

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

DISTRICT ADDRESS AND PHONE NUMBER 1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax: (510) 337-6702	DATE(S) OF INSPECTION 7/28/2025-7/31/2025 FEI NUMBER 3009473818
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Karen J. Purcell, Director

FIRM NAME CARE for the Bay Area	STREET ADDRESS 555 Knowles Dr Ste 212
CITY, STATE, ZIP CODE, COUNTRY Los Gatos, CA 95032-1551	TYPE ESTABLISHMENT INSPECTED Reproductive

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 and clinical evidence of communicable disease agents and diseases.

Specifically,

From (b) (4), your firm has failed to adequately screen (b) (4) donors (b) (4) of anonymous oocyte donors, (b) (4) of directed oocyte donors, and (b) (4) of directed semen donors) based on your donor history questionnaire's titled "FDA Screening Questionnaire".

Your donor history questionnaires failed to screen and elicit for critical risk factors by failing to include the question's.

"Have you tested positive or been treated for syphilis in the preceding 12 months." From (b) (4) (b) (4) involving (b) (4) donors.

"Have you been treated for syphilis, gonorrhea, or chlamydia in the preceding 12 months". From (b) (4) involving (b) (4) donors.

These donors were determined eligible based on these inadequate screening questionnaires. Reproductive tissues were both recovered and fertilized oocytes were transferred into recipients.

There are (b) (4) oocytes and (b) (4) fertilized oocytes remaining that are currently stored at your facility from (b) (4) affected donors. (b) (4) fertilized oocytes have been transferred into (b) (4) recipients from the affected (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Gabryelle J Solverud, Investigator	DATE ISSUED 7/31/2025 Gabrielle J Solverud Investigator Signed By: Gabrielle J. Solverud - Date Signed: 07-31-2025 14:13:25 X _____

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Reproductive

donors since (b) (4) .

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OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Gabryelle J Solverud, Investigator

Gabryelle J Solverud
Investigator
Signed By: Gabryelle J. Solverud -
Date Signed: 07-31-2025
14:13:25

X

DATE ISSUED

7/31/2025

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."