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	12/16/2024-12/17/2024
	FEI NUMBER 3009258903

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Joshua J. Berger, MD, PhD, Medical Director

FIRM NAME	STREET ADDRESS
Innovative Fertility Center	3500 N Sepulveda Blvd Ste 130
CITY, STATE, ZIP CODE, COUNTRY Manhattan Beach, CA 90266-3639	TYPE ESTABLISHMENT INSPECTED 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, your firm's FDA Screening Questions Form, Form #002, Created on 07/01/2021, Revised on 05/20/2024, did not screen donors for all required relevant communicable disease agents and diseases including West Nile Virus (WNV) and for xenotransplantation. Your firm's FDA Screening Questions, Form #002, Created on 07/01/2021, Revised on 05/20/2024, was deficient in screening donors, either whole or in part, for:

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 [redacted].

2. Persons who are xenotransplantation product recipients or intimate contacts of a xenotransplantation product recipient.

During review of all anonymous and directed oocyte donor records from 2022-2024, all [redacted] oocyte donors were screened using FDA Screening Questions, Form #002, Created on 07/01/2021, Revised on 05/20/2024. HCT/Ps from these anonymous oocyte donors were recovered (retrieved), cryopreserved, and/or transferred to recipients.

OBSERVATION 2

You did not establish and maintain procedures for screening of HCT/P donors.

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: 12-17-2024 11:33:40	12/17/2024

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Joshua J. Berger, MD, PhD, Medical Director

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Innovative Fertility Center	3500 N Sepulveda Blvd Ste 130
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Manhattan Beach, CA 90266-3639	HCT/P Reproductive Establishment

Specifically, your firm's procedure Egg/Sperm Donor Eligibility Determination, SOP #002, Effective Date: 07/01/2021, Revision Date: 05/20/2024, specifies screening of oocyte donors using your firm's FDA Screening Questions Form, Form #002, Created on 07/01/2021, Revised on 05/20/2024. However, your FDA Screening Questions Form, Form #002, Created on 07/01/2021, Revised on 05/20/2024, fails to establish and maintain screening of risk factors for and clinical evidence of relevant communicable disease agent and diseases of West Nile Virus (WNV) and xenotransplantation.

OBSERVATION 3

The summary of records for HCT/Ps did not contain the address of the establishment that made the donor-eligibility determination.

Specifically, during review of anonymous and directed oocyte donor Summary of Records (SORs) from 2023-2024, there was no documentation of your firm's address as the establishment that made donor eligibility determination. For example, all [redacted] oocyte donor SORs reviewed from 2023-2024 failed to document your firm's address on your firm's Summary of FDA Required Communicable Disease Screening form.

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: 12-17-2024 11:33:40	12/17/2024

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."