

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax: (303) 236-3100		10/28/2024-11/6/2024*
		FEI NUMBER
		1720911

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Kelly A. Cail, Operations Director

FIRM NAME	STREET ADDRESS
ARUP Laboratories, Inc.	9786 S. Sandy Parkway
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sandy, UT 84070	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 WE OBSERVED:

OBSERVATION 1

(b) (4) are not checked for accuracy.

Specifically, your firm failed to adequately test the (b) (4) of your new (b) (4) related to your (b) (4) and the following occurred after the (b) (4) went live on (b) (4) :

1. On 04/14/2024 it was discovered that the (b) (4) failed to prevent two donors from registering for platelets (DEV-2024-0619)
2. On 03/24/2024, it was discovered that a donation had been (b) (4) when a unit was being (b) (4). The unit was collected on 03/12/2024. Your firm was unaware that the employee had the permissions to (b) (4) a donation (DEV-2024-0262)

Your firm relies on your (b) (4) to (b) (4) the donor (b) (4) process, manage donor (b) (4) dates, allow for donor inquiry and (b) (4) of various (b) (4) such as donor (b) (4), donor (b) (4) and donor (b) (4). It also provides (b) (4) which assist with workflow.

***DATES OF INSPECTION**

10/28/2024(Mon), 10/29/2024(Tue), 10/30/2024(Wed), 10/31/2024(Thu), 11/01/2024(Fri), 11/04/2024(Mon), 11/05/2024(Tue), 11/06/2024(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Emily B Camire, Investigator Deepa E Vadakkan, Investigator	DATE ISSUED 11/6/2024
	X	Emily B Camire Investigator Signed by: Emily B. Camire -S Date Signed: 11-06-2024 13:39:59

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Deepa E Vadakkan
Investigator
Signed By: DEEPA E. VADAKKAN-S
Date Signed: 11-06-2024 13:40:46

X

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED 11/6/2024
	Emily B Camire, Investigator Deepa E Vadakkan, Investigator	
	Emily B Camire Investigator Signed By: Emily B. Camire -S Date Signed: 11-06-2024 13:39:59	X

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."