**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**FOOD AND DRUG ADMINISTRATION**

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 19701 Fairchild<br>Irvine, CA 92612-2445<br>(949)608-2900 Fax:(949)608-4417 | 1/9/2025-1/13/2025*<br>FEI NUMBER<br>3005488001 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michelle Y. Cobb, MA, Clinical Coordinator

| FIRM NAME | STREET ADDRESS |
|---|---|
| Pacific Reproductive Center, Inc. | 3720 Lomita Blvd Ste 200 |
| CITY, STATE, ZIP CODE, COUNTRY<br>Torrance, CA 90505-3884 | TYPE ESTABLISHMENT INSPECTED<br>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 medical and social questionnaire, entitled Donor Medical History Interview Questionnaire, PRC - Questionnaire Donor Risk Factor - (b) (4) -revised 04-2018, does not screen donors for all required relevant communicable disease agents and diseases of West Nile Virus (WNV). Your medical and social questionnaire does not screen donors for persons who have tested positive or reactive for WNV infection using an FDA-licensed during investigational WNV NAT donor screening test in the preceding 120 days.

During review of twenty-six (26) donor records from 2020-2024, twenty-five (25) oocyte and semen donors were screened using Donor Medical History Interview Questionnaire, PRC - Questionnaire Donor Risk Factor - (b) (4) -revised 04-2018, that did not screen for persons who have tested positive or reactive for WNV infection using an FDA-licensed during investigational WNV NAT donor screening test in the preceding 120 days. Human cells, tissues, and cellular and tissue-based products (HCT/Ps) from these oocyte and semen donors were recovered (retrieved) and cryopreserved, and/or gametes were fertilized and then cryopreserved.

## OBSERVATION 2

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

Specifically, your firm's procedure entitled, FDA Protocol for Oocyte Donor, PRC-Protocol, Oocyte

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| | Creighton T Tuzon, Investigator | X Creighton T Tuzon Investigator Signed By: Creighton Tuzon -S Date Signed: 01-13-2025 09:47:03 | 1/13/2025 |

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Donor, (b)(4)-05-2018, and medical and social screening questionnaire entitled, Donor Medical History Interview Questionnaire, PRC-Questionnaire Donor Risk Factor, (b)(4)-revised 04-2018, do not establish screening of risk factor for relevant communicable disease agent and diseases of West Nile Virus (WNV). Both your procedure and medical and social screening questionnaire do not specify for the screening of persons who have tested positive or reactive for WNV infection using an FDA-licensed or investigational WNV NAT donor screening test int he preceding 120 days.

**OBSERVATION 3**

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

Specifically, your firm failed to determine a donor's eligibility based on the donor's response to your medical and social screening questionnaire, Donor Medical History Interview Questionnaire, PRC-Questionnaire Donor Risk Factor-(b)(4)-revised 04-2018. During review of donor records from 2020-2024, an intended parent (using gestational surrogate) semen donor ((b)(6)) answered "Y" for Yes on your firm's medical and social questionnaire, to the following questions:

(b) (4)

The indented parent (using gestational surrogate) semen donor ((b)(6)) was determined eligible on 06/24/2024, and the donor's semen (sperm) was recovered (retrieved) on (b) (6), (b) (7)(C).

Also, the intended parent (using gestational surrogate) oocyte donor ((b)(6),) to semen donor ((b)(6),) was determined eligible on 06/24/2024; however, oocyte donor ((b)(6),) indicated that she was not free of risks factors for infection due to communicable disease agents. In (b)(6), (b)(7), the intended parent (using gestational surrogate) oocyte donor ((b)(6),) answered "Y" for Yes to Question (b)(4)a, that reads in part, "(b) (4) (b) (4)?". In 2024, the same intended parent (using gestational surrogate) oocyte donor ((b)(6),) answered "N" for No to the same Question (b)(4)a. There was no justification for donor eligibility determination based on the discrepant medical and social screening results. Intended parent (using gestational surrogate) donor ((b)(6),) gametes

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were recovered (retrieved) on (b) (6), (b) (7)(C), thawed and fertilized on 06/17/2024, and the resultant HCT/Ps (embryos) were cryopreserved on 06/22-23/2024.

## OBSERVATION 4

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

Specifically, your firm's Summary of Records and Donor Eligibility form versions (PRC-FDA-Donor Eligibility-(b) (4), (b) (6), (b)-07-5-2015 used in 2023; PRC-FDA Donor Eligibility-(b) (4), revised-03-2016 used in 2020-2023; and PRC-FDA Donor Eligibility-(b) (4), revised-03-2017 used in 2021-2024) document the firm's address using a satellite office address and not the location where donor eligibility determination was made.

During review of donor records from 2020-2024, all anonymous oocyte, directed semen, and intended parent (using gestational carrier) records whereby donor eligibility determination was made at the firm documents an office address that differs from the location where donor eligibility determination was made and HCT/Ps were recovered.

## OBSERVATION 5

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

Specifically, during review of donor records from 2020-2024, ten (10) intended parent (using gestational carrier) records that documented the donors were "Ineligible" were not prominently labeled with statement warning, "WARNING: Advise patient of communicable disease risks." on your firm's Summary of Records and Donor Eligibility form.

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## *DATES OF INSPECTION

1/09/2025(Thu), 1/13/2025(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."