DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	9/8/2025-9/9/2025
	FEI NUMBER 3010149285

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Tracy L. Loveless, Lab Manager

FIRM NAME	STREET ADDRESS
Boston IVF Fertility Services at The Women's Hospital, LLC	4199 Gateway Blvd Ste 2600
CITY, STATE, ZIP CODE, COUNTRY Newburgh, IN 47630-8970	TYPE ESTABLISHMENT INSPECTED HCT/P Reproductive Firm

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 of communicable disease agents and diseases.

Specifically,

From June 2022 to January 2025, your firm failed to adequately screen(b) (4) directed donors of semen and oocytes based on your donor medical history interview titled, F-DNE-253"FDA Screening Questionnaire for Risk Factors and Conditions" revision 6 effective 6/20/2022 through revision 9 effective 1/29/25. Your questionnaire failed to screen risk factors for Creutzfeldt-Jakob Disease (CJD), a relevant communicable disease agents or diseases (RCDAD).

The initial question, Question #24, asks "(b) (4) (b) (4) (b) (4) (b) (4) (b) (4) but does not include time spent in the (b) (4) and if answered no by the donor, the questionnaire instructs the donor to skip questions #24a, b, and c, which are:

- Question #24a. "(b) (4) (b) (4) (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Lesley Mae P Lutao, Investigator	DATE ISSUED 9/9/2025

X Lesley Mae P Lutao
Investigator
Signed By: Lesley Mae P. Lutao - S
Date Signed: 09-09-2025 13:39:24

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- Question #24b. "(b) (4) (b) (4) ?"
- Question #24c. "(b) (4) (b) (4) ?

(b) (4) of (b) (4) directed donor records reviewed answered "No" to Question #24, and did not answer Questions #23a, b and c. Since 2022, (b) (4) fertilized oocytes have been transferred into recipients from directed donors with incomplete screening. (b) (4) fertilized oocyte remains in storage.

OBSERVATION 2
You did not establish and maintain procedures for screening of HCT/P donors.

Specifically,

Your procedure titled P-AE-2025 "PROCEDURE FDA regulations" revision 8 effective 1/10/2024, does not address all steps in performing donor screening. For example:

1. The procedure does not address what RCDADs must be screened during review of a donor's relevant medical records. For example, see **OBSERVATION 1** for deficient screening questionnaires.

2. The procedure does not address what clinical evidence to look for when screening a donor for RCDADs.

3. The procedure does not address making inquiries into records and other information when the circumstances indicate that follow-up information might be relevant for screening a potential cell or tissue donor.

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Newburgh, IN 47630-8970	HCT/P Reproductive Firm

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Lesley Mae P Lutao, Investigator

X Lesley Mae P Lutao
Investigator
Signed By: Lesley Mae P. Lutao - S
Date Signed: 09-09-2025 13:39:24

DATE ISSUED

9/9/2025

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."