

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax: (615) 366-7802		DATE(S) OF INSPECTION 2/17/2026-2/17/2026 FEI NUMBER 3005080452	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Julie A. Stajduhar, Team Supervisor			
FIRM NAME Blood Assurance Inc		STREET ADDRESS 604 N Jackson St	
CITY, STATE, ZIP CODE, COUNTRY Tullahoma, TN 37388-3542		TYPE ESTABLISHMENT INSPECTED Donor Center	
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 Blood or blood components were collected from a donor found to be ineligible prior to collection based on the regulations. Specifically, According to standard operating procedure, titled (b) (4) -Screen-019 (b) (4) Thermometer, version 8.0, dated effective 12/06/2024 and version 7.0, dated effective 02/10/2021 your firm determines donors to be acceptable to donate blood and blood components if their body temperature is measured between (b) (4) • On (b) (6), (b) (7)(C), donor (b) (6), (b) (7)(C) was determined eligible with a temperature of 100.0°F and donated a unit of whole blood. • On (b) (6), (b) (7)(C), donor (b) (6), (b) (7)(C) was determined eligible with a temperature of 100.0°F and donated a unit of whole blood. • On (b) (6), (b) (7)(C), donor (b) (6), (b) (7)(C) was determined eligible with a temperature of 99.6°F and donated a unit of double red cells. Since 10/24/2022, your firm has collected blood and blood component units from approximately (b) (4) donors with measured body temperatures exceeding 99.5°F. Your firm failed to establish a standard operating procedure in determining donors ineligible with a body temperature exceeding 99.5°F. Your firm's standard operating procedure fails to establish a			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Cody D Rickman, Investigator Cody D Rickman Investigator Signed By: CODY D. RICKMAN - Date Signed: 02-17-2026 15:16:00 X _____	
		DATE ISSUED 2/17/2026	

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maximum body temperature qualifying test and measurement value of 99.5°F in determining donor acceptability. Since 10/24/2022, your firm has failed to determine approximately (b) (4) donors with measured body temperatures exceeding 99.5°F ineligible to donate blood and blood components.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Cody D Rickman, Investigator	Cody D Rickman Investigator Signed By: CODY D. RICKMAN - Date Signed: 02-17-2026 15:16:00 X	DATE ISSUED 2/17/2026

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."