

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240) 402-9160	DATE(S) OF INSPECTION 4/14/2025-4/15/2025
	FEI NUMBER 3002809584

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Captain Raynese S. Roberts, Commanding Officer/Director of U.S. Naval Hospital Naples

FIRM NAME Department of Defense - Navy (U.S. Naval Hospital Naples)	STREET ADDRESS Via Contrada Boscariello
CITY, STATE, ZIP CODE, COUNTRY Gricignano Di Aversa, CE, 81030 Italy	TYPE ESTABLISHMENT INSPECTED Hospital Blood Bank

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 be as detailed as necessary so as to provide a complete history of the work performed.

Specifically,

1. Your processing records, Appendix 9.001-A titled "Deglycerolization of RBCs Worksheet" fail to be detailed as necessary to provide a complete history of the work performed for 9 of 11 records reviewed. For example:

Unit Number	Comments
(b) (4), (b) (6), (b) (7)(C)	Field box (b) (4) was not completed.
	Field box (b) (4) and (b) (4) were not completed.
	Field box (b) (4) was not completed.
	Field box (b) (4) was not completed.
	Field box (b) (4), (b) (4), (b) (4), and (b) (4) were not completed.
	Field box (b) (4) and (b) (4) was not completed.
	Field box (b) (4) was not completed.
	Field box (b) (4) was not completed.
	Field box (b) (4) and (b) (4) was not completed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Lesley Mae P Lutao, Investigator	Lesley Mae P Lutao Investigator Signed: Lesley Mae P. Lutao - Date Signed: 04-15-2025 09:56:30 X	DATE ISSUED 4/15/2025

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FIRM NAME

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Hospital Naples)

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Gricignano Di Aversa, CE, 81030 Italy

TYPE ESTABLISHMENT INSPECTED

Hospital Blood Bank

You have deglycerolized a total of (b) (4) red blood cells (RBCs) since the last inspection performed on 07/22/2023 to present.

2. Your (b) (4) maintenance record titled "(b) (4) Maintenance" for (b) (4) (b) (4) centrifuge with (b) (4), used to perform compatibility testing, fails to document the tachometer used to perform RPM and timer checks on 12/30/2024.

SEE REVERSE
OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Lesley Mae P Lutao, Investigator

Lesley Mae P Lutao
Investigator
Signed By: Lesley Mae P. Lutao -
Date Signed: 04-15-2025
09:56:30

X

DATE ISSUED

4/15/2025

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."