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 3005002665

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jeff G. Wang, Medical Director

FIRM NAME	STREET ADDRESS
Neway Medical, P.C.	123 W 79th St
CITY, STATE, ZIP CODE, COUNTRY New York, NY 10024-6480	TYPE ESTABLISHMENT INSPECTED 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)Your Donor Screening Questionnaire is used to screen anonymous and directed oocyte and directed semen donors for the risk factors associated with Creutzfeldt-Jacob Disease (CJD) and variant CJD: question #22a "From beginning of 1980 through the end of 1996 did you spend time that adds up to 3 months or more in U.K.?" and question #22b "Since 1980 have you received a transfusion of blood or blood components in the U.K. or France?" Review of - anonymous and - directed oocyte donor cycle records and - directed semen donor records from (b)(4) found that - anonymous oocyte donors, directed oocyte donors and - directed semen donors did not answer questions #22a and #22b but were determined eligible/ineligible and donated reproductive tissues that were used for in-vitro fertilization with subsequent tissues cryopreserved and/or transferred.

Donor Type	Total Donor cycles	Donors Determined Eligible/Ineligible	Tissues Transferred to the Recipients	Fertilized Tissues in Storage
Anonymous Oocyte	(b)(4)	- Eligible	(b)(4)	(b)(4)
Directed Oocyte		- Eligible		
Directed Semen		- Eligible - Ineligible	semen vials used)	vials cryopreserved)

b)Review of relevant medical records for anonymous oocyte donor (b)(6)(7)(C)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Irina Gaberman, Investigator	X Irina Gaberman Investigator Signed By: 1300222798 Date Signed: 12-20-2024 08:08:42	12/20/2024

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found that she lived in [redacted]. She was determined eligible on [redacted] and donated oocytes on [redacted] that were fertilized and [redacted] transferred to recipient [redacted] on [redacted] with [redacted] fertilized tissues cryopreserved.

OBSERVATION 2

The summary of records for HCT/Ps from donors determined to be ineligible based on screening and released for limited use did not contain a statement noting the reasons(s) for the ineligibility.

Specifically,

Directed oocyte donor [redacted] tested [redacted] for [redacted] and [redacted] as documented on the Patient Reports dated [redacted]. However, the reason for ineligibility was listed as "Answered "[redacted]" to HRQ [High Risk Questionnaire, [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 to screen, test and determine donor eligibility do not include all eligibility criteria based on the questions answered on the Donor Screening Questionnaire. This Donor Screening Questionnaire is used to screen anonymous and directed oocyte and directed semen donors. Some examples are: men who had sex with another man in the preceding 5 years and persons 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.

OBSERVATION 4

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Donor eligibility records are not accurate and legible.

Specifically,

a) On , directed semen donor answered "" to question on the Donor Screening Questionnaire: "In the past 12 months, have you had or been treated for ?" and "In the past 12 months, have you with anyone who would answer to questions ?" However, this directed semen donor Health History and Physical Examination Form dated documents that there was no history of (b)(6) (b)(7)(C).
b) anonymous oocyte donors, directed oocyte donors and directed semen donors had incomplete screening but were determined eligible in . Their reproductive tissues were recovered, used for fertilization procedures, cryopreserved and/or transferred to the recipients. These anonymous oocyte and directed oocyte and semen donors eligibility was changed to ineligible by the Medical Director in 2023.
c) On , directed oocyte donor tested for (b)(6) (b)(7)(C), as documented on the Patient Report dated . However, the Summary of Records dated (b)(6) (b)(7)(C) test as Non Reactive and interpreted as Normal.

OBSERVATION 5
Procedures were not designed to ensure compliance with the donor eligibility requirements.

Specifically,

Your standard operating procedure entitled Testing, section 2.2 entitled Diseases To Test For And Result Interpretations states for and testing: "If the results are positive, a confirmatory test will be used to determine the status of the donor. This is due to the potential for the initial result to be a false-positive result." On , directed oocyte donor tested for (b)(6) (b)(7)(C). Her supplemental assay test interpretation was . On , this directed oocyte donor was retested again and tested for the test with the supplemental assay. (b)(6) (b)(7)(C) result was documented on the Summary of Records

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for [redacted] dated [redacted].

***DATES OF INSPECTION**
12/12/2024(Thu), 12/13/2024(Fri), 12/20/2024(Fri)

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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."