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	6/9/2025-6/12/2025* FEI NUMBER 3005405914

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Vuk Jovanovic, MD, Medical Director

FIRM NAME	STREET ADDRESS
California Fertility Clinics LLC	5455 Wilshire Blvd Ste 1904
CITY, STATE, ZIP CODE, COUNTRY Los Angeles, CA 90036-4241	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

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

Specifically, during review of procedure Reproductive Donor Eligibility Determination, DE-01, Rev. A, Effective: 05-01-2021, there was no relevant communicable diseases and associated diseases (RCDADs) testing requirement for West Nile Virus (WNV). There also was no interpretation of RCDAD testing result for WNV to determine a donor's eligibility status.

OBSERVATION 2

A standard operating procedure for the release of HCT/Ps from donors that test reactive for cytomegalovirus (CMV) was not maintained, defined and documented.

Specifically, your procedure Reproductive Donor Eligibility Determination, DE-01, Rev. A, Effective: 05-01-2021, specifies additional testing required for sperm donors to include, in part, cytomegalovirus (CMV) testing. A communicable disease testing result that is IgG (b) (4) and IgM (b) (4) would result in a donor deferral with a repeat IgG testing after (b) (4). If CMV testing with (b) (4) to IgG (b) (4) the donor is determined to be ineligible. Alternatively, if CMV testing with (b) (4) to IgG (b) (4) the donor is determined to be eligible.

During review of records from 2023-2025, at least (b) (4) out of (b) (4) records documented that directed semen donors were positive or reactive to CMV (Total) antibody. CMV (b) (4) testing to IgG and IgM documented that donors were IgG (b) (4), IgM (b) (4). There was no repeat testing of the (b) (4) directed

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: 06-12-2025 09:47:28	6/12/2025

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semen donors as specified in procedure Reproductive Donor Eligibility Determination, DE-01, to determine if CMV IgG levels were (b) (4) that would indicate an (b) (4) CMV infection or when an (b) (4) (b) (4) occurred. Furthermore, the procedure does not specify that retesting is applicable only to anonymous donors. Moreover, the procedure states that a recipient must be informed of associated risks without specifying how recipients are informed of CMV risks and exposure associated with HCT/P release.

***DATES OF INSPECTION**
6/09/2025(Mon), 6/11/2025(Wed), 6/12/2025(Thu)

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	Creighton T Tuzon, Investigator X Creighton T Tuzon Investigator Signed By: Creighton Tuzon -S Date Signed: 06-12-2025 09:47:28	6/12/2025

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."