

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768 orabioinspectionalcorrespondence@fda.hhs.gov		DATE(S) OF INSPECTION 9/30/2024-10/7/2024*	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Katie Leggett, Director of Quality Assurance and Regulatory Affairs		FEI NUMBER 3000207042	
FIRM NAME Innovative Transfusion Medicine, Inc.		STREET ADDRESS 5753 Miami Lakes Dr	
CITY, STATE, ZIP CODE, COUNTRY Miami Lakes, FL 33014-2417		TYPE ESTABLISHMENT INSPECTED 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 Failure to review all records required under the regulations to identify previously donated blood and blood components within 3 calendar days after a donor tests reactive for evidence of HIV infection indicating evidence of HIV infection. Specifically, Three out of the four HIV lookback records failed to notify consignees to quarantine components within 3 calendar days. Donor ID: (b) (6), (b) (7)(C) donated on (b) (6), (b) (7)(C), tested positive for Anti-HIV1/2 and the (b) (4) (HIV-1/HCV/HBV) on (b) (6), (b) (7)(C). The consignee notification was sent on 02/29/2024. Donor ID: (b) (6), (b) (7)(C) donated on (b) (6), (b) (7)(C), tested positive for Anti-HIV1/2 on (b) (6), (b) (7)(C). The consignee notification was sent on 06/24/2024. Donor ID: (b) (6), (b) (7)(C) donated on (b) (6), (b) (7)(C), tested positive for Anti-HIV1/2 on (b) (6), (b) (7)(C). The consignee notification was sent on 06/03/2024.			
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		Nerming V Briones Investigator Signed By: Nerming Briones -B Date Signed: 10-07-2024 15:05:12 X	
		DATE ISSUED 10/7/2024	

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OBSERVATION 2 Failure to review all records required under the regulations to identify previously donated blood and blood components within 3 calendar days after a donor tests reactive for evidence of HCV infection indicating evidence of HCV infection. Specifically, Two out of the four HCV lookback records failed to notify consignees to quarantine components within 3 calendar days. Donor ID: (b) (6), (b) (7)(C) donated on (b) (6), (b) (7)(C), tested positive for Anti-HCV on (b) (6), (b) (7)(C). The consignee notification was sent on 08/30/2024. Donor ID: (b) (6), (b) (7)(C) donated on (b) (6), (b) (7)(C), tested positive for Anti-HCV on (b) (6), (b) (7)(C). The consignee notification was sent on 06/03/2024.			
OBSERVATION 3 Written standard operating procedures including all steps to be followed in the collection, processing and storage of blood and blood components for further manufacturing purposes were not always followed. Specifically, A. Quality assurance review of six calibration records for equipment were not performed as per standard operating procedures (SOPs). SOP titled "General Equipment Use, Maintenance, and Calibration" states (on page 14) "6.6.5.3. All equipment preventative maintenance spreadsheets, printed completed work order, data or documents generated that are related to the maintenance performed shall be reviewed,			
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signed by the Director/Manager of Quality Assurance and retained within a secure location." B. Six out of the seven "Donor Reaction Reports" reviewed failed to perform donor follow-up as mandated by SOP titled "Donor Reaction" (page 7) stating that "7.10.5. All donors who experienced an adverse event will be called to evaluate the donor's wellbeing. QA staff/designee will follow up with donor's condition and document results on the Donor Reaction Report." The following are the six donor unit numbers associated with the Donor Reaction Reports reviewed: - (b) (6), (b) (7)(C) - (b) (6), (b) (7)(C) - (b) (6), (b) (7)(C) - (b) (6), (b) (7)(C) - (b) (6), (b) (7)(C) - (b) (6), (b) (7)(C)		
OBSERVATION 4 Failure to maintain general records. Specifically, Failed to maintain records from the components and processing area for the month of November 2022, missing records include temperature logs for freezers and refrigerators, and centrifuge quality control records.		
*DATES OF INSPECTION 9/30/2024(Mon), 10/01/2024(Tue), 10/02/2024(Wed), 10/03/2024(Thu), 10/04/2024(Fri), 10/07/2024(Mon)		
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FORM FDA 483 (09/08)		PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS
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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."