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	3/10/2025-3/12/2025
	FEI NUMBER 3005405736

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
George Lin, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Lin, James P MD Inc. d.b.a. Reproductive Fertility Center	16300 Sand Canyon Ave Ste 901
CITY, STATE, ZIP CODE, COUNTRY Irvine, CA 92618-3709	TYPE ESTABLISHMENT INSPECTED 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

HCT/P donors were not determined to be eligible based on the results of donor screening and testing.

Specifically,

a) On [redacted], directed oocyte donor [redacted] tested [redacted] as documented on the laboratory test report dated [redacted]. This directed oocyte donor [redacted] was determined eligible and donated [redacted] oocytes on [redacted] that were cryopreserved, thawed on [redacted], fertilized, and [redacted] resulting tissues cryopreserved.

b) On [redacted], directed semen donor [redacted] did not answer question #1 on the Donor Risk Factor Questionnaire that screens for the risk factors associated with Creutzfeldt-Jacob disease. This directed semen donor [redacted] was determined ineligible on 01/08/2025. On [redacted], directed semen donor [redacted] donated semen that was used to fertilize [redacted] oocytes and [redacted] resulting tissues were cryopreserved.

c) Directed semen donor [redacted] tested [redacted] as documented on the laboratory report dated [redacted]. On 07/15/2024, directed oocyte donor [redacted] of directed semen donor [redacted] was determined eligible and donated [redacted] oocytes on [redacted] that were fertilized with [redacted] semen recovered from directed donor [redacted] on the same day and [redacted] resulting tissues cryopreserved.

d) Directed oocyte donor [redacted] tested [redacted] as documented on the laboratory report dated [redacted]. On 11/30/2022, directed semen donor [redacted] of directed oocyte donor [redacted] was determined eligible and donated semen on [redacted] that was used to fertilize [redacted] oocytes donated by directed oocyte donor [redacted] with [redacted] resulting tissues

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	Irina Gaberman, Investigator	X Irina Gaberman Investigator Signed By: 1300222798 Date Signed: 03-12-2025 09:59:21	3/12/2025

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cryopreserved.

e) Directed oocyte donor [redacted] tested [redacted] as documented on the laboratory report dated [redacted]. On 08/29/2023, directed semen donor [redacted] of directed oocyte donor [redacted] was determined eligible and donated semen on 08/22/2023 that was used to fertilize [redacted] oocytes donated by directed oocyte donor [redacted] with [redacted] resulting tissues cryopreserved.

f) Review of [redacted] anonymous and [redacted] directed oocyte donors from [redacted] found that they were not screened for the risk factors associated with HIV and Hepatitis B, such as having sex in the preceding 12 months with a men who had sex with another man in the preceding 5 years. Question #15 on the Donor Risk Factor Questionnaire that was used to screen oocyte donors during this time frame asks oocyte donors if they had sexual contact or participated in sexual activity with someone of the same sex.

OBSERVATION 2

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

Specifically,

a)Review of records for directed oocyte and semen donors from [redacted] found that HCT/Ps were not labeled with a statement advising recipient that screening and testing of the donor(s) [redacted]. For example,

Directed Donor,	Tissue Donation Date	Donor Eligibility, Date	Donor Testing Date	Donor Screening Date	Tissue Disposition
[redacted] (Oocytes)		09/28/2022	[redacted]		1 fertilized tissue transferred on

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					in storage
(Semen)		09/28/2022			fertilized tissue transferred on
					in storage
(oocytes)		01/13/2025	(b)(6) (b)(7)(C)		fertilized tissues cryopreserved
(semen)		01/13/2024			fertilized tissues cryopreserved

b)Review of reproductive tissues sent to facilities for 2023 and 2024 found that they were not always labeled with the labels indicating the risk factors for relevant communicable disease agents and diseases. For example, cryopreserved oocytes recovered from were sent to an facility on vials of semen recovered from were sent to an facility on .

OBSERVATION 3

Donors of viable, leukocyte-rich cells or tissue were not tested for evidence of infection due to cytomegalovirus (CMV).

Specifically,

a) Directed semen donor was not tested for CMV but was determined eligible on 10/07/2024 and donated vials of semen on that were cryopreserved.

b) Directed semen donor was not tested for CMV but was determined eligible on 12/17/2024 and

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donated semen on [redacted]. Semen was used to fertilize [redacted] oocytes with [redacted] resulting tissue cryopreserved.

OBSERVATION 4

HCT/Ps from ineligible donors which were made available for limited use were not prominently labeled with the Biohazard legend, a statement warning of communicable disease risks and a statement warning of the reactive test results.

Specifically,

a) Directed semen donor [redacted] tested [redacted] as documented on the laboratory report dated [redacted]. Oocytes recovered from directed oocyte donor [redacted] on [redacted] and fertilized with directed semen donor [redacted] fresh semen [redacted] were not labeled with a biohazard label, warning statement of [redacted] and communicable disease risks warning.

b) Directed oocyte donor [redacted] tested [redacted] as documented on the laboratory report dated [redacted]. Oocytes recovered from directed oocyte donor [redacted] on [redacted] and fertilized with thawed semen recovered from directed semen donor [redacted] on [redacted] were not labeled with warning of [redacted].

OBSERVATION 5

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 reasons(s) for the ineligibility.

Specifically,

Directed semen donor [redacted] tested [redacted], specimen submitted for testing on [redacted], and determined ineligible on 02/20/2025. However, there was no reason documented noting the reason for the ineligibility.

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OBSERVATION 6

Donor specimens used for testing of communicable disease agents were not collected at the appropriate time.

Specifically,

a) On [redacted], directed semen donor [redacted] donated [redacted] vials of semen that were cryopreserved. Directed semen donor [redacted] blood specimen for communicable disease testing was collected on [redacted], not within [redacted] days of semen donation. Directed semen donor [redacted] was determined ineligible on 11/11/2024.

b) On [redacted], directed semen donor [redacted] donated [redacted] vials of semen that was cryopreserved. However, his blood specimen was submitted for [redacted] testing on [redacted], more than [redacted] from his semen donation. Directed semen donor [redacted] was determined eligible on 07/27/2023.

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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."