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	2/4/2025-2/11/2025* FEI NUMBER 3001236481

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Wanda J. Philippy, Director, Quality Distribution and Donor Services

FIRM NAME	STREET ADDRESS
Lions Medical Eye Bank & Research Center of Eastern VA	600 Gresham Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Norfolk, VA 23507-1904	HCT/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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Environmental conditions are not monitored when such conditions could cause contamination or cross contamination of HCT/Ps or equipment.

Specifically,

Since the previous inspection in 2/2023, your firm processed and distributed approximately (b) (4) corneas, (b) (4) scleras and (b) (4) whole scleras for preservation. However, your firm failed to conduct environmental monitoring during processing in your laminar flow hood to prevent the introduction, transmission, or spread of communicable disease through the use of the HCT/P.

OBSERVATION 2

Acceptable temperature limits were not established for the storage of HCT/Ps at each step of the manufacturing process to inhibit the growth of infectious agents.

Specifically,

During a walk through of your facility on 2/4/25, two corneas from donor (b) (4), (b) (6), (b) (7)(C) were observed in your firm's (b) (4) an area where temperature is not monitored. These corneas were documented as being removed from the “fridge” on 2/4/25 at "0728" and were later documented as returned to the “fridge” on 2/4/25 at "1140". These HCT/Ps were documented as being in this area for over four hours without temperature monitoring.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Amy A Johnson, Investigator Chanel E Crawford, Investigator Kenneth L Smalls, Investigator X Amy A Johnson Investigator Signed By: 2001751346 Date Signed: 02-11-2025 14:35:50	2/11/2025

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	2/4/2025-2/11/2025*
	FEI NUMBER 3001236481

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Wanda J. Philippy, Director, Quality Distribution and Donor Services

FIRM NAME	STREET ADDRESS
Lions Medical Eye Bank & Research Center of Eastern VA	600 Gresham Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Norfolk, VA 23507-1904	HCT/P

*DATES OF INSPECTION

2/04/2025(Tue), 2/05/2025(Wed), 2/06/2025(Thu), 2/07/2025(Fri), 2/11/2025(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Amy A Johnson, Investigator Chanel E Crawford, Investigator Kenneth L Smalls, Investigator	X Amy A Johnson Investigator Signed By: 2001751346 Date Signed: 02-11-2025 14:35:50	DATE ISSUED 2/11/2025

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."