DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	6/10/2026-6/15/2026*
	FEI NUMBER 3010743004

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Claudia T. Martorell, M.D., Clinical Investigator

FIRM NAME	STREET ADDRESS
Claudia T. Martorell, M.D.	57 Mulberry St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Springfield, MA 01105-1406	Clinical Investigator

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

An investigation was not conducted in accordance with the investigational plan.

Specifically,

Inclusion criterion (b) (4) required subject plasma (b) (4) /mL at screening. The screening labs for Subject (b) (6), (b) (7)(C) drawn (b) (6), (b) (7)(C) were reported to and reviewed by the site on 09/19/2024 and indicated the subject had an (b) (4) level of (b) (4) /mL. The site enrolled, randomized, and dosed Subject (b) (6), (b) (7)(C) on (b) (6), (b) (7)(C).

*DATES OF INSPECTION

6/10/2026(Wed), 6/11/2026(Thu), 6/12/2026(Fri), 6/15/2026(Mon)

X Meredith L Miller
Investigator
Signed By: MEREDITH L. MILLER -S
Date Signed: 06-15-2026 11:48:23

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Meredith L Miller, Investigator
Agata E Libera, Investigator

X Agata E Libera
Inves igator
Signed By: AGATA E. LIBERA -S
Date Signed: 06-15-2026
11:47:55

DATE ISSUED
6/15/2026

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."