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	11/4/2025-11/17/2025* FEI NUMBER 3006988080

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sophia Aburmeileh, Director of Donor Operations and Quality

FIRM NAME	STREET ADDRESS
Americord Registry LLC	68 Veronica Ave, Unit #10
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Somerset, NJ 08873	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

Processes with results which could not be fully verified by inspection and tests, were not validated and approved according to established procedures.

Specifically,
a)You failed to validate and approve umbilical cord blood (UCB), cord tissue and placental tissue manufacturing processes, which cannot be fully verified, to ensure that your manufacturing processes do not cause contamination or cross-contamination and prevents the introduction, transmission, or spread of communicable disease through use of the Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). There are currently (b) (4) processed UCB, cord tissue and placental tissues processed and stored at your firm since September 2021. On 08/13/2025, UCB unit #(b) (4), (b) (6), (b) (7)(C) was released for transfusion.
b) In March 2023, (b) (4) UCB units were processed without (b) (4) (b) (4). However, this process was not validated prior to implementation.
c)Since August 13, 2025, your microbiological testing of processed cord blood, cord tissue and placental tissues was changed from (b) (4) to (b) (4) (b) (4) (b) (4) (b) (4). This process of utilizing (b) (4) was not validated; (b) (4) cord blood units have been tested using the (b) (4).

OBSERVATION 2

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

Specifically,
You did not establish and maintain standard operating procedures that describe donor screening, testing and eligibility determination for:
a) your umbilical cord blood (UCB), umbilical cord tissue and placental tissue donors for allogeneic use in a first degree or second degree blood relative;
b)placental tissue donors whose tissues are used for further manufacturing.
There are currently (b) (4) tissues stored at your tissue bank for allogeneic use in first degree or second degree blood relatives. On 08/13/2025, UCB unit #(b) (4), (b) (6), (b) (7)(C) was released for transfusion.

OBSERVATION 3
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,
On 08/13/2025, Umbilical Cord Blood unit #(b) (4), (b) (6), (b) (7)(C) was released from your tissue bank to be used for allogeneic transfusion in a first degree relative. There was no donor eligibility determined and documented for this donor.

OBSERVATION 4
HCT/Ps shipped in quarantine prior to the completion of the donor-eligibility determination were not accompanied by records that stated the product must not be implanted, transplanted, infused or transferred until completion of the donor-eligibility determination.

Specifically,
Placental tissues that are collected from allogeneic donors are processed by your firm, and sent to (b) (4) (b) (4) for further manufacturing. These tissues were not prominently labeled with the warning

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statements indicating that the product must not be implanted, transplanted, infused, or transferred until completion of the donor eligibility determination. There were (b) (4) placental tissues sent to (b) (4) (b) (4) from December 2024 to November 2025.

OBSERVATION 5
Donor eligibility records are not accurate.

Specifically,
Review of the Data Collection Sheet forms that document donor physical examination prior to UCB, cord tissue and placental tissue recovery from January 2024 to November 2025 found that question "Has an examination evaluated for absence of signs of non-medical percutaneous drug use, including examination of tattoos that may cover needle tracks?" was answered as No for the following UCB donors: (b) (4), (b) (6), (b) (7)(C) (collection date (b) (4), (b) (6), (b) (7)(C)), (b) (4), (b) (6), (b) (7)(C) (collection date (b) (4), (b) (6), (b) (7)(C)), (b) (4), (b) (6), (b) (7)(C) (collection date (b) (4), (b) (6), (b) (7)(C)), (b) (4), (b) (6), (b) (7)(C) (collection date (b) (4), (b) (6), (b) (7)(C)).

OBSERVATION 6
The quality program does not include the investigation and the documentation of HCT/P deviations relating to core CTGP requirements.

Specifically,
a) Review of microbiological test reports from January 2023 to November 2025 found that there were no investigations performed for positive microbiological tests reported for your UCB, cord tissue and placental tissue specimens. For example: positive growth was reported for UCB, cord tissue and placental tissue for unit # (b) (4), (b) (6), (b) (7)(C) without further investigation.
b) There was no investigation performed when environmental monitoring (b) (4) (b) (4)) of the Biological Safety Cabinet (b) (4) tested positive from the March 20, 2025 testing. In addition, the standard operating procedure entitled "Environmental Testing of Work Surface and Biological Safety Cabinet" requires (b) (4) but (b) (4) reported on 10/09/2024, 03/20/2025, 03/25/2024, 06/25/2024, 08/01/2024, were

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(b) (4).

OBSERVATION 7

Procedures to control the labeling of HCT/Ps were not established, maintained, defined, documented and implemented.

Specifically,

a) There are no standard operating procedures that describe the UCB, cord tissue and placental tissue labeling process. On 11/05/2025, labels were (b) (4) and (b) (4) to cord blood/tissue processing records. In addition, there were 6 UCB units incorrectly labeled ((b) (4), (b) (6), (b) (7)(C) through (b) (4), (b) (6), (b) (7)(C)) as documented on the Non-conformance report dated 10/29/2024.

b) Review of UCB, cord tissue and placental tissue records from January 2023 to November 2025 found that the cryopreservation date for cord tissue and placental tissue was incorrect. These tissues are (b) (4) (b) (4) and (b) (4). For example, cord tissue unit #(b) (4), (b) (6), (b) (7)(C) was cryopreserved on (b) (4), (b) (6), (b) (7)(C) as documented on the Tissue Processing Form, but labeling stated it was cryopreserved on (b) (4), (b) (6), (b) (7)(C).

OBSERVATION 8

HCT/Ps shipped prior to the completion of the donor-eligibility determination were not kept in quarantine during shipment.

Specifically,

On 08/12/2025, Umbilical Cord Blood unit #(b) (4), (b) (6), (b) (7)(C) was released from your tissue bank to be used for allogeneic transfusion in a first degree relative. There was no donor eligibility determined and documented for this donor. Accompanying records did not indicate the status of this tissue. In addition, there is no standard operating procedure describing issuance of tissue products.

OBSERVATION 9

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Donors were not screened by a review of relevant medical records for of communicable disease agents and diseases.

Specifically,
Review of UCB, cord tissue and placental tissue donor records from January 2023 to November 2025 found that the following donors are missing the (b) (4) that is used to screen donors for the relevant communicable disease agents and diseases: W453225007281 (collection date (b) (4), (b) (6), (b) (7)(C)), and (b) (4), (b) (6), (b) (7)(C) (collection date (b) (4), (b) (6), (b) (7)(C)).

OBSERVATION 10
Records did not identify the person performing the work, did not show the dates of entries and were not detailed as necessary to provide a complete history of work performed.

Specifically,
a) Sterilized utensils are used for tissue cord and placental tissue manufacturing. There are no utensil sterilization records documented including cycle temperature and duration.
b) Processed UCBs are placed in (b) (4) freezer for (b) (4) as stated in the standard operating procedure OP-004 entitled "Cord Blood Processing". However, date of UCB removal from (b) (4) freezer and placement into (b) (4) is not documented for all processed UCBs.

OBSERVATION 11
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include validation of the aseptic process.

Specifically,
There were (b) (4) exosome products manufactured by your facility from January 2024 to August 2025. This process was not validated. Exosome products processed were cryopreserved for future use. In addition, manufacture of maternal exosomes from the blood specimen was implemented in January 2024. This process was not validated. Also, you accumulate and store plasma from UCB processing and

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from maternal blood specimens for future exosomes manufacturing. For example, on 09/26/2025, (b) (4) lot numbers of maternal and baby exosomes were manufactured from the raw materials collected from (b) (4), (b) (6), (b) (7)(C). For example, unit#(b) (4), (b) (6), (b) (7)(C) along with the mother blood specimen was collected on (b) (4), (b) (6), (b) (7)(C), exosomes manufactured on 09/26/2025.

OBSERVATION 12

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards, sampling plans and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,
a)You did not establish release criteria and in-process materials specifications for exosome manufacturing. There were (b) (4) exosome products manufactured from September 2021 to February 2025.
b) Review of manufactured exosome labeling found that labeling incorrectly reflects exosome cryopreservation date. For example, exosome lot#(b) (4), (b) (6), (b) (7)(C) was processed on 04/12/2023 as documented on the (b) (4) but labeling states Date of Cryo 3/21/2023.

OBSERVATION 13

Written procedures are not drafted, reviewed and approved by the appropriate organizational units and reviewed and approved by the quality control unit.

Specifically,
Your firm failed to establish standard operating procedures to prevent microbiological contamination for exosome manufacturing. There are (b) (4) cryopreserved exosomes manufactured and stored at your facility.

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OBSERVATION 14
HCT/Ps were not kept in quarantine until completion of the donor-eligibility determination.

Specifically,
The status of your processed UCB, cord tissue and placental tissue donors is changed from quarantine to (b) (4) storage prior to donor eligibility determination in your computer inventory system upon entering negative infectious disease test results. For example, on 11/07/2025, UCB unit#(b) (4), (b) (6), (b) (7)(C) infectious disease test results were entered as " (b) (4) " in your tissue computer inventory system. This entry converted status for UCB, cord tissue and placental tissue associated with unit#(b) (4), (b) (6), (b) (7)(C) from QUARANTINE to (b) (4) Storage.

OBSERVATION 15
Environmental controls do not provide for adequate cleaning and disinfecting of equipment to ensure aseptic processing.

Specifically,
Your standard operating procedure OP-163 entitled "Cleaning and Operating Biological Safety Cabinets" (b) (4) (b) (4) BSC (b) (4) .
a) On 11/04/2025 and 11/05/2025 Biological Safety Cabinet (BSC) (b) (4) was observed (b) (4) (b) (4) . The following placental donor tissues were processed on 11/04/2025 and 11/05/2025: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)

b) On 11/04/2025 and 11/05/2025, BSC (b) (4) was observed being cleaned with the (b) (4) (b) (4) . In addition, the (b) (4) of the BSC was not cleaned (b) (4) . The following units were processed on these days:#(b) (4), (b) (6), (b) (7)(C), (b) (4), (b) (6), (b) (7)(C), and (b) (4), (b) (6), (b) (7)(C).

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OBSERVATION 16

Procedures appropriate to meet core CGTP requirements for all steps that you perform in the manufacture of HCT/Ps were not followed.

Specifically,
Your standard operating procedure #OP-008 entitled "Cord Tissue Processing" section 6.4.7 states: (b) (4) (b) (4) This step was not performed when cord blood units# (b) (4), (b) (6), (b) (7)(C) were processed on 11/04/2025.

OBSERVATION 17

A sample from the birth mother of a donor one month of age or younger was not used for testing of relevant communicable disease agents.

Specifically,
On 04/23/2025, UCB tissue was collected from donor #(b) (4), (b) (6), (b) (7)(C) and processed under unit #(b) (4), (b) (6), (b) (7)(C). Donor #(b) (4), (b) (6), (b) (7)(C) was not tested for syphilis.

***DATES OF INSPECTION**

11/04/2025(Tue), 11/05/2025(Wed), 11/06/2025(Thu), 11/07/2025(Fri), 11/17/2025(Mon)

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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."