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	4/6/2026-4/8/2026
	FEI NUMBER 3003942600

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David Harari M.D., Chief Medical Officer

FIRM NAME	STREET ADDRESS
Reproductive Sciences Medical Center, Inc.	3661 Valley Centre Dr Ste 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Diego, CA 92130-3340	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

Donors were not screened by a review of relevant medical records for risk factors of communicable disease agents and diseases.

Specifically,

1. Your anonymous oocyte donor (b) (6), (b) (7)(C), failed to answer donor screening question #13a.: "After Age 11 have you had a clinical diagnosis of symptomatic viral hepatitis?" on the donor history questionnaire. The donor was deemed eligible on 3/29/2024, and the donor's oocyte was recovered on (b) (6), (b) (7)(C). A total of (b) (6), (b) (7)(C) oocytes were recovered and are currently in storage.
2. Your anonymous oocyte donor (b) (6), (b) (7)(C), failed to answer donor screening question #5: "In the past 12 months, have you had sex with anyone who would answer yes to any questions 1,2,3 or 4?" on the donor history questionnaire. The donor was deemed eligible on 12/6/2023 and the donor's oocytes were recovered on (b) (6), (b) (7)(C). A total of (b) (6), (b) (7)(C) embryos were created, (b) (6), (b) (7)(C) were transferred and (b) (6), (b) (7)(C) are currently in storage.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Melsomar R Ramos, Investigator	X Melsomar R Ramos Investigator Signed By: MELSOMAR R. RAMOS -S Date Signed: 04-08-2026 11:27:47	4/8/2026

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Melsomar R Ramos, Investigator

X Melsomar R Ramos
Investigator
Signed By: MELSOMAR R. RAMOS -S
Date Signed: 04-08-2026
11:27:47

DATE ISSUED

4/8/2026

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."