DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1777 Hardee Ave SW Atlanta, GA 30310 (404)253-1284 Fax:(404)669-4443	3/30/2026-4/2/2026
	FEI NUMBER 3043422813

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Amit G. Shah, MD, Principal Investigator

FIRM NAME	STREET ADDRESS
Amit G. Shah, MD	1040 Edgewater Parkway, Suite 102, Lancaster County
CITY, STATE, ZIP CODE, COUNTRY Fort Mill, SC 29707	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 WE OBSERVED:
The following observations for (b)(4)

OBSERVATION 1
Failure to report serious adverse events promptly to the sponsor.

Specifically,

As required per Protocol (b)(4), serious adverse events were not reported within (b)(4) of learning of event for Subject (b) (6), (b) (7)(C) :

SAE	Date of SAE Notification	Date SAE Reported
Hypoxia	5 JAN 2024	10 APR 2024

OBSERVATION 2
Failure to report non-serious adverse events to the sponsor in accordance with the study protocol timetable for reporting.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Anthony J Grace, Investigator Peyton L Sloan, Investigator X Anthony J Grace Investigator Signed By: Anthony J. Grace -S Date Signed: 04-02-2026 14:02:57	4/2/2026

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As required per Protocol (b)(4), non-serious events were not reported within (b)(4) of learning of the event for Subject (b) (6), (b) (7)(C) :

AE	Date of AE Notification	Date AE Reported
Small Cell Carcinoma	15 MAY 2024	27 JUN 2024

X Peyton L Sloan
Investigator
Signed By: PEYTON L. SLOAN -S
Date Signed: 04-02-2026 14:03:42

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Anthony J Grace, Investigator
Peyton L Sloan, Investigator

X Anthony J Grace
Investigator
Signed By: Anthony J. Grace -S
Date Signed: 04-02-2026 14:02:57

DATE ISSUED
4/2/2026

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."