DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	10/3/2024-10/7/2024* FEI NUMBER 3005916326

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mey S. Chau, Registered Nurse

FIRM NAME	STREET ADDRESS
Fertility Care of Orange County, A Medical Corporation	203 N Brea Blvd Ste 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Brea, CA 92821-4056	HCT/P 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

Donors were not screened by a review of relevant medical records for risk factors of communicable disease agents and diseases.

Specifically, during review of donor records from (b)(4) and (b)(4) donors were not screened for relevant communicable disease agents and diseases for West Nile Virus (WNV), Creutzfeldt-Jacob Disease (CJD), and for xenotransplantation. Your firm's medical and social screening questionnaire, entitled "HEALTH QUESTIONNAIRE FOR PROSPECTIVE EGG or SPERM DONORS", Updated 04/09/2019, are missing either whole or in part screening questions, as follows:

1. Persons who have tested positive or reactive for WNV infection using an FDA-licensed or investigational WNV NAT donor screening test in the preceding 120 days.
2. Persons who have been diagnosed with vCJD or any other form of CJD.
3. Persons who have been diagnosed with dementia or any degenerative or demyelinating disease of the central nervous system or other neurological disease of unknown etiology.
4. Persons who spent three months or more cumulatively in the United Kingdom (U.K.) from the beginning of 1980 through the end of 1996.
5. Persons who are current or former U.S. military members, civilian military employees, or dependents of a military member or civilian employee who resided at U.S. military bases in Northern Europe for 6 month or more cumulatively from 1980 through 1990, or elsewhere in Europe for 6 months or more cumulatively from 1980 through 1996.
6. Persons who are xenotransplantation product recipients or intimate contacts of a

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Creighton T Tuzon, Investigator X Creighton T Tuzon Investigator Signed By: Creighton Tuzon -S Date Signed: 10-07-2024 12:17:18	10/7/2024

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xenotransplantation product recipient.

During review of records from (b)(4) anonymous (b)(4) donors; (b)(4) (b)(4) donors; (b)(4) donors; and (b)(4) were screened using your firm's medical and social screening questionnaire, entitled "HEALTH QUESTIONNAIRE FOR PROSPETIVE EGG or SPERM DONORS", Updated 04/09/2019, that was deficient in screening donors and recipients for relevant communicable disease agents and diseases.

***DATES OF INSPECTION**
10/03/2024(Thu), 10/04/2024(Fri), 10/07/2024(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Creighton T Tuzon, Investigator X Creighton T Tuzon Investigator Signed By: Creighton Tuzon -S Date Signed: 10-07-2024 12:17:18	10/7/2024

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."