DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707	2/10/2025-2/13/2025* FEI NUMBER 1171573

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Carrie A. Herzke, M.D., Vice President of Medical Affairs

FIRM NAME	STREET ADDRESS
Johns Hopkins Hospital	1800 Orleans St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Baltimore, MD 21287-0010	Hospital Blood Bank/Transfusion Service

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 including signature by the physician requesting the procedure are not maintained of all emergency transfusions.

Specifically,

A. Emergency release of blood product records for emergency room patients dated (b)(4) (b)(4) were reviewed. The records did not include the signature of the physician requesting the emergency release of whole blood and/or red blood cells (RBCs).

Examples include, but are not limited to the following:

1. The emergency release records for patient # [redacted] dated [redacted], did not include the signature of the physician requesting red blood cells and whole blood for emergency release.

2. The emergency release records for patient # [redacted] dated [redacted], did not include the signature of the physician requesting whole blood for emergency release.

3. The emergency release records for patient # [redacted] dated [redacted], did not include the signature of the physician requesting whole blood for emergency release.

4. The emergency release records for patient # [redacted] dated [redacted], did not include the signature of the physician requesting whole blood for emergency release.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	La-Tasha M Gunter, Investigator	X La-Tasha M Gunter Investigator Signed By: LATASHA GUNTER-S Date Signed: 02-13-2025 09:27:50	2/13/2025

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B. Emergency release of blood/blood component records for unidentified emergency room patients dated (b)(4) were reviewed. The records did not include the signature of the physician requesting the emergency release of blood/blood components.

An example includes, but is not limited to the following: The emergency release records for patient # [redacted] dated [redacted], did not include the signature of the physician requesting blood/blood components for emergency release.

C. The following "Emergency Request for Blood and/or Blood Products" forms included the signatures of an (b)(4) and a (b)(4), instead of the signature of a physician requesting red blood cells for emergency release:

1. The emergency request form for patient # [redacted] dated [redacted], included the signature of an (b)(4) instead of a physician.

2. The emergency request form for patient # [redacted] dated [redacted], included the signature of a (b)(4) instead of a physician.

OBSERVATION 2
Written standard operating procedures including all steps to be followed in the compatibility testing and distribution of blood and blood components for allogeneic transfusion were not always maintained.

Specifically,

A. SOP # [redacted] 806, "Haemobank - Emergency Release," and SOP # - 130, "Emergency Release/Uncrossmatched Blood Products," did not include instructions stating that the requesting physician's signature must be documented on emergency release records, for patients receiving

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	La-Tasha M Gunter, Investigator X La-Tasha M Gunter Investigator Signed By: LATASHA GUNTER - S Date Signed: 02-13-2025 09:27:50	2/13/2025

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uncrossmatched blood/blood components emergently in the ER.

B. SOP # *** 806, "Haemobank - - Emergency Release," and SOP # - 130, "Emergency Release/Uncrossmatched Blood Products," did not include instructions stating that complete documentation justifying the emergency release of blood/blood components, must be maintained for patients receiving uncrossmatched blood/blood components emergently in the ER.

***DATES OF INSPECTION**

2/10/2025(Mon), 2/11/2025(Tue), 2/13/2025(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	La-Tasha M Gunter, Investigator X La-Tasha M Gunter Investigator Signed By: LA'TASHA GUNTER-S Date Signed: 02-13-2025 09:27:50	2/13/2025

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."