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	4/7/2026-4/14/2026*
	FEI NUMBER 3004627484

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Vinay Gunnala, Medical Director

FIRM NAME	STREET ADDRESS
Southwest Fertility Center	3125 N 32nd St Ste 200
CITY, STATE, ZIP CODE, COUNTRY Phoenix, AZ 85018-6218	TYPE ESTABLISHMENT INSPECTED Reproductive Tissue

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

Donor testing of HCT/P donors considered eligible was not negative or nonreactive for relevant communicable disease agents.

Specifically, directed/known sperm donor (b) (6), (b) (7)(C) was determined to be eligible by the Medical Director on 1/24/2023; however, lab results reported on 01/23/2023 and 01/30/2023 showed that the donor tested (b) (6), (b) (7)(C) for (b) (6), (b) (7)(C).

OBSERVATION 2

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

Your health history questionnaire entitled "FDA Risk Assessment" forms for donor eligibility (implementation dates: 3/10/2016 and 9/03/2025; current as of 04/07/2026) failed to adequately screen donors for Creutzfeldt-Jakob Disease (CJD) and variant CJD (vCJD).

Specifically, your question to screen former US military members, civilian military employees, or dependents of military members or civilian employees only screened donors for those who resided at a US military base in northern Europe (Germany, Belgium, and the Netherlands) for 6 months or more cumulatively from 1980 through 1996. It did not address those who potentially resided elsewhere in Europe, including Greece, Turkey, Spain, Portugal, and Italy, for 6 months or more cumulatively from 1980 through 1996.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Garrad R Poole, Investigator	X Garrad R Poole Investigator Signed By: GARRAD R. POOLE - S Date Signed: 04-14-2026 08:40:53	4/14/2026

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OBSERVATION 3

The summary of records for HCT/Ps did not contain a listing and an interpretation of results of all communicable disease tests performed.

Specifically,

a. The Summary of Record for anonymous oocyte donor (b) (6), (b) (7)(C) was missing the listings and interpretation of results for (b) (6), (b) (7)(C). Summary of Record was reviewed by Oocyte Donor Coordinator 9/23/2024 and determined to be eligible by the Medical Director on 9/24/2024.

b. The Summary of Record for anonymous oocyte donor (b) (6), (b) (7)(C) was missing the interpretation of results for (b) (6), (b) (7)(C). Summary of Record was reviewed by Oocyte Donor Coordinator and determined to be eligible by the Medical Director on 9/21/2023.

c. The Summary of Record for directed/known sperm donor (b) (6), (b) (7)(C) was missing the missing interpretation of results for (b) (6), (b) (7)(C). Summary of Record was reviewed by Oocyte Donor Coordinator and determined to be eligible by the Medical Director on 4/06/2022.

d. The Summary of Record for directed/known sperm donor C.(b) (6), (b) (7)(C) was missing the listing and interpretation of results for (b) (6), (b) (7)(C). Summary of Record was reviewed by Oocyte Donor Coordinator and determined to be eligible by the Medical Director on 7/17/2025.

OBSERVATION 4

Donor eligibility records are not accurate.

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Specifically,

a. The Summary of Record for anonymous oocyte donor (b) (6), (b) (7)(C) whose oocyte retrieval procedure was performed on (b) (6), (b) (7)(C), was documented eligible for date 12/19/2028 by the Medical Director.

b. The Health History Questionnaire for donor screening entitled "FDA Risk Assessment" for anonymous oocyte donor (b) (6), (b) (7)(C) shows a completion of 2/15/2022; however, the Summary of Records for this donor shows that the FDA Risk Assessment was completed on 12/15/2022.

OBSERVATION 5

Documentation of the date of the donor-eligibility determination was not maintained.

Specifically,

a) The date of final donor eligibility made by the Medical Director was not documented on the Summary of Record for directed/known oocyte donor (b) (6), (b) (7)(C).

b) The date of final donor eligibility made by the Medical Director was not documented on the Summary of Record for directed/known sperm donor (b) (6), (b) (7)(C).

***DATES OF INSPECTION**

4/07/2026(Tue), 4/08/2026(Wed), 4/14/2026(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Garrad R Poole, Investigator X Garrad R Poole Investigator Signed By: GARRAD R. POOLE - S Date Signed: 04-14-2026 08:40:53	4/14/2026

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."