DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	3/4/2026-3/6/2026
	FEI NUMBER 1000523688

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Joleen Aguon, CEO

FIRM NAME	STREET ADDRESS
Guam Memorial Hosp Authority	850 Gov. C. G. Camacho Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Tamuning, GU 96911	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

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.

Specifically, your firm has failed to obtain confirmation from donors on the day of donation regarding whether they will be at their current address for 8 weeks following donation. Neither your printed donor educational materials nor your Medical Questionnaire review process addresses verification of a postal address where prospective donors may be contacted during the 8-week period after donation. Additionally, SOP "Donor Interview and Processing" D105.02, Rev. 9, effective July 9, 2007, and SOP "Donor Notification of Abnormal Results" D117.01, effective January 5, 2000, do not include the requirement for 8-week postal address verification.

Since 2023, your firm has had approximately (b) (4) registered donors and one (1) abnormal result.

OBSERVATION 2

Failure to make reasonable attempts to notify a donor who has been deferred based on the results of tests for evidence of infection with a relevant transfusion-transmitted infection(s).

Specifically, donor (b) (6), (b) (7) (C) was tested positive for hepatitis B core Antibody on (b) (6), (b) (7)(C) and you failed to send a letter of notification within 8 weeks to inform donor with abnormal results. According to your Standard Operative Procedure for Donor Notification of Abnormal Result, January 05, 2000 Dll7.01, the Donor Interview card with abnormal result must be brought to the Blood Bank

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Maurine Fadlalla, Investigator X Maurine Fadlalla Investigator Signed By: MAURINE FADLALLA -S Date Signed: 03-06-2026 14:06:36	3/6/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	3/4/2026-3/6/2026
	FEI NUMBER 1000523688

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Joleen Aguon, CEO	
FIRM NAME Guam Memorial Hosp Authority	STREET ADDRESS 850 Gov. C. G. Camacho Rd
CITY, STATE, ZIP CODE, COUNTRY Tamuning, GU 96911	TYPE ESTABLISHMENT INSPECTED Blood bank

Medical Director for review. Attached letter of notification of abnormal results is sent to the donor. Receipt for certified mail I will be attached to the letter and return receipt will follow. Letters returned to GMH Blood Bank because of change of address and/or foreign donors with incomplete or inaccurate addresses will be further investigated. Outside agencies may be relied on for this duty whenever possible if accepted by said agency. If all efforts fail for acquiring correct information or locating donor, handle as a (b) (4) and file appropriate.

OBSERVATION 3

Written standard operating procedures including all steps to be followed in the collection and distribution of blood and blood components for allogeneic transfusion were not always followed.

Specifically, donor (b) (6), (b) (7)(C) tested positive for hepatitis B core antibody on (b) (6), (b) (7)(C), and you failed to follow Standard Operating Procedure for Donor Notification of Abnormal Results, D117.01, effective January 5, 2000, which requires:

1) The Donor Interview card with abnormal result must be brought to the Blood Bank Medical Director for review. Attached letter of notification of abnormal results is sent to the donor. Receipt for certified mail will be attached to the letter and return receipt will follow.
2) Letters returned to GMH Blood Bank because of change of address and/or foreign donors with incomplete or inaccurate addresses will be further investigated. Outside agencies may be relied on for this duty whenever possible if accepted by said agency. If all efforts fail for acquiring correct information or locating donor, handle as a (b) (4) and file appropriately.
3) Physician test results report can only be released to the Physician upon the donor's request. Be sure a copy of the release request is kept with donor card. Note date and obtain a donor signature on donor card to verify that results were received. (b) (4) as donor picks up letter and/or test results.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	3/4/2026-3/6/2026
	FEI NUMBER 1000523688

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Joleen Aguon, CEO

FIRM NAME	STREET ADDRESS
Guam Memorial Hosp Authority	850 Gov. C. G. Camacho Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Tamuning, GU 96911	Blood bank

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Maurine Fadlalla, Investigator

X Maurine Fadlalla
Investigator
Signed By: MAURINE FADLALLA
-S
Date Signed: 03-06-2026
14:06:36

DATE ISSUED
3/6/2026

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."