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	6/6/2025-6/13/2025* FEI NUMBER 3014721365

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Joua (NMI) Herr, Practice Manager

FIRM NAME	STREET ADDRESS
Conceive Fertility Center	7515 Greenville Ave Suite 1030
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dallas, TX 75231	Reproductive HCT/P

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

After the completion of the donor-eligibility determination, HCT/Ps were not accompanied with a statement whether the donor has been determined to be eligible or ineligible, based on the results of screening and testing.

Specifically, (b)(4) out of (b)(4) directed semen donor eligibility records reviewed from 2022 to 2025 were determined ineligible. The (b)(4) directed semen donor eligibility records did not contain a statement with the reason for ineligibility. In addition, the (b)(4) directed semen donor eligibility records were labeled as eligible.

OBSERVATION 2

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

Specifically, (b)(4) out of (b)(4) donor eligibility records reviewed from 2022 to 2025, the donor eligibility was performed by different nurse practitioners and physician assistants not by the Medical Director or a designated licensed physician. Your Standard Operating Procedure "Office Screening of Patients Donating Human Cells (Oocytes and Sperm)" (Section 5.6 point #2) states that the Medical Director or a designated licensed physician "Sign the Donor Eligibility Determination Form with Eligible or Ineligible status".

In addition, the following donors were determined to be eligible by nurse practitioners and physician assistants without the complete test results or medical screening:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Ramon L Gonzalez-Prieto, Investigator X Ramon L Gonzalez-Prieto Investigator Signed By: RAMON L GONZALEZ-PRIETO -S Date Signed: 06-13-2025 09:40:55	6/13/2025

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-The anonymous oocyte donor (b) (4), (b) (6), (b) (7)(C), was determined to be eligible on 01/04/2022 based on testing, medical screening and physical assessment. The complete testing results were received on 01/05/2022. Donor Eligibility was performed by (b) (6), (b) (7). , PA-C.

-The anonymous oocyte donor (b) (4), (b) (6), (b) (7)(C), Donor (b) (4), (b) (6), (b) (7)(C) was determined to be eligible on 09/28/2024 based on testing, medical screening and physical assessment. The complete testing results were received on 09/30/2024. Donor Eligibility was performed by (b) (6), (b) (7) (No title).

- The directed oocyte donor (b) (6), (b) (7) was determined to be eligible on 02/20/2025 based on testing, medical screening and physical assessment. The complete testing results were received on 02/22/2025. Donor Eligibility was performed by (b) (6), (b) (7) FNP-C.

-The directed semen donor (b) (6), (b) (7) was labeled to be eligible on 10/30/2024 based on testing, medical screening and physical assessment. The physical assessment section is blank. Donor Eligibility was performed by (b) (6), (b) (7)(C) FNP-C.

OBSERVATION 3

A standard operating procedure for the release of HCT/Ps from donors that test reactive for cytomegalovirus (CMV) was not established, defined, documented and implemented.

Specifically, Your Standard Operating Procedure "Office Screening of Patients Donating Human Cells (Oocytes and Sperm)" does not contain procedures describing donors whose specimens test reactive for cytomegalovirus (CMV) and how to interpret those CMV test results including whether the donor is

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eligible, or ineligible based on those results.

(b) (4) out of (b) (4) directed semen donor test results reviewed from 2022 to 2025 tested reactive for CMV Total Ab. A total of (b) (out of the (b) (4) directed semen donors with reactive results for CMV Total Ab were determined eligible from the year 2022 to 2025.

OBSERVATION 4

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

Specifically, Your Standard Operating Procedure "Office Screening of Patients Donating Human Cells (Oocytes and Sperm)" does not contain donor eligibility procedures describing requirements that must be met to determine a donor as eligible or ineligible.

In addition, You do not have documented written or electronic procedures describing a (b) (4) from procedures.

OBSERVATION 5

Information on of donors of HCT/Ps were not in English and not accompanied by a statement of authenticity by the translator that specifically identifies the translated document.

Specifically, the donor screening questionnaire for (b) (out of (b) (4) directed semen donor and (b) (out of (b) (4) directed oocyte donor records reviewed from the year 2022 to 2025 were not in (b) (4), translated to (b) (4), and not accompanied by a statement of authenticity by the (b) (4).

***DATES OF INSPECTION**

6/06/2025(Fri), 6/09/2025(Mon), 6/13/2025(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Ramon L Gonzalez-Prieto, Investigator	X Ramon L Gonzalez-Prieto Investigator Signed By: RAMON L GONZALEZ-PRIETO-S Date Signed: 06-13-2025 09:40:55	6/13/2025

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."