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	3/17/2025-3/20/2025
	FEI NUMBER 3013427685

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ms. Natalie A. Wacks, VP Quality

FIRM NAME	STREET ADDRESS
2seventy bio, Inc.	60 Binney St
CITY, STATE, ZIP CODE, COUNTRY Cambridge, MA 02142-1512	TYPE ESTABLISHMENT INSPECTED Viral Vector Testing Lab

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:

OBSERVATION 1

Laboratory records do not include complete records of any testing and standardization of laboratory reference standards.

Specifically, your firm has not adequately qualified the DNA plasmid reference standard (b) (4) used in the test method TM-0059 Determination of Lentiviral Vector Titer by (b) (4) (b) (4) in Quality Control. This test method relates to the viral vector Anti-BCMA02 CAR aLVV used in manufacturing drug product ABECMA.

Three testing reports speak to the structure of the DNA Plasmid (lot #(b) (4)) expected to be (b) (4) bp in length but give conflicting data:

1. Report (b) (4) dated (b) (4) for (b) (4) with size of (b) (4) bp
2. BioInformatics Report dated (b) (4) shows (b) (4) total size of (b) (4) bp
3. Report #RPT-2265 dated (b) (4) shows (b) (4) plasmid with size greater than or equal to (b) (4) bp.

This plasmid reference standard lot has been used in all testing of viral vector batches with TM-0059 since prior to 2021.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Scott T Ballard, Investigator X Scott T Ballard Investigator Signed By: Scott T. Ballard -S Date Signed: 03-20-2025 10:45:08	3/20/2025

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."