DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	5/16/2025-5/20/2025* FEI NUMBER 1774796

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Christopher Lockhart, Laboratory Director

FIRM NAME	STREET ADDRESS
Altru Health Systems	1200 S Columbia Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Grand Forks, ND 58201-4036	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 standardized on a regularly scheduled basis as prescribed in the SOP Manual.

Specifically, the (b)(4) system used for platelet (b)(4) testing was qualified for use by performing separate process validations for blood and platelet testing.

Specifically, the (b)(4) system used for platelet (b)(4) testing was qualified for use by performing a process validation. The acceptance criteria defined in the Validation Plan require that - (b)(4) with test (b)(4) generate alerts on the [redacted] system. During testing initiated on (b)(4) triggered (b)(4) alerts on the [redacted] system. [redacted] (b)(4) did not generate alerts on initial testing. Testing for the [redacted] discrepant samples was (b)(4) on (b)(4) using [redacted] new (b)(4) with the [redacted] (b)(4) of the (b)(4) samples triggered alerts on the [redacted] system and obtained the expected results.

(b)(4) unexpected results were not investigated or documented in the Validation Summary.

The Validation Plan requires all (b)(4) to be identified as known (b)(4). There was no documentation that (b)(4) was performed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Emily A Walters, Investigator X Emily A Walters Investigator Signed By: EMILY A. WALTERS - S Date Signed: 05-20-2025 17:38:30	5/20/2025

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Testing was performed between [(b)(4)]. The Validation Plan was approved 3/26/2024, after test results were obtained. Your SOP in use at the time of the validation indicates that the Validation Plan should be approved [(b)(4)] the validation [(b)(4)] whenever possible.

The [(b)(4)] has been used to detect [(b)(4)] contamination in platelets since [(b)(4)]. Since the instrument was implemented, [-] platelet products have been distributed and transfused

***DATES OF INSPECTION**
5/16/2025(Fri), 5/19/2025(Mon), 5/20/2025(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Emily A Walters, Investigator X Emily A Walters Investigator Signed By: EMILY A. WALTERS - S Date Signed: 05-20-2025 17:38:39	5/20/2025

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."