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	12/12/2024-12/20/2024* FEI NUMBER 3003972435

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Eric J. Forman, Medical Director

FIRM NAME	STREET ADDRESS
Columbia University Fertility Center	5 Columbus Circle, PH
CITY, STATE, ZIP CODE, COUNTRY New York, NY 10019-1412	TYPE ESTABLISHMENT INSPECTED Human Reproductive 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

Donor specimens used for testing of communicable disease agents were not collected at the appropriate time.

Specifically, directed semen donor [redacted] was not tested for syphilis (T. pallidum) within 7 days of collection. Semen was collected on [redacted] and the donor was tested for syphilis on [redacted] (specimen collection date).

OBSERVATION 2

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

Specifically, the following anonymous donor ([redacted]) and directed donor ([redacted]) had oocytes retrieved with a physical examination performed and documented after the donors were determined eligible:

Donor ID	Date of Donor Eligibility	Date of Physical Examination	Retrieval of Oocytes
[redacted]	1/23/2023	b)(6) b)(7)(C)	[redacted] oocytes on [redacted]
	11/2/2023		[redacted] oocytes on [redacted]

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EMPLOYEE(S) SIGNATURE
Amy Kim, Investigator

X Amy Kim
Investigator
Signed By: 2000481080
Date Signed: 12-20-2024
08:40 ST

DATE ISSUED
12/20/2024

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Columbia University Fertility Center	5 Columbus Circle, PH
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New York, NY 10019-1412	Human Reproductive Tissue Establishment

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, semen from directed donor [redacted] was collected on [redacted]. Semen from this donor was utilized to fertilize oocytes and transferred to a gestational carrier on [redacted]. The donor eligibility was determined for this donor on [redacted] by the Clinical Director.

OBSERVATION 4

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

Specifically, reproductive tissue created from an ineligible directed oocyte donor and ineligible directed semen donors were not labeled with a Biohazard legend and the warning statement, "WARNING: Advise patient of communicable disease risks." Examples include:

(1)Reproductive tissue created from ineligible directed semen donor [redacted] who answered "[redacted]" to the screening question regarding [redacted] in the preceding [redacted] was not labeled with a Biohazard legend and the required statement, "WARNING: Advise patient of communicable disease risks."

(2)Reproductive tissue created from ineligible directed semen donor [redacted] who answered "[redacted]" to the screening question regarding European travel, was not labeled with a Biohazard legend and the required statement, "WARNING: Advise patient of communicable disease risks." This donor

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Amy Kim, Investigator	X Amy Kim Investigator Signed By: 2000481080 Date Signed: 12-20-2024 08:40 ST	12/20/2024

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was also not tested for syphilis (T. pallidum) within 7 days of semen collection.

(3)Reproductive tissue created from ineligible directed oocyte donor [redacted] who answered "[redacted]" to the screening question regarding European travel, was not labeled with a Biohazard legend and the required statement, "WARNING: Advise patient of communicable disease risks."

OBSERVATION 5

A standard operating procedure for the release of HCT/Ps from donors that test reactive for cytomegalovirus (CMV) was not established.

Specifically, your firm does not have a written standard operating procedure for the release of HCT/Ps from semen donors that tests reactive for CMV.

***DATES OF INSPECTION**

12/12/2024(Thu), 12/13/2024(Fri), 12/17/2024(Tue), 12/18/2024(Wed), 12/20/2024(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Amy Kim, Investigator	X Amy Kim Investigator Signed By: 2000481080 Date Signed: 12-20-2024 08:40 ST	12/20/2024

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."