

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

DISTRICT ADDRESS AND PHONE NUMBER 1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax: (510) 337-6702	DATE(S) OF INSPECTION 8/14/2025-8/19/2025* FEI NUMBER 3003971346
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Denise M. Koenes, Executive Director

FIRM NAME NCFMC, a Medical Corporation	STREET ADDRESS 4320 Auburn Blvd
CITY, STATE, ZIP CODE, COUNTRY Sacramento, CA 95841-4166	TYPE ESTABLISHMENT INSPECTED Human Reproductive Tissue 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 determined to be ineligible that had risk factors or clinical evidence of communicable disease agents.

Specifically, your firm did not determine ineligible known sperm donor (b) (4), (b) (6), (b) (7)(C) after he reported (b) (6), (b) (7)(C) (b) (6), (b) (7)(C) within the preceding five years. Your firm determined the donor to be eligible on 5/7/2021. Sperm was collected on (b) (6), (b) (7)(C) and transferred to a gestational carrier on (b) (6), (b) (7)(C), (b) (6), (b) (7)(C) and (b) (6), (b) (7)(C).

OBSERVATION 2

Testing for communicable disease agents was not performed in accordance with the manufacturer's instructions.

Your firm is not following the manufacturer's instructions for testing reproductive tissue donors for evidence of *Chlamydia trachomatis* and *Neisseria gonorrhea*. Specifically,

1. Your firm collects (b) (4) of urine rather than the required amount of between 20 mL to 30 mL. According to the manufacturer's instructions, collection of more than 30 mL may result in specimen dilution that may reduce test sensitivity; and
2. Your firm provides female HCT/P donors with (b) (4) (b) (4) with the request for the patient to (b) (4) the (b) (4) collection of the specimen that is sent for use by the laboratory to perform donor testing. According to the instructions provided by the contract testing laboratory, female patients should not (b) (4) the

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Shelley H Beausoleil, Investigator	DATE ISSUED 8/19/2025
	Shelley H Beausoleil Investigator Signed By: Shelley H. Beausoleil - 8 Date Signed: 08-19-2025 15:27:51 X	

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(b) (4) providing their specimen for testing.			
OBSERVATION 3 Procedures were not designed to ensure compliance with the donor eligibility requirements. Your firm's written procedures have not been designed to ensure compliance with donor eligibility requirements. Specifically, 1. Your firm's written procedures do not always establish donor acceptance criteria for donors with identified risk factors. For example, your firm's procedures do not specify the criteria or timeframe for when donors will be acceptable to continue with their donation process after risk factors or conditions relevant to the following diseases or disease agents are identified through screening or testing. This is not an all-inclusive list. a. Syphilis b. Gonorrhea c. Chlamydia d. Neurological diseases e. Vaccinia f. West Nile Virus 2. Your written procedures make statements that donor have to meeting waiting requirements, but the time frames were not established as part of the written procedure. For example, your firm's procedure SOP # 05 called "Informing Donors/Intended Parents with Positive Chlamydia Test *Initial Screening*" states a positive test result for Chlamydia will have a waiting period; however, this waiting period has not been defined. 3. Written procedures were observed to be inconsistent with each other. For example, your firm's procedure SOP # 04 called "Informing Egg Donors/Intended Parents with Positive Communicable Disease Tests" states any donor with a positive communicable disease test will be ineligible; however, there are other written procedures that allow the donation to continue when an unspecified waiting period has lapsed.			
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Denise M. Koenes, Executive Director

FIRM NAME

NCFMC, a Medical Corporation

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4. Written procedures covering the review of all available medical records for clinical evidence of HIV have not been established. For example, there is not a procedure that states if, and how, your firm will review all available relevant medical records for a prior positive or reactive screening test for HIV.
5. Your firm provides egg bank services for your clients which includes the recovery and storage of oocytes for later use by the client. Your firm has not established a procedure that covers the donation of oocytes originally exempted from an eligibility determination. A written procedure covering the donation of male gametes has also not been established.

***DATES OF INSPECTION**

8/14/2025(Thu), 8/15/2025(Fri), 8/18/2025(Mon), 8/19/2025(Tue)

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Shelley H Beausoleil, Investigator

Shelley H Beausoleil
Investigator
Signed By: Shelley H. Beausoleil -
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Date Signed: 08-19-2025
15:27:51

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DATE ISSUED

8/19/2025

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."