DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707	6/15/2026-6/24/2026*
	FEI NUMBER 3017812890

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kerry Adamik, Site Head, Associate Vice President

FIRM NAME	STREET ADDRESS
Lentigen Technology Inc.	1201 Clopper Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Gaithersburg, MD 20878-4000	Drug Substance Intermediate Manufacturer

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:

(b) (4)

Discrepancies involving bioburden excursions are not always fully evaluated. LTI-MSAT 000024, Version 0.2, "*Risk Assessment of Lentiviral Production Process Controls for Microbial Contamination*", approved on 16 May 2025, and effective on 19 May 2025, is deficient in the evaluation of microbial contamination event(s) which occurred during the manufacture of lentiviral products for commercial use, including root causes and actions taken for correction, prevention and eradication. The risk assessment did not include the evaluation of the Out of Specification (OOS) ISSUE-2025-000084 initiated on 25 Apr 2025. This OOS addressed a bioburden excursion of (b) (4) (b) (4) in the (b) (4) of MAGE-A4-c1032 lentiviral vector (b) (4) (b) (4) batch number (b) (4), collected on (b) (4). The organism identified in this OOS sample was (b) (4), a (b) (4), which was also identified in (b) (4) samples taken from other purification steps on the (b) (4). MAGE-A4-c1032 lentiviral vector is used for further manufacture of afamitresgene autoleucel drug product.

***DATES OF INSPECTION**

6/15/2026(Mon), 6/16/2026(Tue), 6/17/2026(Wed), 6/18/2026(Thu), 6/22/2026(Mon), 6/23/2026(Tue), 6/24/2026(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Priscilla M Pastrana, Investigator	X Priscilla M Pastrana Investigator Signed By: PRISCILLA M. PASTRANA -S Date Signed: 06-24-2026 15:43:47	6/24/2026

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."