DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	3/31/2026-4/1/2026 FEI NUMBER 3008545334

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michelle L. Hinds, Office Manager

FIRM NAME	STREET ADDRESS
Repromed Fertility Center	3800 San Jacinto St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dallas, TX 75204-5225	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 WE OBSERVED:

OBSERVATION 1

HCT/P donors were not determined to be eligible based on the results of donor screening and testing.

Specifically,

You determined five (5) anonymous and directed oocyte donors as eligible to donate based on an incomplete donor screening questionnaire and/or prior to the collection of testing samples and receipt of all required donor testing results.

_You determined the following oocyte donors as "eligible" prior to collection and review of test results:

Donor Type	Donor ID/Initials	Donor Eligibility Determination (DED) Date	RCDAD Testing Sample Collection Date	Test Result Report Date	Transfer Date
Directed Oocyte		02/19/2024		06/07/2024	
Anonymous Oocyte		01/09/2026		01/30/2026	
Directed Oocyte		05/08/2025		05/23/2025	
Directed Oocyte		10/09/2024		03/11/2025	
Directed		6/28/2023		11/07/2023	

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Michelle Paxon, Investigator
Abby L Mozeke, Investigator

X Michelle Paxon Investigator Signed By: 2003998263 Date Signed: 04-01-2026 08:57:38

DATE ISSUED
4/1/2026

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Oocyte					

For Directed Donor [redacted], questions #10 and #11 of your Donor Medical History Interview were left blank. An incomplete Donor Risk Assessment Interview (DRAI) screening was performed on [redacted] on Directed Donor [redacted] and then used to determine eligibility on [redacted]. Oocytes collected from Directed Donor [redacted] were utilized, and the resulting tissue was transferred on [redacted].

From 2020 to 2026, [redacted] anonymous and directed oocyte donors were determined as eligible to donate prior to your review of testing and screening results.

OBSERVATION 2

The accompanying records for HCT/Ps included the donor's name and personal information that might identify the donor.

Specifically,

You failed to remove the anonymous oocyte donor's full name and Date of Birth (DOB) from the accompanying records prior to submission of the records to a third-party embryology/storage facility.

Your Donor Medical History Interview Form, Donor Physical Assessment Form, and Donor Testing Form for the following anonymous oocyte donors contain the donor's full name and DOB:

	Donor ID	Donor Initials
	(b)(6) (b)(7)(C)	

Your Office Manager confirmed that these records were submitted to a third-party embryology/storage facility.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Michelle Paxon, Investigator Abby L Mozeke, Investigator	X Michelle Paxon Investigator Signed By: 2003998263 Date Signed: 04-01-2026 08:57:38	4/1/2026

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You failed to remove the donor's full name and DOB from accompanying records for a total of (b)(4) anonymous oocyte donors who you screened, tested, and made a Donor Eligibility Determination (DED) for between the years 2020 and 2026.

X Abby L Mozeke
Investigator
Signed By: 2001648021
Date Signed: 04-01-2026 08:58:21

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Michelle Paxon, Investigator Abby L Mozeke, Investigator	X Michelle Paxon Investigator Signed By: 2003998263 Date Signed: 04-01-2026 08:57:38	4/1/2026

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."