DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	4/23/2025-4/28/2025* FEI NUMBER 3005081370

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Miriam S. Krause, Medical Director

FIRM NAME	STREET ADDRESS
Louisville Reproductive Center	4123 Dutchmans Ln Ste 416
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Louisville, KY 40207-4733	Human Tissue Establishment

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

Donors were not tested for evidence of infection with relevant communicable disease agents.

Specifically,

Directed semen donor (b) (6), (b) (7)(C) deposited semen for donation on (b) (6), (b) (7)(C). This donor tissue was used for a fresh (b) (6), (b) (7)(C) on (b) (6), (b) (7)(C) and was determined eligible on 07/12/2024. This donor was not tested for the following relevant communicable disease agents:

HIV NAT, HBV NAT, HCV NAT, West Nile Virus NAT, and HBc.

This donor provided screen shots of testing done at another clinic to include (b) (6), (b) (7)(C) (b) (6), (b) (7)(C). This testing record was not the source record of testing and the firm is unable to determine if the testing lab was CLIA approved and/or if cleared and approved test kits were used.

OBSERVATION 2

Donors of l(b) (6), (b) (7)(C) cells or tissues were not tested for cell-associated communicable diseases.

Specifically,

Directed semen donor (b) (6), (b) (7)(C) deposited semen for donation on (b) (6), (b) (7)(C). This donor tissue was used for a fresh (b) (6), (b) (7)(C) on (b) (6), (b) (7)(C) and was determined eligible on 07/12/2024. This donor was not

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jennifer L Sheehan, Investigator	X Jennifer L Sheehan Investigator Signed By: Jennifer L. Sheehan - S Date Signed: 04-28-2025 07:37:05	4/28/2025

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Miriam S. Krause, Medical Director	
FIRM NAME Louisville Reproductive Center	STREET ADDRESS 4123 Dutchmans Ln Ste 416
CITY, STATE, ZIP CODE, COUNTRY Louisville, KY 40207-4733	TYPE ESTABLISHMENT INSPECTED Human Tissue Establishment

tested for HTLV 1 and 2.

OBSERVATION 3

HCT/Ps were not kept in quarantine until completion of the donor-eligibility determination.

Specifically,

Directed semen donor (b) (6), (b) (7)(C) deposited semen for donation on (b) (6), (b) (7)(C). This donor tissue was used for a fresh (b) (6), (b) (7)(C) on (b) (6), (b) (7)(C) and was not determined eligible until 07/12/2024.

***DATES OF INSPECTION**

4/23/2025(Wed), 4/28/2025(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jennifer L Sheehan, Investigator	X Jennifer L Sheehan Investigator Signed By: Jennifer L. Sheehan - S Date Signed: 04-28-2025 07:37:05	4/28/2025

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."