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	5/12/2025-5/14/2025
	FEI NUMBER 3005188109

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Keith L. Blauer, Medical Director

FIRM NAME	STREET ADDRESS
Reproductive Care Center	10150 Petunia Way
CITY, STATE, ZIP CODE, COUNTRY Sandy, UT 84092-4380	TYPE ESTABLISHMENT INSPECTED Human Tissue Reproductive 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

Donor screening of HCT/P donors considered eligible indicated that the donor was not free of risk factors for infection due to communicable disease agents and clinical evidence of infection due to communicable disease agents.

Specifically, the following donors were determined eligible when they should have been determined ineligible:

- Directed semen donor [redacted] tested [redacted] for [redacted] and answered [redacted] to "have you spent 3 months or more, cumulatively, in the [redacted] from the beginning of 1980 through 1996?" on [redacted] Donor [redacted] was determined to be eligible on 11/11/2022. A total of [redacted] fertilized oocytes were frozen on [redacted] and [redacted]. On [redacted], one (1) fertilized oocyte was transferred into gestational carrier [redacted].
- Directed semen donor [redacted] answered [redacted] to "if male: [redacted] in the preceding 5 years?" on 12/3/2022. Donor [redacted] was determined eligible on 5/18/2023. A total of [redacted] fertilized oocytes were frozen on [redacted] and are intended for use in a gestational carrier.

OBSERVATION 2

HCT/P donors were not determined to be eligible based on the results of donor screening and testing.

Specifically, the following directed semen donor was determined eligible prior to the completion of

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Emily B Camire, Investigator	X Emily B Camire Investigator Signed By: EMILY B. CAMIRE -S Date Signed: 05-14-2025 10:15:38	5/14/2025

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	5/12/2025-5/14/2025
	FEI NUMBER 3005188109

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Dr. Keith L. Blauer, Medical Director

FIRM NAME	STREET ADDRESS
Reproductive Care Center	10150 Petunia Way
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sandy, UT 84092-4380	Human Tissue Reproductive Establishment

donor history questionnaire and fertilized oocytes were created prior to determining donor eligibility of the directed semen donor:

- On [redacted], a blood sample and semen were collected for directed semen donor [redacted]. A total of [redacted] fertilized oocytes were frozen on [redacted]. Donor [redacted] was determined eligible on 2/7/2022. The donor history questionnaire (DHQ) was completed by the donor on 2/15/2022 and reviewed on 2/17/2022. All [redacted] fertilized oocytes were transferred to gestational carrier [redacted] on (b)(6) (b)(7)(C).

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Emily B Camire, Investigator

X Emily B Camire
Investigator
Signed By: EMILY B. CAMIRE -S
Date Signed: 05-14-2025
10:15:38

DATE ISSUED
5/14/2025

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."