

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312) 353-5863 Fax: (312) 596-4187		DATE(S) OF INSPECTION 12/2/2024-12/5/2024 FEI NUMBER 1475369	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Phillip DeChristopher, MD, Medical Director			
FIRM NAME Loyola Univ Medical Center		STREET ADDRESS 2160 S 1st Ave	
CITY, STATE, ZIP CODE, COUNTRY Maywood, IL 60153-3328		TYPE ESTABLISHMENT INSPECTED 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 made concurrently with the performance of each step in the manufacture of products. Specifically, On 12/3/2024, I observed staff label platelet unit, number W18092481158, as (b)(4) the unit being placed inside the (b)(4) this manufacturing step being completed.			
OBSERVATION 2 Written standard operating procedures including all steps to be followed in the processing of blood and blood components for further manufacturing purposes were not always established. Specifically, A.) On 12/4/2024, during SOP review, I was unable to find a written procedure outlining instructions on how to label (b)(4) blood components after this manufacturing step has been performed. Platelet unit number W18092481158 was labeled as (b)(4) being placed inside the (b)(4) this manufacturing step being completed. B.) On 12/4/2024, during SOP review, I was unable to find a written procedure adequately outlining instructions on how to completely fill out all fields on (b)(4) record.			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Gabryelle J Solverud, Investigator Gabryelle J Solverud Investigator Signed By: Gabryelle J Solverud - Date Signed: 12-05-2024 11:56:10	
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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Gabryelle J Solverud, Investigator		DATE ISSUED 12/5/2024
			Gabryelle J Solverud Investigator Signed By: Gabryelle J. Solverud - Date Signed: 12-05-2024 11:56:19 X
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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."