**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 404 BNA Dr., Bldg. 200, Ste. 500<br>Nashville, TN 37217-2597<br>(615)366-7801 Fax:(615)366-7802 | 9/11/2025-9/15/2025*<br>FEI NUMBER<br>3015364206 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Cecil A. Long, MD, Medical Director

| FIRM NAME | STREET ADDRESS |
|---|---|
| Alabama Center for Reproductive Medicine | 2006 Brookwood Medical Ctr Dr Ste 302 |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Birmingham, AL 35209-6823 | Reproductive 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

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

Specifically,

A. There is no written procedure discussing all the steps in conducting the physical exam. For example:
   1) There is an exam form but there are no written instructions regarding the examination of the parts of the body that are necessary to evaluate for clinical signs and symptoms and risk factors for communicable disease agents and diseases.
   2) There are no instructions on what would be eligible or ineligible, based on the findings of the physical exam.

B. There is no Donor Eligibility procedure that specifically describe the requirements that must be met to determine a donor as eligible or when the donor should be determined ineligible. For example:
   1) There is no instruction on how to review the questionnaire and what are acceptable answers.
   2) It does not specify which questions on the questionnaire with a "yes" answer must have further questions asked to determine whether the donor is eligible. It does not specify what those further specific

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Juanelma H Palmer, Investigator<br>X Juanelma H Palmer Investigator Signed By: Juanelma H. Palmer - S Date Signed: 09-15-2025 11:39:16 | 9/15/2025 |

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| CITY, STATE, ZIP CODE, COUNTRY<br>Birmingham, AL 35209-6823 | TYPE ESTABLISHMENT INSPECTED<br>Reproductive Tissue |

questions are. It does not specify what would be acceptable or not acceptable based on the answers to further questioning.

C. There is no procedure describing exception activities.

D. There is no procedure for Embryo Donation that describes requirements. For example:

1) There are no instructions describing what documentation is necessary (other than test results), such as a donor eligibility statement and a summary of records.

2) It does not describe the labeling requirements, such as warning statements that may be necessary.

Since 2023, you are screened (b) (4) donors using your current donor history questionnaire.

Reference: 21 CFR 1271.47(a)

***DATES OF INSPECTION**

9/11/2025(Thu), 9/12/2025(Fri), 9/15/2025(Mon)

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|---|---|---|
| | Juanelma H Palmer, Investigator<br>X Juanelma H Palmer Investigator Signed By: Juanelma H. Palmer - S Date Signed: 09-15-2025 11:39:16 | 9/15/2025 |

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."