DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	1/29/2025-1/30/2025
	FEI NUMBER 1000220724

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Tricia L. Denton , Laboratory Director Allen County

FIRM NAME	STREET ADDRESS
Parkview Health Laboratories	11109 Parkview Plaza Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fort Wayne, IN 46845-1701	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

Records including signature by the physician requesting the procedure are not maintained of all emergency transfusions.

Specifically,

A. The following "Physician Order for Emergency Release of Uncrossmatched Blood Products" form (b) (4) dated (b) (4), (b) (6), (b) for Emergent Transfusion did not include the requesting physician's signature which is indicated by instructions on the form:

1. Patient identified by MRN #(b) (4), (b) (6), (b) (7)(C), dated (b) (6), (b) (7)(C) Additionally, the words "verbal consent," were documented on the form in lieu of the requesting physician's signature.
2. Patient identified by MRN #(b) (4), (b) (6), (b) (7)(C), dated (b) (6), (b) (7)(C) Additionally, the words "verbal consent," and signatures of the nurses were documented on the form in lieu of the requesting physician's signature.
3. Patient identified by MRN #(b) (4), (b) (6), (b) (7)(C) lated (b) (6), (b) (7)(C) Additionally, no form was included in package.

B. The following "Physician Order for Emergency Release of Uncrossmatched Blood Products" form (b) (4) dated (b) (4), (b) (6), (b) for Massive Transfusion did not include the requesting physician's signature which is indicated by instructions on the form:

1. Patient identified by MRN #(b) (4), (b) (6), (b) (7)(C) dated (b) (6), (b) (7)(C). Additionally, the words "verbal consent," were documented on the form in lieu of the requesting physician's signature.
2. Patient identified by MRN #(b) (4), (b) (6), (b) (7)(C) dated (b) (6), (b) (7)(C) Additionally, the words "verbal orders," were documented on the form in lieu of the requesting physician's signature.
3. Patient identified by MRN #(b) (4), (b) (6), (b) (7)(C) dated (b) (6), (b) (7)(C) Additionally, the words "verbal order," and the provider's name were documented on the form in lieu of the requesting physician's signature.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Richard J Bashay, Investigator	X Richard J Bashay Investigator Signed By: 2001575282 Date Signed: 01-30-2025 08:22:07	1/30/2025

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4. Patient identified by MRN #(b) (4), (b) (6), (b) (7)(C) dated (b) (6), (b) (7)(C). Additionally, the word "verbal," and the provider's name were documented on the form in lieu of the requesting physician's signature.
5. Patient identified by MRN #(b) (4), (b) (6), (b) (7)(C), dated (b) (6), (b) (7)(C). Additionally, the word "verbal," was documented on the form in lieu of the requesting physician's signature.
6. Patient identified by MRN #(b) (4), (b) (6), (b) (7)(C) dated (b) (6), (b) (7)(C) Additionally, a provider's name and signature of the nurse were documented on the form in lieu of the requesting physician's signature.
7. Patient identified by MRN #(b) (4), (b) (6), (b) (7)(C) dated (b) (6), (b) (7)(C) Additionally, the words "verbal order," and the provider's name were documented on the form in lieu of the requesting physician's signature.
8. Patient identified by MRN #(b) (4), (b) (6), (b) (7)(C) dated (b) (6), (b) (7)(C) Additionally, the words "verbal order read back," were documented on the form in lieu of the requesting physician's signature.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Richard J Bashay, Investigator X Richard J Bashay Investigator Signed By: 2001575282 Date Signed: 01-30-2025 08:22:07	1/30/2025

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."