DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707	6/9/2026-6/12/2026
	FEI NUMBER 1172512

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Danielle Griggs, Chief Operating Officer

FIRM NAME	STREET ADDRESS
University Of Virginia Health System	1215 Lee St
CITY, STATE, ZIP CODE, COUNTRY Charlottesville, VA 22908-0001	TYPE ESTABLISHMENT INSPECTED Transfusion Medicine Services

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

The standard operating procedure fails to include written descriptions of the methods for component preparation, including any time restrictions for specific steps in processing.

Specifically,
SOP BB 116 (D42), UVA (Version 4.2), effective 1/23/2026, IRRADIATION OF BLOOD PRODUCTS, Procedure 1c, and IRRADIATOR LOG BB:88 (revised 06/03/2019) fail to establish a maximum allowable out-of-storage time for refrigerated blood products (normally stored at 1–6°C) removed for irradiation processing.
SOP BB 116 (D42) requires documentation of the time a refrigerated product is removed from its 1–6°C storage environment prior to irradiation but contains no defined time limit within which the product must be returned to storage. Without an established maximum out-of-storage interval or procedural safeguard, there is no mechanism to prevent refrigerated blood products from experiencing temperature excursions that could potentially compromise product integrity and render units unsuitable for transfusion.
IRRADIATOR LOG BB:88 (revised 06/03/2019) captures the time products are "removed from storage" and "returned to storage," but similarly provides no guidance, threshold, or alert criteria indicating the maximum permissible duration a product may remain outside its required storage environment during processing. The log functions solely as a record of elapsed time, without any mechanism to flag or prevent out-of-range temperature exposure.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Charles D Boison, Investigator	X Charles D Boison Investigator Signed By: Charles D. Boison -S Date Signed: 06-12-2026 13:27:35	6/12/2026

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."