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	2/19/2025-2/24/2025* FEI NUMBER 3016710849

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
James P. Lin, MD, Medical Director

FIRM NAME	STREET ADDRESS
Incinta Fertility Center, LLC	21545 Hawthorne Blvd, Pavilion B
CITY, STATE, ZIP CODE, COUNTRY Torrance, CA 90503-6609	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

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

Specifically, your firm failed to label HCT/Ps that were made available for use with warning labels, to include, "WARNING: Advise patient of communicable disease risks" and "WARNING: Reactive test results for [name of disease agent or diseases]". During review of donor records from 2023-2025, four (4) out of (b) (4) directed oocyte and twelve (12) out of (b) (4) directed semen donor records reviewed were not labeled with appropriate warning labels on the Donor Summary of Records and Eligibility and Embryo Vitrification/Warming Inventory Record forms.

THIS IS A REPEAT OBSERVATION.

OBSERVATION 2

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

Specifically, your firm's implemented medical and social screen questionnaire entitled, Donor Medical History Interview Questionnaire, FDA Questionnaire. (b) (6), (b) (7) (C) 02/2022, did not screen donors for all required relevant communicable disease agents and diseases including West Nile Virus (WNV) and variant Creutzfeldt-Jakob Disease (vCJD) or any other form of CJD.

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: 02-24-2025 08:39:08	2/24/2025

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CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Torrance, CA 90503-6609	HCT/P Reproductive Establishment

During review of donor records from 2023-2025, all anonymous and directed oocyte and semen donors were screened using your firm's Donor Medical History Interview Questionnaire, FDA Questionnaire, (b) (6), (b) (7) (C) 02/2022. HCT/Ps from anonymous and directed oocyte and semen donors were recovered, cryopreserved, and/or fertilized. The resultant HCT/Ps (embryos) were subject to embryo vitrification and/or transferred to recipients.

OBSERVATION 3

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

Specifically, your firm's Donor Medical History Interview Questionnaire, IFC-Questionnaire Donor Risk Factor (b) (6), (b) (7)(C) -revised 05-2024, and Donor Medical History Interview Questionnaire, FDA Questionnaire, (b) (6), (b) (7) (C) 02/2022, did not screen donors for all required relevant communicable disease agents and diseases. Your firm's medical and social screening questionnaires fail to establish and maintain screening of risk factors 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 120 days.

2. Persons who have been diagnosed with vCJD (variant Creutzfeldt-Jakob Disease) or any other form of CJD.

OBSERVATION 4

The accompanying records for HCT/Ps included the donor's name and personal information that might identify the donor.

Specifically, your firm documented the name and date of birth on accompanying summary of records (SORs) of anonymous oocyte and semen donors from 2023-2025. In total, (b) (4) anonymous oocyte donors and (b) (4) anonymous semen donor records documented personal identifiable information on the Donor Summary of Records and Eligibility form.

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*DATES OF INSPECTION

2/19/2025(Wed), 2/21/2025(Fri), 2/24/2025(Mon)

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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."