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	9/5/2025-9/10/2025* FEI NUMBER 3003926882

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kevin J. Doody, Director

FIRM NAME	STREET ADDRESS
Center for Assisted Reproduction (CARE Fertility)	1701 Park Place Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bedford, TX 76022-6033	Reproductive Human 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

The summary of records for HCT/Ps from donors determined to be ineligible based on screening and released for limited use did not contain a statement noting the reason(s) for the ineligibility.

Specifically, you fail to state the reason (s) of ineligibility for the following directed donors:

Donor initials or number	Eligibility determination	Donated Tissue	Reason for ineligibility
(b) (6), (b) (	Ineligible 1/31/20	Semen	Risk assessment (born or sexually intimate with someone from certain countries in Africa)
(b) (6), (b) (7	Ineligible 2/13/20	Oocyte	Risk assessment (born or sexually intimate with someone from certain countries in Africa)
(b) (6), (b) (7	Ineligible 11/16/22	Oocyte	Physical exam (body piercing – (b) (6), (b) (7)(C)); risk assessment (tattoo, body piercing – (b) (6), (b) (7)(C)
(b) (6), (b) (	Ineligible 12/5/24	Semen	Physical exam (history of sexually transmitted diseases); risk assessment (Men who have had sex with another man in the preceding 5 years)
(b) (6), (b) (7	Ineligible 12/16/24	Semen	Risk assessment (born or sexually intimate with someone from certain countries in Africa), positive HBV (core)

AMENDMENT 1

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EMPLOYEE(S) SIGNATURE
Elyshia Q Danaher, Investigator

X Elyshia Q Danaher
Investigator
Signed By: Elyshia Danaher -S
Date Signed: 09-10-2025
15:01:54

DATE ISSUED
9/10/2025

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Kevin J. Doody, Director	
FIRM NAME Center for Assisted Reproduction (CARE Fertility)	STREET ADDRESS 1701 Park Place Ave
CITY, STATE, ZIP CODE, COUNTRY Bedford, TX 76022-6033	TYPE ESTABLISHMENT INSPECTED Reproductive Human Tissue

Since 12/4/2019, you have determined donor eligibility and created summary of records for (b) (4) oocyte (directed and anonymous) donors and (b) (4) directed semen donors.

OBSERVATION 2

You did not establish and maintain procedures that address the accompanying records after the donor eligibility determination is complete of HCT/Ps.

Specifically, you fail to have procedures established that describe how to complete a summary of record and accompanying records.

- From 2/24/23 – 7/1/24, your summary of records were missing the statement that testing was performed by a Clinical Laboratory Improvement Amendments certified laboratory. I observed (b) (4) summary of records for directed semen and oocyte donors where the statement was missing.

- From 12/4/19 – 1/25/23, your summary of records were missing the results and interpretation of the Hepatitis B virus Nucleic Acid Test. I observed (b) (4) summary of records for semen and oocyte donors (anonymous and directed) where the results and interpretation of the HBV NAT testing were missing.

Since 12/4/2019, you have determined donor eligibility and created summary of records for (b) (4) oocyte (directed and anonymous) donors and (b) (4) directed semen donors. From (b) (4) to current, you did and do not have established or maintained a procedure for the summary of record and accompanying records.

OBSERVATION 3

HCT/Ps from ineligible donors which were made available for limited use were not prominently labeled with a statement warning of communicable disease risks.

Specifically, semen, oocytes, or combined reproductive tissue from directed ineligible donors did not include the label "WARNING: Advise patient of communicable disease risks."

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Elyshia Q Danaher, Investigator	X Elyshia Q Danaher Investigator Signed By: Elyshia Danaher -S Date Signed: 09-10-2025 15:01:54	9/10/2025

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Kevin J. Doody, Director

FIRM NAME	STREET ADDRESS
Center for Assisted Reproduction (CARE Fertility)	1701 Park Place Ave
CITY, STATE, ZIP CODE, COUNTRY Bedford, TX 76022-6033	TYPE ESTABLISHMENT INSPECTED Reproductive Human Tissue

I observed the following directed semen, oocytes and combined reproductive tissue lacked appropriate labeling:

Donor initials or number	Eligibility determination	Donated Tissue	Reason for ineligibility
(b) (6), (b) (	Ineligible 1/31/20	Semen	Risk assessment (born or sexually intimate with someone from certain countries in Africa)
(b) (6), (b) (7	Ineligible 2/13/20	Oocyte	Risk assessment (born or sexually intimate with someone from certain countries in Africa)
(b) (6), (b) (	Ineligible 12/5/24	Semen	Physical exam (history of sexually transmitted diseases); risk assessment (Men who have had sex with another man in the preceding 5 years)
(b) (6), (b) (7	Ineligible 12/16/24	Semen	Risk assessment (born or sexually intimate with someone from certain countries in Africa), positive HBV (core)
(b) (6), (b) (7	Ineligible 12/16/2024	Combined reproductive tissue	Positive HBV (core), positive HIV 1 and 2 antibody
(b) (6), (b)	Ineligible 7/16/2025	Oocyte	Positive HBV (surface and core)

Since 12/4/2019, you have determined donor eligibility for (b) (4) oocyte (directed and anonymous) donors and (b) (4) directed semen donors.

***DATES OF INSPECTION**
9/05/2025(Fri), 9/08/2025(Mon), 9/09/2025(Tue), 9/10/2025(Wed)

AMENDMENT 1

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	Elyshia Q Danaher, Investigator	X Elyshia Q Danaher Investigator Signed By: Elyshia Danaher -S Date Signed: 09-10-2025 15:01:54	9/10/2025

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."