

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612) 334-4100 Fax: (612) 334-4134		<small>DATE(S) OF INSPECTION</small> 6/9/2025-6/11/2025 <small>FEI NUMBER</small> 3003169765			
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Dr. Thomas C. Ortmeier, Medical Director, Department of Laboratory Medicine and Pathology					
<small>FIRM NAME</small> Innovis Health, LLC d.b.a. Essentia Health		<small>STREET ADDRESS</small> 3000 32nd Ave S			
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Fargo, ND 58103-6132		<small>TYPE ESTABLISHMENT INSPECTED</small> 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>DURING AN INSPECTION OF YOUR FIRM I OBSERVED:</p> <p>OBSERVATION 1</p> <p>Failure to submit a biological product deviation report.</p> <p>Specifically,</p> <p>On 04/11/2025, (b) (4) was identified for patient with medical record number (MRN) # (b) (4) upon review of (b) (4) performed on (b) (6), (b) (7)(C). On (b) (6), (b) (7)(C), Red Blood Cells (RBC) unit # (b) (4), (b) (6), (b) (7)(C) was issued to patient with MRN # (b) (6), (b) (7)(C). This unit was not checked for presence of (b) (4) prior to issuance.</p>					
<p>OBSERVATION 2</p> <p>Failure to maintain quality control and general records.</p> <p>Specifically,</p> <p>a) On (b) (6), (b) (7)(C), Red Blood Cells unit # (b) (4), (b) (6), (b) (7)(C) was issued to patient with MRN # (b) (4), (b) (6), (b) (7)(C) instead of (b) (4). However, this deviation was not documented and investigated in your (b) (4) computer program designed to document and investigate deviations and incident reports.</p> <p>b) On (b) (6), (b) (7)(C), two reconstituted whole blood units with hematocrit between (b) (4) were requested for (b) (4) for patient with MRN # (b) (4), (b) (6), (b) (7)(C). Two units of reconstituted whole blood # (b) (4) and # (b) (4) were prepared with hematocrits (b) (4) and (b) (4) respectively. There were no calculations documented to determine added volumes of RBC and FFP (Fresh Frozen Plasma). In addition, (b) (4) was not reviewed to ensure</p>					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> <small>EMPLOYEE(S) SIGNATURE</small> Irina Gaberman, Investigator </td> <td style="width: 40%; vertical-align: top;"> <small>DATE ISSUED</small> 6/11/2025 <div style="text-align: center;"> <small>Irina Gaberman Investigator Signed By: 1300222798 Date Signed: 06-11-2025 07:34:32</small> </div> </td> </tr> </table>		<small>EMPLOYEE(S) SIGNATURE</small> Irina Gaberman, Investigator	<small>DATE ISSUED</small> 6/11/2025 <div style="text-align: center;"> <small>Irina Gaberman Investigator Signed By: 1300222798 Date Signed: 06-11-2025 07:34:32</small> </div>
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FOOD AND DRUG ADMINISTRATION

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Minneapolis, MN 55401
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DATE(S) OF INSPECTION

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Dr. Thomas C. Ortmeier, Medical Director, Department of Laboratory Medicine and Pathology

FIRM NAME

Innovis Health, LLC d.b.a. Essentia Health

STREET ADDRESS

3000 32nd Ave S

CITY, STATE, ZIP CODE, COUNTRY

Fargo, ND 58103-6132

TYPE ESTABLISHMENT INSPECTED

Blood Bank

calculations were correct.

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Irina Gaberman, Investigator

Irina Gaberman
Investigator
Signed By: 1300222798
Date Signed: 06-11-2025
07:34:32

X

DATE ISSUED

6/11/2025

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."