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	5/1/2025-5/1/2025
	FEI NUMBER 3005106396

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Bonnie J. Day, Nurse Practioner

FIRM NAME	STREET ADDRESS
Advanced Fertility Associates Medical Group, Inc.	4690 Hoen Ave
CITY, STATE, ZIP CODE, COUNTRY Santa Rosa, CA 95405-7823	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 screening of HCT/P donors considered eligible indicated that the donor was not free of risk factors for infection due to communicable disease agents.

Specifically,

1. Directed semen donor (b) (6), (b) (7)(C) was determined eligible on 08/23/2024. The donor answered (b) (6), (b) (7)(C) to the question (b) (6), (b) (7)(C) Collection of the HCT/P occurred on (b) (6), (b) (7)(C).

2. Directed oocyte donor (b) (6), (b) (7)(C) was determined eligible on 03/20/2025. The donor answered (b) (6), (b) (7)(C) to the question (b) (6), (b) (7)(C) The donor commented, "Born (b) (6), (b) (7)(C) Collection of the HCT/P occurred on (b) (6), (b) (7)(C)

OBSERVATION 2

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 does not screen directed HCT/P donors for a history of the following:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Emily S Mcgann, Investigator X Emily S Mcgann Investigator Signed By: Emily S. Mcgann -S Date Signed: 05-01-2025 15:26:28	5/1/2025

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1. Positive or reactive West Nile Virus test using an FDA-licensed or investigational WNV NAT donor screening test in the preceding 120 days.

2. Persons who have been diagnosed with vCJD or any other form of CJD.

3. Persons who received any transfusion of blood or blood components in France between 1980 and the present.

4. Persons who have undergone tattooing, ear piercing, or body piercing in the last 12 months in which sterile procedures were not used.

You have screened (b)(4) directed donors since (b) (4)

OBSERVATION 3
You did not establish and maintain procedures for screening and determining the eligibility of HCT/P donors.

Specifically,
Your standard operating procedure for Donor Screening does not include directions for decisions on donor eligibility for situations that include but are not limited to:

1. Persons who have had a medical diagnosis with West Nile Virus (WNV) within last 120 days;

2. Persons who have had a positive WNV infection with an FDA-licensed test kit within last 120 days;

3. Persons who have injected drugs for a non-medical reason in last five years;

4. Persons who have engaged in sex in exchange for money or drugs within last five years;

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5. Men who have sex with another men in the last five years.

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."