DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	5/8/2025-5/9/2025
	FEI NUMBER 1671035

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kendra S. Thompson, Director, Labcorp, Ascension St. John Medical Center

FIRM NAME	STREET ADDRESS
Ascension Saint John Medical Center	1923 S Utica Ave
CITY, STATE, ZIP CODE, COUNTRY Tulsa, OK 74104-6520	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

All records pertinent to a lot or unit were not reviewed before the release or distribution of a lot or unit of final product.

Specifically,

The documentation of all significant manufacturing steps associated with the firm's irradiation of blood and blood components is not reviewed (b) (4) of said irradiated blood or blood components for transfusion.

According to the firm's Blood Bank Lead, a review of associated records is performed at approximately (b) (4) intervals, but not (b) (4) of the irradiated blood or blood components for transfusion.

No review of irradiation manufacturing records, (b) (4), has occurred since, at least, the previous Food and Drug Administration (FDA) inspection, occurring on July 19, 2022. Furthermore, no firm standard operating procedure (SOP) requires such a review (b) (4) (b) (4) of irradiated blood or blood components.

OBSERVATION 2

Failure to perform a thorough investigation and make a record of the conclusions and follow-up of an unexplained discrepancy and a failure of a lot or unit to meet any of its specifications.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	William F Lagud, Investigator X William F Lagud Investigator Signed By: William F. Lagud Jr -S Date Signed: 05-09-2025 17:05:31	5/9/2025

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Kendra S. Thompson, Director, Labcorp, Ascension St. John Medical Center	
FIRM NAME Ascension Saint John Medical Center	STREET ADDRESS 1923 S Utica Ave
CITY, STATE, ZIP CODE, COUNTRY Tulsa, OK 74104-6520	TYPE ESTABLISHMENT INSPECTED Hospital Blood Bank

Specifically,

Status alarms and other unexpected events observed during the irradiation of blood or blood products using the firm's (b) (4) are not always thoroughly investigated, including conclusion and follow-up.

During the current inspection, a (b) (4) Irradiation Report generated for the time-period of 12/20/2024 to 5/08/2025 revealed approximately seven (7) status error codes. No documentation of investigation of the unexplained events could be provided by the firm. The Irradiator QA Log, which has been used to document such errors, was last documented on 04/14/2023.

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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."