DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707	12/5/2024-12/6/2024
	FEI NUMBER 3004731585

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Susan Sarajari, Medical Director

FIRM NAME	STREET ADDRESS
Dominion Fertility & Endocrinology	4040 Fairfax Dr Ste 600
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Arlington, VA 22203-1765	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

You did not establish and maintain procedures for testing of HCT/P donors.

Specifically,

During the current inspection, I observed that the SOPs identified below were not maintained **[REPEAT]**. These SOPs were also cited on the FDA 483, "Inspectional Observations," during the previous inspection dated 1/18-24/2023. The corrected versions of these SOPs from the previous inspection were not maintained in the firm's active SOP binders.

The following versions of the SOPs were maintained as active in the firm's SOP binders:

A. SOP #2, "Egg Donor Initial Eligibility Determination Based On Communicable Disease Criteria," Revision Date: September 3, 2019, did not include HBV NAT testing among the list of relevant communicable disease agent and diseases (RCDADs) donor screening tests.

B. SOP #17, "Known Egg Donor Initial Eligibility Determination Based on Communicable Disease Criteria," Revision Date: September 3, 2019, did not include HIV-1/HBV/HCV NAT testing among the list of RCDADs donor screening tests.

C. SOP #32, "Known Sperm Donor Initial Eligibility Determination Based on Communicable Disease Criteria," Revision Date: September 17, 2019, did not include HIV-1/HBV/HCV NAT testing among the list of RCDADs donor screening tests.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	La-Tasha M Gunter, Investigator	X La-Tasha M Gunter Investigator Signed By: La'tasha Gunter -S Date Signed: 12-06-2024 11:27:35	12/6/2024

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D. SOP #47, "Genetic Parents Using A Gestational Carrier for Directed Donation Initial Eligibility Determination Based on Communicable Disease Criteria," Revision Date: September 17, 2019, did not include HIV-1/HBV/HCV NAT testing among the list of RCDADs donor screening tests.

E. SOP #64.1, "Genetic Parents Donating Embryos Eligibility Determination Based on Communicable Disease Criteria at Time of Embryo Creation," Revision Date: September 17, 2019, did not include HIV-1/HBV/HCV NAT testing among the list of RCDADs donor screening tests.

F. SOP #65, "Genetic Parents Donating Embryos Eligibility Determination Based on Communicable Disease Criteria after Cryopreservation," Revision Date: September 17, 2019, did not include HIV-1/HBV/HCV NAT testing among the list of RCDADs donor screening tests.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	La-Tasha M Gunter, Investigator	X La-Tasha M Gunter Investigator Signed By: La'tasha Gunter -S Date Signed: 12-06-2024 11:27:35	12/6/2024

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."