DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	5/6/2026-5/8/2026
	FEI NUMBER 3003929738

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mark P. Leondires, M.D. , Medical Director

FIRM NAME	STREET ADDRESS
Illume Fertility	761 Main Ave Ste 200
CITY, STATE, ZIP CODE, COUNTRY Norwalk, CT 06851-1080	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 WE OBSERVED:

OBSERVATION 1

The accompanying records for HCT/Ps included the donor's name.

Specifically,
Review of (b)(4) anonymous oocyte cycle records from (b)(4) found that "Donor Eligibility Determination and Summary of Records - Oocyte Donor" forms contain the names of anonymous oocyte donors. These anonymous oocyte donors were screened, tested, their donor eligibility determined. Oocytes were donated, fertilized and transferred to the recipients and/or cryopreserved.

OBSERVATION 2

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

Specifically,
a) The following fertilized oocyte tissues donated to your firm were not labeled with the warning labels advising recipient that screening and testing of the donors were not performed at the time of cryopreservation but have been performed subsequently:
- fertilized oocytes from (b)(6) (b)(7)(C) (cryopreservation date (b)(6) (b)(7)(C)) that are available for transplantation.
- fertilized oocytes from eligible oocyte donor and male donor (b)(6) (b)(7)(C) who did not initially require donor eligibility determination (cryopreservation date (b)(6) (b)(7)(C)) that were transferred to recipient (b)(6) (b)(7)(C) on (b)(6) (b)(7)(C).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Irina Gaberman, Investigator Chanel E Crawford, Investigator	X Irina Gaberman Investigator Signed By: 1300222798 Date Signed: 05-08-2026 08:27:15	5/8/2026

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b) On (b)(6) (b)(7)(C), one fertilized tissue from (b)(6) (b)(7)(C) with MRN (b)(6) (b)(7)(C) and MRN (b)(6) (b)(7)(C) was transferred to (b)(6) (b)(7)(C). However, this reproductive human tissue was not labeled with applicable labels: identifying tissues for autologous use only; not evaluated for infectious substances.

c) On (b)(6) (b)(7)(C) semen vials from ineligible semen donor (b)(6) (b)(7)(C) were transferred to (b)(6) (b)(7)(C) (b)(6) (b)(7)(C). However, accompanied records did not have adequate labeling, such as: Warning: Advise recipient of communicable disease risks, and did not have a biohazard legend.

d) On (b)(6) (b)(7)(C) oocytes from autologous oocyte donor (b)(6) (b)(7)(C) (cryopreservation date (b)(6) (b)(7)(C)) and (b)(6) (b)(7)(C) oocytes from autologous oocyte donor (b)(6) (b)(7)(C) (cryopreservation date (b)(6) (b)(7)(C)) were transferred to (b)(6) (b)(7)(C) However, these tissues were not labeled with applicable labels, such as for autologous use only, Not Evaluated for Infectious Substances.

e) Fertilized oocytes form eligible oocyte donor and ineligible directed semen donor (b)(6) (b)(7)(C) was transplanted to (b)(6) (b)(7)(C) on (b)(6) (b)(7)(C). Semen tissues and fertilized tissues were not labeled with the following label reflecting screening and testing status of ineligible directed semen donor: Warning: Reactive test result for (b)(6) (b)(7)(C) and there was no biohazard legend.

In addition, your standard operating procedure SOP.LAB.GEN.500 entitled "FDA 21 CFR 1271 Labeling and Storage Regulations" is not detailed enough to include all required labeling such as: "For Autologous use only", "Advise recipient that screening and testing of the donors were not performed at the time of cryopreservation but have been performed subsequently" and does not advise to include a Biohazard legend if the results of any screening or testing performed indicate the presence of relevant communicable disease agents and/or risk factors for or clinical evidence of relevant communicable disease agents and diseases.

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Norwalk, CT 06851-1080	Reproductive Human Tissue

X Chanel E Crawford
Investigator
Signed By: CHANEL E. CRAWFORD -S
Date Signed: 05-08-2026 08:27:57

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EMPLOYEE(S) SIGNATURE
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Investigator
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FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE **INSPECTIONAL OBSERVATIONS** PAGE 3 of 3 PAGES

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."