

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 1201 Main Street, Suite 7200 Dallas, TX 75202 (214) 253-5200 Fax: (214) 253-5314		<small>DATE(S) OF INSPECTION</small> 6/30/2025-7/2/2025 <small>FEI NUMBER</small> 1671244			
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Kyle D. Cooper, Abilene Market Director					
<small>FIRM NAME</small> Hendrick Regional Laboratory Transfusion Services		<small>STREET ADDRESS</small> 1900 Pine St			
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Abilene, TX 79601-2432		<small>TYPE ESTABLISHMENT INSPECTED</small> Transfusion Services/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: OBSERVATION 1 Failure to maintain reports of complaints of adverse reactions regarding each unit of blood or blood product arising as a result of transfusion.</p> <p>Specifically,</p> <p>Your Medical Director did not complete the Transfusion Related (b) (4) Injury ((b) (4)) Investigation Summary form for the transfusion reaction experienced by Patient (b) (6), (b) (7) on (b) (6), (b) (7)(C)</p> <p>A Transfusion Reaction Form demonstrated that Patient (b) (6), (b) (7)(C) experienced a transfusion reaction on (b) (6), (b) (7)(C) after being transfused with the following (b) (4) Red Blood Cell units:</p> <ul style="list-style-type: none"> • (b) (4), (b) (6), (b) (7)(C) • (b) (4), (b) (6), (b) (7)(C) <p>A (b) (4) investigation request was submitted by hospital staff to the Transfusion Services Department on (b) (4), (b) (6), (b) (7)(C). However, your Medical Director did not complete the (b) (4) investigation.</p> <p>Your Regional Blood Center Manager informed me that notification regarding this transfusion reaction was not received from the Transfusion Services Department, thus an investigation pertaining to the transfused units at the collection facility was not initiated.</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> Michelle Paxton, Investigator </td> <td style="width: 40%; vertical-align: top;"> <div style="text-align: right;"> <small>DATE ISSUED</small> 7/2/2025 </div> <div style="text-align: right; margin-top: 20px;"> <small>Michelle Paxton Investigator Signed By: 2003998263 Date Signed: 07-02-2025 15:37:08</small> X _____ </div> </td> </tr> </table>		<small>EMPLOYEE(S) SIGNATURE</small> Michelle Paxton, Investigator	<div style="text-align: right;"> <small>DATE ISSUED</small> 7/2/2025 </div> <div style="text-align: right; margin-top: 20px;"> <small>Michelle Paxton Investigator Signed By: 2003998263 Date Signed: 07-02-2025 15:37:08</small> X _____ </div>
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FOOD AND DRUG ADMINISTRATION

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Dallas, TX 75202
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DATE(S) OF INSPECTION

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Kyle D. Cooper, Abilene Market Director

FIRM NAME

Hendrick Regional Laboratory Transfusion
Services

STREET ADDRESS

1900 Pine St

CITY, STATE, ZIP CODE, COUNTRY

Abilene, TX 79601-2432

TYPE ESTABLISHMENT INSPECTED

Transfusion Services/Blood Bank

On 07/01/2025, I requested follow-up on the incomplete documentation. In response, your Medical Director determined that "the signs + symptoms are consistent with (b) (4) per the CDC NHSN HV protocol."

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Michelle Paxon, Investigator

Michelle Paxon
Investigator
Signed By: 2003998263
Date Signed: 07-02-2025
15:37:08

X

DATE ISSUED

7/2/2025

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."