DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	7/6/2026-7/9/2026
	FEI NUMBER 3043865065

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Tomasz M. Ziedalski, M.D., Clinical Investigator

FIRM NAME	STREET ADDRESS
Tomasz M. Ziedalski, M.D.	12728 19th Ave Se Ste 300
CITY, STATE, ZIP CODE, COUNTRY Everett, WA 98208-6676	TYPE ESTABLISHMENT INSPECTED 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 I OBSERVED:
The following observations pertain to your conduct of the clinical study protocols (b)(4) -

OBSERVATION 1
Failure to obtain informed consent in accordance with 21 CFR Part 50 from each human subject prior to conducting study-related tests.

Specifically,

For clinical trial protocol (b)(4) the investigator failed to obtain informed consent from Subject (b) (6), (b) (7)(C) prior to study-related procedures, as the subject underwent a protocol-required (b)(4) (b)(4) on (b) (6), (b) (7)(C) before consent was obtained on 5/12/2025.

OBSERVATION 2
An investigation was not conducted in accordance with the investigational plan.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Logan M Jones, Investigator X Logan M Jones Investigator Signed By: 2004013644 Date Signed: 07-09-2026 17:08:09	7/9/2026

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For clinical trial protocol (b)(4) the investigator failed to document a Clinically Significant (CS) laboratory value as an Adverse Event (AE). Section 7.7 states, "Abnormal findings that are deemed CS or that are associated with signs and/or symptoms must be recorded as AEs if they meet the definition of an AE".

- Subject (b) (6), (b) (7)(C) who was consented on 10/24/2024, experienced an elevated White Blood Cell (WBC) laboratory result of (b) (6), (b) (7)(C) on 11/25/2024. The investigator marked this elevated laboratory result as CS on 12/2/2024. This CS laboratory result was not recorded by firm management in the subject's electronic Case Report Form (eCRF) as an AE.

For clinical trial protocol (b)(4) (Amendment 4), the investigator failed to document a CS laboratory value as an AE. Section 9.2.6 states, "Laboratory test result abnormalities should be captured on the AE CRF page - Any laboratory test result that is clinically significant."

- Subject (b) (6), (b) (7)(C) who was consented on (b) (6), (b) (7)(C), experienced a low sodium laboratory result for (b) (6), (b) (7)(C) from 10/8/2025 through 6/8/2026. The investigator marked this low sodium result as CS on 10/13/2025 for mild hyponatremia. This CS laboratory result was not recorded by firm management in the subject's eCRF as an AE.

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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."