

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417		DATE(S) OF INSPECTION 4/20/2026-4/22/2026 FEI NUMBER 3004445465			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Dr. Maria A. Proytcheva, CLIA Medical Director					
FIRM NAME Banner - University Medical Center Tucson		STREET ADDRESS 1625 N Campbell Ave			
CITY, STATE, ZIP CODE, COUNTRY Tucson, AZ 85724-0001		TYPE ESTABLISHMENT INSPECTED Transfusion Service			
<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 Records including signature by the physician requesting the procedure are not maintained of all emergency transfusions including complete documentation justifying the emergency action.</p> <p>Specifically, while reviewing available emergency release documents for blood components released between June 2025 and April 2026, it was noted that:</p> <ol style="list-style-type: none"> 1. The Emergency Transfusion Request Form (LSA Transfusion Medicine Form 1840) does not contain documentation for the justification for the emergency release of blood products or the date of physician signature. 2. Approximately 30 of the (b)(4) Emergency Transfusion Request Forms reviewed were signed by individuals who are not physicians. <p>Since 2025, your firm has emergency released approximately (b)(4) units of blood components</p>					
<p>OBSERVATION 2 Failure to perform a thorough investigation and make a record of the conclusions and follow-up of an unexplained discrepancy.</p> <p>Specifically, when reviewing your firm's variances the documentation does not include information need to demonstrate a thorough investigation was completed. This includes a lack of description of issue with detail (i.e. units involved), all corrective actions taken, employee(s) involved and product suitability review.</p>					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%;"> EMPLOYEE(S) SIGNATURE Emily S McGann, Investigator </td> <td style="width: 40%; text-align: right; vertical-align: bottom;"> <small>Emily S McGann Investigator Signed By: Emily S. McGann -S Date Signed: 04-22-2026 09:34:32</small> X </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Emily S McGann, Investigator	<small>Emily S McGann Investigator Signed By: Emily S. McGann -S Date Signed: 04-22-2026 09:34:32</small> X
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		DATE ISSUED 4/22/2026			

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."