DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	5/5/2026-5/11/2026* FEI NUMBER 3022888428

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Anita (NMI) Srivastava, Center Manager

FIRM NAME	STREET ADDRESS
Grifols Biomat, INC	5651 38th Ave N
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Saint Petersburg, FL 33710-1923	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

Failure to maintain donor records.

Specifically, you were unable to provide the donor records from January 2023 to April 2026 containing the adverse reaction investigation for the following donor reaction records:

- I(b) (6), (b) (7)(C) associated with donor number (b) (6), (b) (7)(C)
- I(b) (6), (b) (7)(C) associated with donor number (b) (6), (b) (7)(C)
- I(b) (6), (b) (7)(C) associated with donor number (b) (6), (b) (7)(C)
- I(b) (6), (b) (7)(C) associated with donor number (b) (6), (b) (7)(C)
- I(b) (6), (b) (7)(C) associated with donor number (b) (6), (b) (7)(C)
- I(b) (6), (b) (7)(C) associated with donor number (b) (6), (b) (7)(C)
- I associated with donor number
- I associated with donor number
- I associated with donor number
- I associated with donor number
- I associated with donor number
- I associated with donor number
- I associated with donor number
- I associated with donor number
- I associated with donor number

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Steen N Graham, Investigator

X Steen N Graham
Investigator
Signed By: Steen N. Graham -S
Date Signed: 05-11-2026
15:54:53

DATE ISSUED
5/11/2026

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*DATES OF INSPECTION

5/05/2026(Tue), 5/06/2026(Wed), 5/07/2026(Thu), 5/08/2026(Fri), 5/11/2026(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Steen N Graham, Investigator	X Steen N Graham Investigator Signed By: Steen N. Graham -S Date Signed: 05-11-2026 15:54:53	DATE ISSUED 5/11/2026

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."