DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	9/10/2019-9/11/2019
	FEI NUMBER 1671802

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Barbara J. Bryant, MD, Medical Director Transfusion Medicine

FIRM NAME	STREET ADDRESS
University of Texas Medical Branch (UTMB) Blood Center	301 University Blvd Ste 1.120
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Galveston, TX 77555-5302	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 are not maintained of all emergency transfusions including complete documentation justifying the emergency action.

Specifically,

Of the 79 forms reviewed for 2019, 13 of the Emergency Release of Blood Products forms signed by the Requesting Physicians are lacking the reason for the release, such as "cross match waived, antibody unidentified, transmissible disease tests waived, antibody screen incomplete, CMV waived, or least incompatible."

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Darla J Christopher, Investigator

X Darla J Christopher
Investigator
Signed By: Darla J. Christopher -S
Date Signed: 09-11-2019 13:53:08

DATE ISSUED
9/11/2019

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."