

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 4/9/2025-4/11/2025 FEI NUMBER 3018118424	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Laura A. Bergquist RN, BSN, Third Party / IVF Coordinator		
FIRM NAME Global Premier Fertility Orange County LLC	STREET ADDRESS 3333 W Coast Hwy Ste 300	
CITY, STATE, ZIP CODE, COUNTRY Newport Beach, CA 92663-4058	TYPE ESTABLISHMENT INSPECTED Human Reproductive Tissue 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 The accompanying records for HCT/Ps included the donor's name and personal information that might identify the donor. Specifically, Anonymous Oocyte donor (b) (6), (b) (7)(C), Donor ID #: (b) (4), (b) (6), (b) (7)(C) personal identifiable information such as Name and Date of Birth are present on the Accompanying records which include the Donor Eligibility Form, Risk Factor Questionnaires, History and Physical, and Laboratory Test results. The accompanying records: Donor Eligibility Form, and Laboratory Test results which contains personal Identifiable information were sent to the recovering firm on (b) (6), (b) (7)(C) The donor's Oocyte were recovered on (b) (6), (b) (7)(C)		
OBSERVATION 2 The summary of records for HCT/Ps did not contain a statement that the communicable disease testing was performed by a laboratory certified to perform such testing on human specimens under the Clinical Laboratory Improvement Act of 1988 or has met equivalent requirements determined by the Centers for Medicare and Medicaid Services. Specifically, While reviewing your firm's Summary of Record(s), "Donor Eligibility Form", dated between January 2023 to December 2024, it was determined that (b) (4) of (b) (4) "Donor Eligibility Forms"		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Melsomar R Ramos, Investigator Melsomar R Ramos Investigator Signed By: Melsomar R. Ramos - S Date Signed: 04-11-2025 09:51:58 	DATE ISSUED 4/11/2025

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does not contain a statement that the communicable disease testing was performed by a laboratory certified to perform testing under the CLIA of 1988 or has met equivalent requirements determined by the Centers for Medicare and Medicaid Services OBSERVATION 3 Documentation of the donor-eligibility determination and the date of the donor-eligibility determination was not maintained. Specifically, During the review of your firm's donor records between January 2023 to December 2024. (b) (4) of the (b) (4) anonymous and directed donor records does not indicate the date when they were determined eligible or ineligible which does not provide a complete history of work performed.		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Melsomar R Ramos, Investigator	DATE ISSUED 4/11/2025
	Melsomar R Ramos Investigator Signed By: Melsomar R. Ramos - S Date Signed: 04-11-2025 09:51:58 X	
FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 2 of 2 PAGES		

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."