DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	2/28/2025-3/5/2025* FEI NUMBER 3003971359

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Butch A. Hobson, Office Manager

FIRM NAME	STREET ADDRESS
Richard Joseph Schmidt, MD, Inc.	2500 Hospital Dr Bldg 7
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mountain View, CA 94040-4115	Reproductive Firm

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, your firm did not screen donors for the following:

- Donor who has been treated for or had syphilis within the preceding 12 months.
- Donor who has tested positive or reactive for WNV infection using an FDA-licensed or investigational WNV NAT donor screening test in the preceding 120 days.
- Donor who has a suspicion of WNV infection.
- Donors who received any transfusion of blood or blood components in France between 1980 and the present

Since 2019, your firm has screened approximately (b) (4) anonymous and directed oocyte donors and directed semen donors.

OBSERVATION 2

HCT/Ps from ineligible donors which were made available for limited use were not prominently labeled with the Biohazard legend, a statement warning of communicable disease risks and a statement warning of the reactive test results.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Emily B Camire, Investigator	X Emily B Camire Inves igator Signed By: EMILY B. CAMIRE -S Date Signed: 03-05-2025 08:31:17	3/5/2025

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CITY, STATE, ZIP CODE, COUNTRY Mountain View, CA 94040-4115	TYPE ESTABLISHMENT INSPECTED Reproductive Firm

Specifically, oocytes and semen used from ineligible donors were not labeled with the Biohazard legend and were missing the following statement: "WARNING Advise patient of communicable disease risks" and if the donor tested positive for a communicable disease the following statement: "WARNING: Reactive test results for (name of disease agent or disease)"

Since 2019, your firm has screened approximately (b) (4) ineligible oocyte and semen donors.

OBSERVATION 3

Documentation of the results and the interpretation of all donor screening for communicable diseases was not maintained.

Specifically, your firm conducts an initial physical (b) (4) to oocyte retrieval and documents it on one "Donor Physical Assessment Form F-2." Donors are asked the screening questionnaire questions (b) (4) (b) (4) and it is documented on a single "Donor Medical History Interview Form F-1." Your firm does not document each individual screening interview questionnaire or physical exam that is completed for each time it is performed.

Since 2019, your firm has screened approximately (b) (4) anonymous oocyte donors.

OBSERVATION 4

You did not establish and maintain procedures for screening and determining the eligibility of HCT/P donors.

Specifically, your firm has not established procedures that describe when and for how long to defer a donor based on their screening question answers.

Since 2019, your firm has screened approximately (b) (4) anonymous and directed oocyte donors and directed semen donors.

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*DATES OF INSPECTION

2/28/2025(Fri), 3/03/2025(Mon), 3/04/2025(Tue), 3/05/2025(Wed)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Emily B Camire, Investigator

X Emily B Camire
Inves igator
Signed By: EMILY B. CAMIRE -S
Date Signed: 03-05-2025
08:31:17

DATE ISSUED
3/5/2025

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."