product per your procedure.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Nisha C Patel, Investigator X Nisha C Patel Investigator Signed By: 2003100102 Date Signed: 01-12-2026 13:47:22	1/12/2026

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***DATES OF INSPECTION**
1/05/2026(Mon), 1/06/2026(Tue), 1/07/2026(Wed), 1/08/2026(Thu), 1/09/2026(Fri), 1/12/2026(Mon)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Nisha C Patel, Investigator

X Nisha C Patel
Investigator
Signed By: 2003100102
Date Signed: 01-12-2026
13:47:22

DATE ISSUED
1/12/2026

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."