DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	4/20/2026-4/22/2026
	FEI NUMBER 3030378634

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Sherman J. Silber, Medical Director/Owner

FIRM NAME	STREET ADDRESS
New Infertility Center of St Louis	224 S Woods Mill Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Chesterfield, MO 63017-3513	HCT/P Reproductive Establishment

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,

1. You have not performed a physical examination to assess high-risk behavior for or infection with a relevant communicable disease agents and diseases (RCDAD). This incomplete physical examination affects at least (b) (4) anonymous oocyte and (b)(directed oocyte donors from January 2024 through January 2026.

2. Your donor medical history questionnaire titled, "REPRODUCTIVE DONOR MEDICAL HISTORY QUESTIONNAIRE" dated 4/2022, used to perform donor screening, does not elicit all required risk factors of communicable disease agents and diseases. For example:
   a. Question #20 asks "In the past 12 months have you: had sexual contact with a person who has clinically active Hepatitis B or C?" rather than asking if they've had sexual contact with a person who has Hepatitis B infection, or clinically active (symptomatic) hepatitis C infection.

   b. Question #22 asks "In the past 12 months have you: Lived with a person who has clinically active Hepatitis?" rather than asking if they've lived with another person who has hepatitis B or clinically active (symptomatic) hepatitis infection.

   c. Question #34 asks "From 1980 through 1996: Did you spend time that adds up to three (3)

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	Lesley Mae P Lutao, Investigator	X Lesley Mae P Lutao Investigator Signed By: Lesley Mae P. Lutao - S Date Signed: 04-22-2026 10:22:48	4/22/2026

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months or more in the United Kingdom? (England, Ireland, Scotland, Wales, the Isle of Man, The Channel Islands, Gibralter or the Falkand Islands)" which does not include Northern Ireland in the United Kingdom.

This incomplete screening affects at least [(b)(4)] anonymous oocyte and [(b)] directed oocyte donors from (b) (4) through (b) (4)

3. Anonymous oocyte donor [(b) (6), (b) (7)(C)] did not answer the question "Have you are any of your sexual partners ever had one of the following?...[(b) (6), (b) (7)(C)]?" in your "DONOR HISTORY FORM" dated 4/2022 during screening. This anonymous oocyte donor was determined eligible on 07/11/2024, and oocytes were retrieved on [(b) (6), (b) (7)(C)]. [(b) (6), (b) (7)(C)] fertilized tissue was transferred to recipient [(b) (6), (b)]. on [(b) (6), (b) (7)(C)]

OBSERVATION 2

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

Specifically,

You determined the following donors eligible when screening was incomplete:

1. (b) (4) anonymous and directed oocyte donor records reviewed were determined eligible using your deficient donor medical history questionnaire titled, "REPRODUCTIVE DONOR MEDICAL HISTORY QUESTIONNAIRE" dated 4/2022, to perform complete donor screening (see **OBSERVATION 1**).

2. (b) (4) anonymous and directed oocyte donor records reviewed were determined eligible when no physical examination was performed to assess high-risk behavior for or infection with relevant communicable disease agents and diseases (RCDADs) (see **OBSERVATION 1**).

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For example:

a. Anonymous oocyte donor (b) (6), (b) (7)(C) did not have a donor medical history questionnaire in the past 6 months or physical examination for RCDADs performed. This donor was determined eligible on 6/10/2025. Oocytes were retrieved on (b) (6), (b) (7)(C) and (b) (6), (b) (6), (b) fertilized tissue was transferred to recipient (b) (6), (b). on (b) (6), (b) (7)(C).

b. Directed oocyte donor (b) (6), (b) (7)(C) was screened using the deficient questionnaire on (b) (6), (b) (7)(C) no physical examination for RCDADs were performed, and determined eligible on 11/13/2024, prior to the questionnaire being completed. Oocytes were retrieved on (b) (6), (b) (7)(C)

c. Anonymous oocyte donor (b) (6), (b) (7)(C) was screened using the deficient questionnaire on (b) (6), (b) (7)(C), no physical examination for RCDADs were performed, and determined eligible on 02/03/2025. Oocytes were retrieved on (b) (6), (b) (7)(C). (b) (6), (b) (7)(C) fertilized tissue was transferred to recipient (b) (6), (b) (on (b) (6), (b) (7)(C). This donor has (b) (6), (b) (7)(C) oocytes and (b) (6), (b) (7)(C) fertilized tissues currently in storage.

d. Directed oocyte donor (b) (6), (b) (7)(C) was screened using the deficient questionnaire on (b) (6), (b) (7)(C) no physical examination for RCDADs were performed, and determined eligible 11/11/2025. Oocytes were retrieved on (b) (6), (b) (7)(C). (b) (6), (b) (7)(C) fertilized tissue was transferred to recipient (b) (6), (b) (on (b) (6), (b) (7)(C) and on (b) (6), (b) (7)(C).

OBSERVATION 3
Procedures were not designed to ensure compliance with the donor eligibility requirements.

Specifically,

Your standard operating procedure, HCT/Ps Procedure Manual v.2.00, titled "Human Cells, Tissues, and Cellular and Tissue Based Products (HCT/Ps)" were not designed to ensure compliance with the donor

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eligibility requirements:

1. The procedure does not detail what signs or physical evidence to look for that would indicate high-risk behavior for or infection with a relevant communicable disease.

2. The procedure does not provide instructions for follow-up questions when a donor answers "(b) (6), (b)" to a screening question. For example, anonymous oocyte donor (b) (6), (b) (7)(C) answered "(b) (6), (b)" to having (b) (6), (b) (7)(C) and in current treatment via (b) (6), (b) (7)(C), in the "DONOR MEDICAL HISTORY." Additionally, the donor answered "(b) (6), (b)" to Question #19 which asks, "In the past 12 months have you: Had or been treated for (b) (6), (b) (7)(C) or other sexually transmitted infections?" in "REPRODUCTIVE DONOR MEDICAL HISTORY QUESITONNAIRE." No follow-up was performed, and the donor was determined eligible on 04/17/2024. Oocytes were retrieved on (b) (6), (b) (7)(C), and (b) (6), (b) (7)(C) fertilized tissues are currently in storage.

3. Under "Donor Screening" of anonymous and directed donors, the firm does not include:
   a. France is not included when asking about receiving any transfusion of blood or blood components between 1980 and the present for CJD or vCJD infection.

   b. Chlamydia is not included when assessing donors who have been treated for or had *Chlamydia trachomatis* infection in the preceding 12 months.

4. Under "Donor Testing" of anonymous and directed donors, the firm does not include Nucleic Acid Testing (NAT) of West Nile Virus (WNV) of HCT/Ps recovered from June 1st through October 31st every year.

This procedure was reviewed and approved on 01/21/2026.

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	Lesley Mae P Lutao, Investigator X Lesley Mae P Lutao Investigator Signed By: Lesley Mae P. Lutao - S Date Signed: 04-22-2026 10:22:48	4/22/2026

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."