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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 1201 Harbor Bay Parkway<br>Alameda, CA 94502-7070<br>(510)337-6700 Fax:(510)337-6702 | 4/29/2025-4/30/2025 |
| | FEI NUMBER<br>3009682116 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kirsten E. Eckert, Nurse Practioner

| FIRM NAME | STREET ADDRESS |
|---|---|
| MFC Lab, Inc. | 1100 S Eliseo Dr Ste 107 |
| CITY, STATE, ZIP CODE, COUNTRY<br>Greenbrae, CA 94904-2017 | TYPE ESTABLISHMENT INSPECTED<br>Reproductive Tissue Facility |

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

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,

Directed semen donor (b) (6), (b) ( had no donor eligibility determination made. The tissue was collected on 11/30/2023 and (b) (4), (b) (6), (b) (7)(C).

## OBSERVATION 2

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

Specifically,

You have not established procedures for screening of directed semen donors.

**SEE REVERSE OF THIS PAGE**

EMPLOYEE(S) SIGNATURE
Emily S Mcgann, Investigator

X Emily S Mcgann
Investigator
Signed By: Emily S. Mcgann -S
Date Signed: 04-30-2025
13:57:50

DATE ISSUED
4/30/2025

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."