

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 22215 26th Ave SE Suite 210 Bothell, WA 98021 (425) 302-0340 Fax: (425) 302-0404		<small>DATE(S) OF INSPECTION</small> 3/2/2026-3/4/2026 <small>FEI NUMBER</small> 1000307166	
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Michelle Dorman , Department Head			
<small>FIRM NAME</small> Department of Defense - Navy		<small>STREET ADDRESS</small> Bldg #50 Farenholt Ave, Us Navy Medicine Readiness And Training Command	
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Agana Heights, GU 96910		<small>TYPE ESTABLISHMENT INSPECTED</small> Hospital Blood Bank	
<p>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.</p>			
<p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 Failure to obtain from the donor on the day of donation a postal address where the donor may be contacted for 8 weeks after donation.</p> <p>Specifically, your firm has failed to obtain confirmation from donors on the day of donation regarding whether they will be at their current address 8 weeks after donation. On (b) (6), (b) (7)(C) I observed donor screenings (b) (4), (b) (6), (b) (7)(C) and (b) (4), (b) (6), (b) (7)(C). The donors were not asked if they would be at their current address for the next 8 weeks after donation. Neither your printed donor educational material, your one-on-one donor screening, nor your Medical Questionnaire review, conducted by the donor center staff, addressed verification of a postal address where the prospective donor may be contacted for 8 weeks after the donation in all donor registrations observed. In addition, SOP " (b) (4) 204: Performing the donor physical examination," version 4, effective date 9/16/2025, fails to state the requirement of the 8-week postal address verification.</p> <p>Since 2023, your firm has had approximately (b) (4) registered donors.</p>			
SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Maurine Fadlalla, Investigator		<small>DATE ISSUED</small> 3/4/2026 <div style="text-align: right; font-size: small;"> Maurine Fadlalla Investigator Signed By: MAURINE FADLALLA Date Signed: 03-04-2026 06:31:49 X </div>

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."