

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

DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768	DATE(S) OF INSPECTION 2/24/2026-3/2/2026* FEI NUMBER 3021867303
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Timothy E. Maye, CEO / Management Representative

FIRM NAME C5 Biomedical LLC	STREET ADDRESS 6452 E Rogers Cir
CITY, STATE, ZIP CODE, COUNTRY Boca Raton, FL 33487-2653	TYPE ESTABLISHMENT INSPECTED Human 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 WE OBSERVED:

OBSERVATION 1

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

Specifically,

You have not and do not check the effectiveness of the use of (b) (4) to clean and disinfect biological safety cabinets (BSCs), tables, chairs, etc., inside clean-rooms (b) (4) (b) (4) processing of donors.

You do have a cleaning validation report, (b) (4) -013 - Clean Room Disinfection Program Validation Report: Characterization and (b) (4) Disinfection Effectiveness and Hold Time Testing Results & Clean Room Disinfection Program Validation Report: (b) (4) Disinfection Effectiveness and Hold Time Testing Results; however, it does not measure the effectiveness of the cleaning that occurs (b) (4) processing events on the (b) (4). It focused on measuring the effectiveness of the (b) (4) cleaning and (b) (4) cleaning events.

For example, on 2/25/2026, you processed (b) (4) donors inside small clean room (b) (4), and use (b) (4) to disinfect BSC (b) (4) table and chair (b) (4) processing of donors (b) (6), (b) (7)(C) (b) (6), (b) (7)(C).

***DATES OF INSPECTION**

2/24/2026(Tue), 2/25/2026(Wed), 2/26/2026(Thu), 3/02/2026(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Ivan E Reyes, Investigator Nermin V Briones, Investigator	Ivan E Reyes Investigator Signed By: 2000357185 Date Signed: 03-02-2026 13:34:33 X	DATE ISSUED 3/2/2026

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X
Nerming V Briones
Investigator
Signed By: Nerming Briones -S
Date Signed: 03-02-2026 13:35:01

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Ivan E Reyes, Investigator Nerming V Briones, Investigator	Ivan E Reyes Investigator Signed By: 2000357185 Date Signed: 03-02-2026 13:34:33 X	DATE ISSUED 3/2/2026

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."