DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Lead Insp.: Christine Harman Telephone: 240-402-9580 Industry Information: www.fda.gov/oc/industry	April 29, 2024 to May 3, 2024
	FEI NUMBER 3017812890

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Kerry Adamik, Site Head, Associate Vice President

FIRM NAME	STREET ADDRESS
Lentigen Technology, Inc.	1201 Clopper Rd
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Gaithersburg, MD 20878	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) (WE) OBSERVED:

1. There are deficiencies in the testing and qualification of raw materials used in the manufacturing of the MAGE-A4-c1032 lentiviral vector. Specifically,
a. (b) (4) and (b) (4) used for (b) (4) do not have a defined (b) (4) test and thus are not tested for (b) (4) for qualification and release.
b. Confirmatory Certificate of Analysis (CoA) testing of the (b) (4) is not performed for three consecutive lots as per LTI-SOP-QA-000060 and there is no defined (b) (4) test performed for qualification and release testing.
c. Confirmatory CoA testing of (b) (4) is inadequate. Specifically, testing does not include tests for product (b) (4)
d. Consumables such as (b) (4) do not have an adequate test for visual inspection.

SEE REVERSE OF THIS PAGE

/S/

EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
Christine Harman, Lead Consumer Safety Officer; Laura DeMaster, Biological Reviewer; Y Nguyen, Biologist; Sharmila Shrestha, Biological Reviewer; Alan Baer, Staff Fellow	May 3, 2024

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 judgement, 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."