

| <b>DEPARTMENT OF HEALTH AND HUMAN SERVICES</b><br><b>FOOD AND DRUG ADMINISTRATION</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |                                                                                                                                                                                                                                                                                               |  |
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| <small>DISTRICT ADDRESS AND PHONE NUMBER</small><br>250 Marquette Ave, Ste. 600<br>Minneapolis, MN 55401<br>(612) 334-4100 Fax: (612) 334-4134                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  | <small>DATE(S) OF INSPECTION</small><br>5/13/2025-5/16/2025<br><small>FEI NUMBER</small><br>3009905846                                                                                                                                                                                        |  |
| <small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small><br>Dr. Heidi A. Jess, Medical Director                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  |                                                                                                                                                                                                                                                                                               |  |
| <small>FIRM NAME</small><br>Altru Health System                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |  | <small>STREET ADDRESS</small><br>3375 Demers Ave                                                                                                                                                                                                                                              |  |
| <small>CITY, STATE, ZIP CODE, COUNTRY</small><br>Grand Forks, ND 58201-4006                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  | <small>TYPE ESTABLISHMENT INSPECTED</small><br>Blood Bank                                                                                                                                                                                                                                     |  |
| <p>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.</p>                                                                                                                                                                                                                                                                                   |  |                                                                                                                                                                                                                                                                                               |  |
| <p><b>DURING AN INSPECTION OF YOUR FIRM I OBSERVED:</b></p> <p><b>OBSERVATION 1</b></p> <p>Medical history assessment failed to include factors that make the donor ineligible to donate because of an increased risk for, or evidence of, a relevant transfusion-transmitted infection such as behaviors associated with a relevant transfusion-transmitted infection.</p> <p>Specifically, your donor medical history interview questionnaire, effective 7/17/2022, does not include a question asking if the donor has had sexual contact with a new partner or had sexual contact with more than one partner in the past three months before donating whole blood, platelets, plasma, or red blood cells. Since <span style="border: 1px solid black; padding: 0 20px;">(b)(4)</span> donors have been screened and donated.</p>                                                                          |  |                                                                                                                                                                                                                                                                                               |  |
| <p><b>OBSERVATION 2</b></p> <p>Failure to submit a biological product deviation report.</p> <p>Specifically, whole blood donor <span style="border: 1px solid black; padding: 0 20px;">(b)(4)</span> was registered under the incorrect gender, causing a screening question to be omitted from the donor medical history interview questionnaire on <span style="border: 1px solid black; padding: 0 20px;">(b)(4)</span> and <span style="border: 1px solid black; padding: 0 20px;">(b)(4)</span>. Whole blood units <span style="border: 1px solid black; padding: 0 20px;">(b)(4)</span> and <span style="border: 1px solid black; padding: 0 20px;">(b)(4)</span> were collected and the <span style="border: 1px solid black; padding: 0 20px;">(b)(4)</span> resulting red cell and plasma products distributed for transfusion. No biological product deviation report was submitted to the FDA.</p> |  |                                                                                                                                                                                                                                                                                               |  |
| <b>SEE REVERSE OF THIS PAGE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |  | <small>EMPLOYEE(S) SIGNATURE</small><br>Emily A Walters, Investigator<br><br><div style="text-align: right;"> <small>Emily A Walters<br/>Investigator<br/>Signed by: EMILY A. WALTERS - S<br/>Date Signed: 05-16-2025<br/>09:17:19</small><br/> <span style="font-size: 2em;">X</span> </div> |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |  | <small>DATE ISSUED</small><br>5/16/2025                                                                                                                                                                                                                                                       |  |

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."