DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	1/28/2025-2/5/2025* FEI NUMBER 3004744097

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Victoria D. Meagher, Donor Coordinator

FIRM NAME	STREET ADDRESS
InVia Fertility Specialists, PLLC	1585 Barrington Rd Ste 406
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hoffman Estates, IL 60169-5020	Fertility Center

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,

You failed to screen the following donors for risk factors for, and clinical evidence of, relevant communicable disease agents and diseases; and communicable disease risks associated with xenotransplantation. You did not perform a review of the donors' relevant medical records. For example:

1. Donor medical history interview and physical examination were not performed on the following donors:

Donor	Date of Tissue Recovery	Fertilized Oocytes Still in Inventory	Fertilized Oocytes Transferred
Directed Semen Donor (b) (4), (b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	(b) (4), (b) (6), (b) (7)(C)	
Directed Semen Donor			
Directed Semen Donor			

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EMPLOYEE(S) SIGNATURE
Zoey A Trombley, Investigator

X Zoey A Trombley Investigator Signed By: Zoey A. Trombley -S Date Signed: 02-05-2025 11:33:59

DATE ISSUED
2/5/2025

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Directed Semen Donor	(b) (4), (b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	(b) (4), (b) (6), (b) (7)(C)	
Directed Semen Donor				
Directed Semen Donor				
Directed Semen Donor				
Directed Semen Donor				
Anonymous Oocyte Donor (b) (4), (b) (6), (b) (7)(C) (Cycle ID: (b) (4), (b) (6), (b) (7)(C))				

2.Donor medical history interview was not performed on the following donor:

Donor	Date of Tissue Recovery	Fertilized Oocytes Still in Inventory	Fertilized Oocytes Transferred
Anonymous Oocyte Donor (b) (4), (b) (6), (b) (7)(C) (Cycle ID: (b) (4), (b) (6), (b) (7)(C))	(b) (6), (b) (7)(C)	(b) (4), (b) (6), (b) (7)(C)	

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OBSERVATION 2
Donors were not tested for evidence of infection with relevant communicable disease agents.

Specifically,

You failed to perform HIV/HCV/HBV nucleic acid testing for anonymous oocyte donor (b) (4), (b) (6), (b) (7)(C). On (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) oocytes were fertilized, and on (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) oocytes were fertilized. One fertilized oocyte was transferred to recipient (b) (4), (b) (6), (b) (7)(C) on (b) (6), (b) (7)(C) fertilized oocytes remain.

OBSERVATION 3
Documentation of the donor-eligibility determination, the responsible person who made the donor-eligibility determination and the date of the donor-eligibility determination was not maintained.

Specifically,

You failed to document and determine donor eligibility determination for the following anonymous oocyte donors, directed oocyte donors, and directed semen donors. For example:

1. Anonymous oocyte donors

Donor	Date of Tissue Recovery	Fertilized Oocytes Still in Inventory	Oocytes Tissue Transferred
(b) (4), (b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	(b) (4), (b) (6), (b) (7)(C)	

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2.Directed oocyte donors

Donor	Date of Tissue Recovery	Fertilized Oocytes Still in Inventory	Fertilized Oocytes Transferred
(b) (4), (b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	(b) (4), (b) (6), (b) (7)(C)	

3.Directed semen donors

Donor	Date of Tissue Recovery	Fertilized Tissue Still in Inventory	Fertilized Tissue Transferred
(b) (4), (b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	(b) (4), (b) (6), (b) (7)(C)	

Since 09/09/2022 to 01/30/2024 the firm has retrieved and utilized tissues from a total of (b) (4) anonymous oocyte donors, (b) (4) directed oocyte donors, and (b) (4) directed semen donors.

OBSERVATION 4

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

Specifically,

You failed to label the following ineligible directed semen donors with the Biohazard legend and

warning statement of reactive test results. For example:

Donor	Reactive Test Results	Fertilized Oocytes Still in Inventory	Fertilized Oocytes Transferred
(b) (4), (b) (6), (b) (7)(C)	-Chlamydia -Syphilis	(b) (4), (b) (6), (b) (7)(C)	
	-HTLV I/II -Syphilis		

OBSERVATION 5

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

Specifically,

You failed to establish and maintain procedures for testing, screening, and determining eligibility of all donor tissues. The following standard operating procedures (SOP) "SOP#1 Administrative Manual Egg Donor Application Screening" effective date 10/05/2015, and "SOP # 2 Egg Donor Initial Eligibility Determination Based on Communicable Disease Criteria" effective date 09/16/2005, fails to include physical assessment, determination of donor eligibility, documentation of donor eligibility determination by a responsible individual, and required screening tests for HIV/HCV/HBV NAT, WNV, and for semen donors CMV, and HTLV I/II.

This is a repeat violation.

OBSERVATION 6

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

Specifically,

You failed to collect a donor specimen 30 days before or seven days after recovery for directed oocyte donor (b) (4), (b) (6), (b) (7)(C). The donor tissue was recovered on (b) (6), (b) (7)(C) and the donor specimen for testing was collected (b) (6), (b) (7)(C), therefore the donor specimen was collected 31 days before recovery. (b) (6), (b) (7)(C) oocyte were fertilized and transferred to recipient (b) (4), (b) (6), (b) (7)(C) on (b) (6), (b) (7)(C). No fertilized oocytes remain in storage.

OBSERVATION 7
HCT/Ps from ineligible donors are not stored in a manner to prevent improper release.

Specifically,

You failed to quarantine the following ineligible directed semen donors who tested reactive for the following communicable diseases:

Donor	Reactive Test Results	Fertilized Oocytes Still in Inventory	Fertilized Oocytes Transferred
(b) (4), (b) (6), (b) (7)(C)	-Chlamydia -Syphilis	(b) (4), (b) (6), (b) (7)(C)	
	-HTLV I/II -Syphilis		

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OBSERVATION 8

The summary of records for HCT/Ps did not contain the name and address of the establishment that made the donor-eligibility determination.

Specifically,

Your summary of records fail to contain the name and address of the establishment that made donor eligibility. For example:

1.Anonymous oocyte donors

Donor	Date of Tissue Recovery	Fertilized Oocytes Still in Inventory	Fertilized Oocytes Transferred
(b) (4), (b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	(b) (4), (b) (6), (b) (7)(C)	

2.Directed oocyte donors

Donor	Date of Tissue Recovery	Fertilized Oocytes Still in Inventory	Fertilized Oocytes Transferred

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(b) (4), (b) (6), (b) (7)(C)		(b) (6), (b) (7)(C)		(b) (4), (b) (6), (b) (7)(C)	

3.Directed semen donors

Donor	Date of Tissue Recovery	Fertilized Oocytes Still in Inventory	Fertilized Oocytes Transferred
(b) (4), (b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	(b) (4), (b) (6), (b) (7)(C)	

I reviewed 37 of (b) (4) summary of records that fail to include the name and address of the establishment that made donor eligibility.

OBSERVATION 9

The summary of records for HCT/Ps did not contain a statement that the communicable disease testing was performed by a laboratory certified to perform such testing on human specimens under the Clinical Laboratory Improvement Act of 1988 or has met equivalent requirements determined by the Centers for Medicare and Medicaid Services.

Specifically,

Your summary of records fail to contain a statement that the communicable disease testing was performed by a laboratory certified to perform such testing on human specimens under the Clinical

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Laboratory Improvement Amendments of 1988. For example:

1.Anonymous oocyte donors

Donor	Date of Tissue Recovery	Fertilized Oocytes Still in Inventory	Fertilized Oocytes Transferred
(b) (4), (b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	(b) (4), (b) (6), (b) (7)(C)	

2. Directed oocyte donors

Donor	Date of Tissue Recovery	Fertilized Oocytes Still in Inventory	Fertilized Oocytes Transferred
(b) (4), (b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	(b) (4), (b) (6), (b) (7)(C)	

3.Directed semen donors

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
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Donor	Date of Tissue Recovery	Fertilized Oocytes Still in Inventory	Fertilized Oocytes Transferred
(b) (4), (b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	(b) (4), (b) (6), (b) (7)(C)	

I reviewed 37 of (b) (4) summary of records that fail to include a statement that the communicable disease testing was performed by a laboratory certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988.

***DATES OF INSPECTION**
1/28/2025(Tue), 1/29/2025(Wed), 1/30/2025(Thu), 1/31/2025(Fri), 2/03/2025(Mon), 2/04/2025(Tue), 2/05/2025(Wed)

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X Zoey A Trombley
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."