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	3/31/2025-4/9/2025* FEI NUMBER 3004753467

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. George D Kofinas, Medical Director

FIRM NAME	STREET ADDRESS
Kofinas Fertility Group	65 Broadway Fl 14
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
New York, NY 10006-2516	Reproductive Human Tissues

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) On (b) (6), (b) (7)(C), anonymous oocyte donor (b) (4), (b) (6), (b) (was determined eligible by the Medical Director as documented on her Donor Eligibility - Summary of Records Female form prior to receipt of the infectious disease test results for Chlamydia and Gonorrhea that were reported on 09/03/2023. Anonymous oocyte donor (b) (4), (b) (6), (b) (donated oocytes on (b) (6), (b) (7)(C) that were fertilized on the same day and resulting tissues cryopreserved.
b) On (b) (6), (b) (7)(C), directed semen donor (b) (6), (b was determined eligible as documented on the Summary of Records form. However, directed semen donor (b) (6), (b answered yes to question #1 on the Donor Risk Behavior Assessment dated (b) (6), (b) (7)(C) that asks "Are you a male who had sex with another male in the preceding five years?". Male to male sex is a risk factor for HIV and Hepatitis B. Directed semen donor (b) (6), (b donated semen on (b) (6), (b) (7)(C) that was used to fertilize oocytes retrieved from anonymous oocyte donor (b) (4), (b) (6), (b) (with one resulting tissue transferred to recipient (b) (6), (b) (on (b) (6), (b) (7)(C). In addition, transferred tissue was not adequately labeled with the warning label advising the recipient of communicable disease risks.
c) Directed semen donor (b) (6), (b) donated his semen on (b) (6), (b) (7)(C) that was used to fertilized oocytes donated by directed oocyte donor (b) (6), (b) (. However, his blood specimen for infectious disease testing was collected on (b) (6), (b) (7)(C) and not within 7 days of his semen donation. This directed semen donor (b) (6), (b) was not screened for the risk factors associated with relevant communicable disease agents and diseases (RCDAD) and did not have current physical examination. Directed semen donor physical examination and screening for the risk factors associated with RCDAD was performed on (b) (6), (b) (7)(C). Directed

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semen donor (b) (6), (b) was determined eligible on (b) (6), (b) (7)(C) by the Medical Director.
d) Directed oocyte donor (b) (6), (b) donated oocytes on (b) (6), (b) (7)(C) and was tested for infectious diseases on 10/23/2023 but was not screened for the risk factors associated with relevant communicable disease agents and diseases (RCDAD) and did not have current physical examination. Directed semen donor physical examination and screening for the risk factors associated with RCDAD was performed on (b) (6), (b) (7)(C). This directed oocyte donor was determined eligible on (b) (6), (b) (7)(C).

OBSERVATION 2

HCT/Ps for which the donor eligibility determination was not required and applicable donor eligibility requirements were not met were not prominently labeled with the appropriate warning statements.

Specifically,
a) Review of shipping records for reproductive tissues sent to outside firms from August 2023 to March 2025 found that these tissues that were not sent in quarantine status, were not prominently labeled with required labeling. For example,
i) 13 oocytes belonging to female patient (b) (6), (b) (no partner documented) sent out on 03/31/2025 were not labeled with a warning advising the recipient of communicable disease risks and/or if they were cryopreserved for autologous use only; and did not have a biohazard legend shown.
ii) On 07/24/2024 semen from directed semen donor (b) (6), (b) was used to fertilize oocytes from directed oocyte donor (b) (4), (b) (6), (b, and 5 resulting cryopreserved tissues were sent to an outside facility on 11/22/2024. There was no labeling indicating directed semen donor eligibility status and no warnings.

OBSERVATION 3

The eligibility of an HCT/P donor was not determined and documented by a responsible person, based on results of donor screening and donor testing.

Specifically,
a)Review of shipping records for tissues sent to outside firms from August 2023 to March 2025 found that on 07/24/2024 semen from directed semen donor (b) (6), (b) was used to fertilize oocytes retrieved from

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directed oocyte donor (b) (4), (b) (6), (b, and 5 resulting cryopreserved tissues were sent to outside facility on 11/22/2024. This directed semen donor (b) (6), (b) was not screened for the risk factors for the relevant communicable disease agents and diseases, and there was no physical examination performed. The eligibility of directed semen donor (b) (6), (b) was not determined and documented, and there was no Summary of Records generated for directed semen donor (b) (6), (b) to accompany these tissues.
b) Review of tissue disposition records for anonymous oocyte donor (b) (4), (b) (6), (b) (7)(C found that oocytes retrieved from anonymous oocyte donor (b) (4), (b) (6), (b)(were fertilized with directed semen donor (b) (6), (b) and cryopreserved on (b) (6), (b) (7)(C) and (b) (6), (b) (7)(C) with resulting 14 tissues cryopreserved. This directed semen donor (b) (6), (b) was not screened for the risk factors for the relevant communicable disease agents and diseases, and there was no physical examination performed. Eligibility for directed semen donor (b) (6), (b) was not determined and documented, and there was no Summary of Records generated.

OBSERVATION 4
Donor eligibility records are not accurate, indelible and legible.

Specifically,
a) Review of Summary of Records for 22 directed semen and oocyte donors from August 2023 to March 2025 found:
i) One donor eligibility determination was documented for both directed oocyte and directed semen donor on the same Summary of Records form. For example: directed oocyte donor (b) (6), (b) (and directed semen donor (b) (6), (b) eligibility was documented as eligible on 02/05/2024; directed oocyte donor (b) (6), (b) (and (b) (6), (b) eligibility was documented as eligible on 12/16/2024.
ii) One donor eligibility determination was documented for multiple oocyte and semen donations: directed oocyte donor (b) (6), (b) (and directed semen donor (b) (6), (b) eligibility determination was documented on the same donor eligibility form for (b) (6), (b) (7)(C) for (b) (6), (b) (7)(C) and (b) (6), (b) (7)(C) tissue donation cycles.
b) Review of Donor Risk Behavior Assessment questionnaires that is used for screening for relevant communicable disease agents and diseases for directed oocyte and semen donors found that questions related to smallpox vaccination, #14, #17, and #18 are not always answered. For example directed

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semen donor (b) (6), (b) (questionnaire dated (b) (6), (b) (7)(C)), directed oocyte donor (b) (6), (b) (questionnaire dated (b) (6), (b) (7)(C)) and directed semen donor (b) (6), (b (questionnaire dated (b) (6), (b) (7)(C)) checked N/A (Not Applicable) answer on the questionnaire without explanation.

c) Review of Donor Risk Behavior Assessment questionnaires that is used for screening for relevant communicable disease agents and diseases for anonymous and directed oocyte donors and directed semen donors from August 2023 to March 2025 found that identity of the individual completing the questionnaire is not documented. The standard operating procedure #DE-03 states: (b) (4)

***DATES OF INSPECTION**
3/31/2025(Mon), 4/01/2025(Tue), 4/09/2025(Wed)

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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."