

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417		<small>DATE(S) OF INSPECTION</small> 3/12/2025-3/14/2025 <small>FEI NUMBER</small> 3005887264	
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Dr. Ilene E. Hatch, Medical Director			
<small>FIRM NAME</small> Fertility Center of Southern California		<small>STREET ADDRESS</small> 4980 Barranca Pkwy Ste 200	
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Irvine, CA 92604-8653		<small>TYPE ESTABLISHMENT INSPECTED</small> Reproductive Human Tissue	
<p>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.</p>			
<p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 HCT/P donors were not determined to be eligible based on the results of donor screening and testing.</p> <p>Specifically,</p> <p>Directed donor [REDACTED] stated that she lived in [REDACTED] (risk factor for Creutzfeldt-Jacob Disease) as documented on her Donor Medical History Questionnaire dated and reviewed on 09/16/2024. However, she was determined eligible by the Medical Director as documented on her Donor Eligibility Determination Form dated 09/18/2024, donated [REDACTED] oocytes that were fertilized, and [REDACTED] resulting tissues cryopreserved.</p>			
SEE REVERSE OF THIS PAGE		<small>EMPLOYEE(S) SIGNATURE</small> Irina Gaberman, Investigator <div style="text-align: right;"> <small>Irina Gaberman Investigator Signed By: 130022798 Date Signed: 03-14-2025 09:24:49</small> </div>	
<small>DATE ISSUED</small> 3/14/2025			

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."