DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	12/2/2024-12/9/2024* FEI NUMBER 3013389992

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
J. Kendall Smalls, Director of Operations

FIRM NAME	STREET ADDRESS
GLOBAL FERTILITY & GENETICS	115 E 57th St Ste 420
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
New York, NY 10022-2049	Reproductive Human Tissue

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

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

Specifically,
a) Review of anonymous oocyte donor # [redacted] and anonymous oocyte donor # [redacted] records found that they reside in [redacted], respectively, as documented on the sample collection form for donor # [redacted] dated [redacted] and Egg Donation Process, Risk, Consent and Agreement form dated 06/17/2024 for donor # [redacted]. However, anonymous oocyte donor # [redacted] was determined eligible on 03/19/2024 and donated oocytes on [redacted], anonymous oocyte donor # [redacted] was determined eligible on 06/24/2024 and on 01/12/2024, and donated oocytes on [redacted] and on [redacted].
b) Directed oocyte donor [redacted] was determined eligible on 05/03/2023 and donated oocytes that were fertilized with directed donor [redacted] semen and subsequent tissue transferred to recipient [redacted] on [redacted]. However, [redacted] tested [redacted] and was determined ineligible on 05/11/2023. There was no explanation documented.
c) Directed oocyte donor [redacted] was determined eligible on 08/09/2023 and donated oocytes that were fertilized with directed donor [redacted] semen and [redacted] subsequent tissues cryopreserved. However, [redacted] tested [redacted] and was determined ineligible on 08/09/2023. There was no explanation documented.

OBSERVATION 2

HCT/Ps from ineligible donors which were made available for limited use were not prominently labeled with the Biohazard legend, a statement warning of communicable disease risks and a statement warning of the reactive test results.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Irina Gaberman, Investigator	X Irina Gaberman Investigator Signed By: 1300222798 Date Signed: 12-09-2024 08:48:48	12/9/2024

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Specifically,
Review of records documenting reproductive tissue shipment from your facility to [(b)(4)] found that they are not always labeled appropriately showing screening and/or eligibility status. For example:
a) [redacted] semen vials distributed on [redacted] from directed semen donor [redacted] who was determined ineligible on 06/23/2022 due to [redacted] test results were not labeled with a Biohazard legend and warning indicating [redacted] test.
b) [redacted] cryopreserved oocytes from patient [redacted] distributed on [redacted] were not labeled with labels indicating that tissues were not evaluated for infectious disease substances and warning the recipient of communicable disease risks. Embryology laboratory records dated 10/19/2022 document that oocytes were intended to be transferred to a recipient [redacted].
c) [redacted] cryopreserved tissues from [redacted] distributed on [redacted] were not labeled with labels indicating that tissues were not evaluated for infectious disease substances and warning the recipient of communicable disease risks. Embryology laboratory records dated 05/28/2022 document tissues were intended to be transferred to a recipient not related to [redacted].

OBSERVATION 3
You did not establish and maintain procedures for screening and determining the eligibility of HCT/P donors.

Specifically,

Your standard operating procedures entitled "Anonymous Oocyte Donor Screening and Eligibility Determination" effective date 08/22/23 and "Directed Donor Screening and Eligibility Determination" effective date 11/07/2022, do not include detailed oocyte donor eligibility criteria. For example, the following criteria are missing: men who had sex with another man in the preceding 5 years and persons

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who had sex in the preceding 12 months with these men; and persons who have been in juvenile detention, lock up, jail or prison for more than 72 consecutive hours in the preceding 12 months.

***DATES OF INSPECTION**
12/02/2024(Mon), 12/03/2024(Tue), 12/04/2024(Wed), 12/09/2024(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Irina Gaberman, Investigator X Irina Gaberman Investigator Signed By: 1300222799 Date Signed: 12-09-2024 06:48:48	12/9/2024

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."