DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	4/15/2025-4/24/2025* FEI NUMBER 3007268508

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Robert A. Kaufmann, Medical Director/Owner

FIRM NAME	STREET ADDRESS
Fort Worth Fertility P.A.	1800 Mistletoe Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fort Worth, TX 76104-4062	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,

Your screening document, "Risk Assessment Questionnaire" does not create a complete screening process to assess the donor's medical history and relevant social behaviors - including high risk behaviors. Since 4/20/2017, the donor Risk Assessment Questionnaire that has been in use by you is insufficient for the following:

- Your current screening questionnaire does not screen for persons who have had sex in the preceding 12 months with **any person who has HIV infection, including a positive or reactive test for HIV virus, hepatitis B infection, or clinically active (symptomatic) hepatitis C infection.**

You stated that, since 2022, you have screened a total of (b) (4) anonymous oocyte donors and (b) (4), (b) (6), (b) directed semen donors.

OBSERVATION 2

The eligibility of an HCT/P donor was not determined by a responsible person, based on results of donor screening and donor testing.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Michelle Paxon, Investigator X Michelle Paxon Investigator Signed By: 2003998263 Date Signed: 04-24-2025 14:23:09	4/24/2025

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Specifically,

For directed semen donors (b) (4), (b) (6), (b) (7 and (b) (4), (b) (6), (b) (7, you made a Donor Eligibility Determination (DED) prior to the Responsible Person's completion and review of the donors' physical examination, the Donor Risk Assessment Questionnaire (DRAE), and/or the Communicable Disease Testing (RCDAD) Results.

For Directed Semen Donor (b) (4), (b) (6), (b) (7)(C
You deemed the directed semen donor ineligible on (b) (6), (b) (7)(C), but documentation shows that you did not review the donor's Risk Assessment Questionnaire and deem them eligible to proceed until (b) (6), (b) (7)(C). Documentation shows that you did not review and complete the History and Physical for the Semen Donor until (b) (6), (b) (7)(C).

Donor (b) (4), (b) (6), (b) (7)(C) semen was collected and cryopreserved on (b) (6), (b) (7)(C). Reproductive HCT/Ps were created and cryopreserved using Donor (b) (4), (b) (6), (b) (7)(C) donated semen on (b) (6), (b) (7)(C). The resultant reproductive HCT/Ps were transferred to Gestational Carrier, (b) (6), (b) (7) on (b) (6), (b) (7)(C)

For Directed Semen Donor (b) (4), (b) (6), (b) (7)(C)
You deemed the donor ineligible on (b) (6), (b) (7)(C) but the donor's communicable disease results were made available to you on (b) (6), (b) (7)(C) You did not review the donor's Risk Assessment Questionnaire and the History and Physical until (b) (6), (b) (7)(C)

Donor (b) (4), (b) (6), (b) (7)(C) semen was collected and cryopreserved on (b) (6), (b) (7)(C) Reproductive HCT/Ps were created and cryopreserved using Donor (b) (4), (b) (6), (b) (7)(C) donated semen on (b) (6), (b) (7)(C). The resultant reproductive HCT/Ps made from Donor (b) (4), (b) (6), (b) (7)(C) semen was transferred into Gestational Carrier, (b) (6), (b) (7)(C on (b) (6), (b) (7)(C)

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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,

Your Summary of Records (SOR) does not contain results for (b) (4) . On your SOR, you only report the (b) (4)) (b) (4)).

You utilize " (b) (4) " to test for (b) (4). The test kit is intended and approved for the detection of (b) (4) .

You failed to report (b) (4), (b) (6), (b) (7) of (b) (4), (b) (6), (b) (7) directed semen donors records that tested reactive for (b) (4) between 2022 and 2025 on your SOR for semen donors. For (b) (4), (b) (6), (b) directed semen donors that tested reactive to (b) (4) , your SOR interpreted their " (b) (4) " result as "Negative."

Impacted donor SORs include the following: (b) (4), (b) (6), (b) (7)(C)

You stated that since 2022, you have screened a total of (b) (4), (b) (6), (b) (7 directed semen donors.

You stated that all donated semen is distributed to another, independent firm for storage and further distribution. You stated that all HCT/Ps, including donated, directed semen are distributed to an independent firm ((b) (4) for storage and further distribution.

For example, directed semen donor (b) (4), (b) (6), (b) (7)(C also tested reactive to (b) (4) Donor (b) (4), (b) (6), (b) (7)(C) SOR reports that the donor resulted as "Negative" for (b) (4) . (b) (4), (b) (6), (b) (7)(C) of semen from donor (b) (4), (b) (6), (b) (7)(were stored at the independent firm for storage and was further distributed to another clinic on 2/2/2024.

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In addition, there is no procedure for documenting, interpreting, and communicating test results for reactive (b) (4) test results.

Your current Standard Operating Procedures (SOP) for (b) (4) titled "SOP (b) (4) (b) (4)" only details how to interpret donor eligibility based on (b) (4) results. You do not have procedures on how to report a reactive (b) (4) test result.

OBSERVATION 4

HCT/Ps for which the donor eligibility determination was not required and applicable donor eligibility requirements were not met were not prominently labeled with the appropriate warning statements.

Specifically,

Labeling for subsequently donated reproductive HCT/Ps does not contain the following warning statements:

-"NOT EVALUATED FOR INFECTIOUS SUBSTANCES."
-"WARNING: Advise patient of communicable disease risks."

Recipient (b) (6), (b) (7) received one (1) subsequently donated reproductive tissue originally excepted at the time of recovery that was subsequently intended for directed donation from known donor, (b) (6), (b) (7)(You were unable to complete subsequent testing on donor (b) (6), (b) (and the embryo was transferred on (b) (6), (b) (7)(C) to recipient (b) (6), (b) (7)

You were unable to provide me a total number of subsequently donated reproductive HCT/Ps that were transferred since 2022.

OBSERVATION 5

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Donor eligibility records are not accurate, indelible and legible.

Specifically,

Your firm does not have an accurate account of all directed an anonymous reproductive donors utilized since 2022.

When I requested the total number of anonymous oocyte donors and directed semen donors since 2022, your (b) (4), (b) (6), (b) (7 Manager stated that since all donor records are on paper, the best way she could account for all donors was through your appointment software- where she had identified and counted the number of anonymous and directed reproductive donors from memory.

Your (b) (4), (b) (6), (b) (7 Manager stated that since 2022, the firm has screened a total of (b) (4) anonymous oocyte donors and (b) (4), (b) (6), (b) (7 directed semen donors.

During my inspection, I requested to review directed semen donor records from 2022 until 2025 and was provided (b) (4), (b) (6), (b) (7)(C) records for review.

In addition, several dates on donor records were difficult to read, and corrections do not always identify when and the person who made the corrections. Examples include the following:

-Anonymous oocyte donor (b) (4), (b) (6), (b) (7)(C) Risk Assessment Questionnaire Physician review date is illegible.

-The Donor Eligibility Determination date for directed semen donor (b) (4), (b) (6), (b) (7)(C and (b) (4), (b) (6), (b) (7 was also difficult to read.

-The Semen cryopreservation date on directed semen donor (b) (4), (b) (6), (b) (7)(C) Donor Eligibility Form was written over.

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*DATES OF INSPECTION

4/15/2025(Tue), 4/16/2025(Wed), 4/17/2025(Thu), 4/18/2025(Fri), 4/21/2025(Mon), 4/24/2025(Thu)

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Investigator
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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."