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	3/5/2026-3/18/2026*
	FEI NUMBER 1671793

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Trent K Freeman, Administrative Director of Laboratory Services

FIRM NAME	STREET ADDRESS
Methodist Hospital Blood Bank	7700 Floyd Curl Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Antonio, TX 78229-3902	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

Equipment used in the processing of blood and blood components is not observed, standardized and calibrated on a regularly scheduled basis as prescribed in the SOP Manual.

Specifically, you do not have records or documentation to show scheduled (b) (4) maintenance was performed on the (b) (4) Irradiator for (b) (4) (b) (4)

The maintenance includes (b) (4) for (b) (4) Computer System, and Final adjustments. Also, for the (b) (4) maintenance was not done for the device (b) (4)

Your procedure, Methodist Hospital, Lab: Blood Product Irradiation, Maintenance, and Safety-MH, originally dated 12/2013 and last updated on 6/2025, show under the header Quality Control on page 2 of 6, under header, The device maintenance and or quality control services are provided and performed by an outside vendor on an (b) (4) basis, and would provide record(s) to show what services were done. The irradiator is used to irradiate blood products for patient use.

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Robert M Tillman, Investigator X Robert M Tillman Investigator Signed By: ROBERT M. TILLMAN -S Date Signed: 03-18-2026 09:36:04	3/18/2026

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Failure to maintain equipment used in the storage and distribution of blood and blood products.

Specifically, you failed to concurrently generate a documented record of your (b) (4) Freezer (b) (4) (serial number (b) (4)) to maintain an acceptable temperature. The (b) (4) Freezer (b) (4) malfunctioned on 1/29 to 31/2026, and the monitoring temperature dropped below (b) (4) degrees C to (b) (4) degrees C. Your normal acceptable temperature range is (b) (4) or colder with an average temperature reading of about (b) (4) degrees C.

Reportedly, upon discovery of the issue the blood products were moved from the malfunctioning freezer (b) (4) to another freezer, and freezer (b) (4) was placed out of service for repair. The blood products stored in the freezer at the time included (b) (4) units of (b) (4) (b) (4) units of Pooled Cryoprecipitated AHF, and (b) (4) units of (b) (4) (b) (4)

The staff member(s) failed to generate a work order with (b) (4) or Facilities management to get the freezer fixed. The staff members failed to fill out a (b) (4) (b) (4)

The staff failed to place the freezer out of service by placing a (b) (4) Out of Service tag on the equipment. Staff failed to generate an incident report to cover the malfunctional equipment, transfer of the blood products to another freezer and steps taken to repair the freezer, and test the freezer prior to returning it to service, and returning the blood products back to the freezer (b) (4)

There are no records to show how the staff handled the incident of the malfunctioning freezer in accordance with Methodist Hospital procedures, originally dated 8/2011, and last revised on 1/2024. Lab: Equipment QC, Maintenance and Repair-MH, on page 2, under header Equipment Repair on page 2 of 4, and under header Refrigerator/Freezer Failure on page 3 of 4.

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*DATES OF INSPECTION

3/05/2026(Thu), 3/06/2026(Fri), 3/09/2026(Mon), 3/10/2026(Tue), 3/11/2026(Wed), 3/18/2026(Wed)

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

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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."