

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 1201 Main Street, Suite 7200 Dallas, TX 75202 (214) 253-5200 Fax: (214) 253-5314		DATE(S) OF INSPECTION 3/27/2025-3/28/2025 FEI NUMBER 3023212478	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Natalia Schlabritz-Lutsevich, Chief Scientist & Practice Director			
FIRM NAME Elite IVF & Fertility Solutions LLC		STREET ADDRESS 420 E 6th St Ste 101	
CITY, STATE, ZIP CODE, COUNTRY Odessa, TX 79761-4537		TYPE ESTABLISHMENT INSPECTED Reproductive	
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 The summary of records for HCT/Ps did not contain the address of the establishment that made the donor-eligibility determination. Specifically, Your Summary of Records (SOR) for anonymous oocyte donor does not contain the complete address of your establishment where you made the donor eligibility determination. The SOR is missing the city, state, and zip code of the firm. The firm only utilizes this version of the SOR form, currently. Oocyte retrieval from donor was completed on and oocytes were recovered. Failing to include the firm's complete address on the SOR was a discussion item on the last inspection.			
OBSERVATION 2 Donor eligibility records are not accurate and legible. Specifically, Your donor eligibility records for anonymous oocyte donor is incomplete and missing information/signatures. Certain dates and notes throughout the donor's records are also not legible or difficult to read.			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Michelle Paxon, Investigator Michelle Paxon Investigator Signed By: 2003998263 Date Signed: 03-28-2025 14:04:42 _____ X	
		DATE ISSUED 3/28/2025	

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FIRM NAME

STREET ADDRESS

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TYPE ESTABLISHMENT INSPECTED

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EMPLOYEE(S) SIGNATURE

Michelle Paxon
Investigator
Signed By: 2003996263
Date Signed: 03-28-2025
14:04:42

X

DATE ISSUED

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."