DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	10/10/2024-10/25/2024* FEI NUMBER 3027287618

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sonali S. Joshi, Manager, Laboratory

FIRM NAME	STREET ADDRESS
Rejuvenating Fertility Center PLLC	225 Main St Ste 101
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Westport, CT 06880-3216	Human Reproductive Tissue

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DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

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

Specifically,

Your Standard Operating Procedure does not include specific screening criteria including but not limited to diseases or conditions:

a. Persons who have had sex in the preceding 12 months with any person who has HIV infection, including a positive or reactive test for HIV virus, hepatitis B infection or clinically active symptoms of hepatitis C infection.

b. Persons who have been exposed in the preceding 12 months to known or suspected HIV, HBV, and/or HCV infected blood through percutaneous inoculation needle stick or through contact with an open wound, non-intact skin, or mucous membrane.

c. Persons who are current or former US military members, civilian military employees, or dependents of a military member or civilian employee who resided at US military bases in Northern Europe (Germany, Belgium, and the Netherlands) for 6 months or more cumulatively from 1980 through 1990, or elsewhere in Europe (Greece, Turkey, Spain, Portugal, and Italy) for 6 months or more cumulatively from 1980 through 1996.

d. From the beginning of 1980 through the end of 1996 did you spend time that adds up to 3 months or more in the UK?(includes England, Ireland, Scotland, Wales, the Isle of Man, the Channel

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	Anthony N Onianwa, Investigator	X Anthony N Onianwa Investigator Signed By: Anthony N. Onianwa -S Date Signed: 10-25-2024 10:31:23	10/25/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	10/10/2024-10/25/2024* FEI NUMBER 3027287618

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Sonali S. Joshi, Manager, Laboratory	
FIRM NAME Rejuvenating Fertility Center PLLC	STREET ADDRESS 225 Main St Ste 101
CITY, STATE, ZIP CODE, COUNTRY Westport, CT 06880-3216	TYPE ESTABLISHMENT INSPECTED Human Reproductive Tissue

Islands, Gibraltar and the Falkland Islands).

e. Since 1980 have you spent time that adds up to 5 years or more in Europe, including time spent in the UK between 1980 and 1996(Includes Albania, Austria, Belgium, Bosnia Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Liechtenstein, Luxembourg, Macedonia, Netherlands, Norway, Poland, Portugal, Romania, Slovak Republic, Yugoslavia, Spain, Sweden, Switzerland)

OBSERVATION 2

Donor specimens used for testing of communicable disease agents were not collected at the appropriate time.

Specifically,

1. A directed egg donor# (b)(4) (b)(6) (b)(7)(C) specimen was collected for communicable disease testing on (b)(6) (b)(7)(C). The donor egg was retrieved on (b)(6) (b)(7)(C). However, the donor specimen was collected outside the appropriate time required. The tissue was transferred on (b)(6) (b)(7)(C).
2. A directed sperm donor# (b)(4) (b)(6) (b)(7)(C) tissue was retrieved on (b)(6) (b)(7)(C). The donor specimen was collected for communicable disease testing on (b)(6) (b)(7)(C). However, the donor specimen was not collected at the appropriate time. The donor tissue was transferred on (b)(6) (b)(7)(C).

OBSERVATION 3

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

Specifically,

Your firm determined eligibility of donor # (b)(4) (b)(6) (b)(7)(C) on (b)(6) (b)(7)(C) and donor # (b)(4) (b)(6) (b)(7)(C) on (b)(6) (b)(7)(C) respectively. The testing for donors # (b)(4) (b)(6) (b)(7)(C) and # (b)(4) (b)(6) (b)(7)(C) were performed on (b)(6) (b)(7)(C) and (b)(6) (b)(7)(C).

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Westport, CT 06880-3216	Human Reproductive Tissue

However, donor eligibility determination should not have been made because the testings were performed outside the required timeframes. Tissue transferred on (b)(6) (b)(7)(C)

***DATES OF INSPECTION**
10/10/2024(Thu), 10/15/2024(Tue), 10/16/2024(Wed), 10/18/2024(Fri), 10/21/2024(Mon), 10/25/2024(Fri)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	11/1/2024-11/19/2024* FEI NUMBER 3000974212

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Awilda D. Grillo, Tissue Bank Director

FIRM NAME	STREET ADDRESS
Repro Lab, Inc.	332 E 30th St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
New York, NY 10016-8327	Reproductive Tissue Establishment

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DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

The abbreviated donor screening procedure did not determine and document changes in the donor's medical history that would make the donor ineligible.

Specifically, your firm did not utilize an abbreviated donor screening procedure on repeat anonymous semen donor (b)(4) (b)(6) (b)(7)(C) to determine and document any changes in the donor's medical history since the previous donation that would make the donor ineligible, including relevant social behavior.

Donor records for your repeat anonymous semen donor (b)(4) (b)(6) (b)(7)(C) does not include documentation of an abbreviated screening prior to each repeat donation.

- Anonymous semen donor (b)(4) (b)(6) (b)(7)(C) completed the Donor Medical History Screening Questionnaire version 3.6.23 on (b)(6) (b)(7)(C) and the physical examination was performed on (b)(6) (b)(7)(C). This donor was determined eligible on (b)(6) (b)(7)(C) by the Medical Director. A total of [redacted] donations collected from (b)(6) (b)(7)(C) through (b)(6) (b)(7)(C) were released from quarantine on (b)(6) (b)(7)(C)
- A total of [redacted] repeat semen donations (donations (b)(6) (b)(7)(C)) collected from (b)(6) (b)(7)(C) through (b)(6) (b)(7)(C) were released from quarantine on (b)(6) (b)(7)(C) without an abbreviated screening procedure performed on each repeat semen donation for this anonymous donor.

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Amy Kim, Investigator X Amy Kim Investigator Signed By: 2000481080 Date Signed: 11-19-2024 10:45:37	11/19/2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	11/1/2024-11/19/2024* FEI NUMBER 3000974212

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Awilda D. Grillo, Tissue Bank Director	
FIRM NAME Repro Lab, Inc.	STREET ADDRESS 332 E 30th St
CITY, STATE, ZIP CODE, COUNTRY New York, NY 10016-8327	TYPE ESTABLISHMENT INSPECTED Reproductive Tissue Establishment

A standard operating procedure for the release of HCT/Ps from donors that test reactive for cytomegalovirus (CMV) was not established.

Specifically, your firm does not have a written standard operating procedure for the release of HCT/Ps from semen donors that test reactive for CMV.

***DATES OF INSPECTION**
11/01/2024(Fri), 11/04/2024(Mon), 11/05/2024(Tue), 11/07/2024(Thu), 11/12/2024(Tue), 11/19/2024(Tue)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900	11/6/2024-11/19/2024* FEI NUMBER 2270838

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Trish O'Keefe, PhD, RN, President

FIRM NAME	STREET ADDRESS
Morristown Medical Center Blood Bank	100 Madison Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Morristown, NJ 07960-6136	Hospital Blood Bank

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DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Written standard operating procedures including all steps to be followed in the processing of blood and blood components for allogeneic transfusion, autologous transfusion and further manufacturing purposes were not always established and followed.

Specifically, SOP (b)(4) (b)(4) was not always followed by blood bank staff in that it states:

(b)(4)

From (b)(4) the task to indicate (b)(4) was not always documented to demonstrate the completion of (b)(4) for each blood unit. Failure to document these tasks occurred on multiple occasions during this timeframe. This log has been utilized to document all activities related to the (b)(4) since (b)(4)

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	Amy W Yan-Mai, Investigator X Amy W Yan-Mai Investigator Signed By: 1300188340 Date Signed: 11-19-2024 09:43:53	11/19/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900	11/6/2024-11/19/2024* FEI NUMBER 2270838

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Trish O'Keefe, PhD, RN, President	
FIRM NAME Morristown Medical Center Blood Bank	STREET ADDRESS 100 Madison Ave
CITY, STATE, ZIP CODE, COUNTRY Morristown, NJ 07960-6136	TYPE ESTABLISHMENT INSPECTED Hospital Blood Bank

Techs did not always document their initials to demonstrate that the work was actually performed as stated in the above written procedure.

In addition, the blood bank did not establish specific written procedures describing all steps necessary; in an event when the blood bank deviates from their normal (b)(4)

Approximately (b)(4) Red Blood Cells (RBCs) and (b)(4) platelet products were (b)(4) during this time frame.

OBSERVATION 2

Records fail to identify the person performing the work, include dates of the various entries and be as detailed as necessary so as to provide a complete history of the work performed.

Specifically, from (b)(4) significant information listed below was not always documented on the (b)(4) so that all steps can be clearly traced:

a) Supervisory Review & Date
b) Tech Initials
c) (b)(4) Date/Year
d) (b)(4) (Y/N)
e) # of Faults

***DATES OF INSPECTION**

11/06/2024(Wed), 11/07/2024(Thu), 11/19/2024(Tue)

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FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	10/15/2024-11/6/2024* FEI NUMBER 3027446107

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mingxue Yang, Medical Director

FIRM NAME	STREET ADDRESS
ALLcare Fertility Center	369 Lexington Ave Fl 6
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
New York, NY 10017-6540	Reproductive Human Tissue

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DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

The eligibility of an HCT/P donor was not determined and documented by a responsible person, based on results of donor screening and donor testing.

Specifically,
a) On (b)(6) (b)(7)(C), directed semen donor (b)(4) (b)(6) (b)(7)(C) freshly recovered semen was used to fertilize oocytes recovered from anonymous oocyte donor (b)(4) (b)(6) (b)(7)(C) and three fertilized oocytes were cryopreserved. On (b)(6) (b)(7)(C), one fertilized tissue was transferred to recipient (b)(4) (b)(6) (b)(7)(C) who is not related to directed donor (b)(4) (b)(6) (b)(7)(C) and his sexually intimate partner. There was no testing, screening and eligibility determination performed for directed semen donor (b)(4) (b)(6) (b)(7)(C)
b) On (b)(6) (b)(7)(C), directed semen donor (b)(4) (b)(6) (b)(7)(C) freshly donated semen was used to fertilize oocytes donated by anonymous donor (b)(4) (b)(6) (b)(7)(C) on (b)(6) (b)(7)(C) and subsequent tissues were transferred to (b)(4) recipients, not related and not sexually intimate partners of the semen donor: to recipient (b)(4) (b)(6) (b)(7)(C) on (b)(6) (b)(7)(C); (b)(4) (b)(6) (b)(7)(C) on (b)(6) (b)(7)(C), (b)(4) (b)(6) (b)(7)(C) on (b)(6) (b)(7)(C), and (b)(4) (b)(6) (b)(7)(C) on (b)(6) (b)(7)(C) Eligibility for this directed semen donor (b)(4) (b)(6) (b)(7)(C) was not determined and documented.
c) Directed oocyte donor (b)(4) (b)(6) (b)(7)(C) donated oocytes on (b)(6) (b)(7)(C) that were fertilized with fresh semen from directed donor (b)(4) (b)(6) (b)(7)(C) on the (b)(6) (b)(7)(C) with (b)(4) subsequent tissues cryopreserved on (b)(6) (b)(7)(C) and (b)(6) (b)(7)(C). Donor eligibility determination was documented by the Medical Director on (b)(6) (b)(7)(C) for both donors on the Donor Eligibility Determination Forms. Screening and physical examination of these directed donors was performed on (b)(6) (b)(7)(C) as documented on the Donor Risk Assessment Questionnaires for both donors. Specimen for infectious disease testing were collected on (b)(6) (b)(7)(C) as documented on the laboratory reports for both donors.

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	Irina Gaberman, Investigator X Irina Gaberman Investigator Signed By: 1300222798 Date Signed: 11-06-2024 07:05:02	11/6/2024

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158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	10/15/2024-11/6/2024* FEI NUMBER 3027446107

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mingxue Yang, Medical Director

FIRM NAME	STREET ADDRESS
ALLcare Fertility Center	369 Lexington Ave Fl 6
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
New York, NY 10017-6540	Reproductive Human Tissue

OBSERVATION 2
Donor specimens used for testing of communicable disease agents were not collected at the appropriate time.

Specifically,
Directed oocyte donor (b)(4) (b)(6) (b)(7)(C) donated oocytes on (b)(6) (b)(7)(C) that were fertilized with fresh semen recovered from directed donor (b)(4) (b)(6) (b)(7)(C) on the (b)(6) (b)(7)(C) with [redacted] subsequent tissues cryopreserved on (b)(6) (b)(7)(C) and (b)(6) (b)(7)(C). Infectious disease testing was performed for the specimen collected from oocyte donor (b)(4) (b)(6) (b)(7)(C) and semen donor (b)(4) (b)(6) (b)(7)(C) on (b)(6) (b)(7)(C) which is not within [redacted] days of oocyte retrieval or [redacted] days after and not within [redacted] days of semen donation.

OBSERVATION 3
You did not establish and maintain procedures for testing, screening and determining the eligibility of HCT/P donors.

Specifically,
Policy Manual for Tissue Bank, Effective Date 05/12/2023 and your standard operating procedure (SOP) entitled "Anonymous Oocyte Donor Screening and Eligibility Determination", Effective Date 02/01/2023 describe screening of anonymous oocyte donors at your facility. Your standard operating procedure (SOP) entitled "Directed Oocyte Donor Screening and Eligibility Determination", Effective Date 02/01/2023 and "Directed Semen Donor Screening and Eligibility Determination" Effective Date 02/01/2023 describe screening of directed oocyte and semen donors at your facility.
The screening criteria described in the SOPs is not detailed and do not cover all questions on the Donor Risk Assessment Questionnaire that is used to screen anonymous and directed oocyte and directed semen donors for the risk factors for relevant communicable disease agents and diseases. For example: engaging in sex with a person who is known or suspected to have HIV infection, hepatitis B infection, or clinically significant hepatitis C infection; having close contact with (e.g. resided in the same dwelling where sharing of kitchen and bathroom facilities occurs regularly) another person who has hepatitis B or clinically active hepatitis C infection in the preceding 12 months; being exposed in the preceding 12

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months to known or suspected HIV, HBV, and /or HCV – infected blood through percutaneous inoculation (e.g. needle stick) in the preceding 12 month; having been incarcerated for more than 72 hours during the previous 12 months; having tattoo or body piercing in the last 12 months where sterile procedures were not used; having a medical diagnosis or suspicion of West Nile Virus infection or having a tested positive within the past 120 days; having a blood relative diagnosed with HTE including CJD.
In addition, these SOPs state that a (b)(4) (b)(4)

OBSERVATION 4
HCT/Ps for which the donor eligibility determination was not required were not prominently labeled with the appropriate warning statements.

Specifically,
Two fertilized oocytes created by sexually intimate partners (b)(4) (b)(6) (b)(7)(C) and (b)(4) (b)(6) (b)(7)(C) and cryopreserved on (b)(6) (b)(7)(C) and (b)(6) (b)(7)(C) were sent to (b)(6) (b)(7)(C) to be transplanted to a recipient on (b)(6) (b)(7)(C). These tissues were not labeled with appropriate warning statements advising the recipient of communicable disease risks indicating that tissues were not evaluated for infectious disease substances.

OBSERVATION 5
Donor eligibility records are not accurate and legible.

Specifically,
a) Directed oocyte donor (b)(4) (b)(6) (b)(7)(C) answered (b)(6) (b)(7)(C) to the question: (b)(6) (b)(7)(C) (b)(6) (b)(7)(C)

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(b)(6) (b)(7)(C) as documented on the General Assessment Questionnaire dated (b)(6) (b)(7)(C). However, her (b)(6) (b)(7)(C) (b)(4) (b)(6) (b)(7)(C) (b)(6) (b)(7)(C) (b)(4) (b)(6) (b)(7)(C) (b)(6) (b)(7)(C) (b)(6) (b)(7)(C) (b)(6) (b)(7)(C) General Assessment Questionnaire dated (b)(6) (b)(7)(C)

b) The Donor Eligibility Determination Form documents (b)(6) (b)(7)(C) (b)(6) (b)(7)(C) (b)(4) (b)(6) (b)(7)(C) who was determined eligible by the Medical Director on the same form dated (b)(6) (b)(7)(C)

***DATES OF INSPECTION**

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