

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 8/6/2025-8/14/2025*
	FEI NUMBER 3012673301

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Patrick C. Boylan, Site Head

FIRM NAME SAFC Carlsbad Inc.	STREET ADDRESS 6219 El Camino Real
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CITY, STATE, ZIP CODE, COUNTRY Carlsbad, CA 92009-1604	TYPE ESTABLISHMENT INSPECTED Viral Vector Manufacturer
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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:

1. Failure to follow and/or establish written procedures for manufacturing equipment.
Specifically,

- a. Your firm failed to replace (b) (4) and perform (b) (4) (b) (4) testing according to your established procedure (SOP (b) (4), Operation, Maintenance, Cleaning, and Calibration of the (b) (4), version 27). Your procedure/ work plan template requires (b) (4) to be replaced (b) (4) and (b) (4) test to be performed. For example:
 - Replacement of (b) (4) and performance of (b) (4) testing of (b) (4) was not performed in 2022 and 2023.
 - Except for (b) (4) and (b) (4), replacement of (b) (4) and performance of (b) (4) testing was not performed in 2022, 2023, and 2024.

- b. Your firm has not established procedure/ work plan template for tracking and maintaining (b) (4) in your (b) (4). (b) (4) was installed on (b) (4).

***DATES OF INSPECTION**

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Alan L Truong, Investigator Lewis K Antwi, Investigator	Lewis K Antwi Investigator Signed By: 2001796124 Date Signed: 08-14-2025 15:20:03 X	DATE ISSUED 8/14/2025

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8/06/2025(Wed), 8/07/2025(Thu), 8/08/2025(Fri), 8/11/2025(Mon), 8/12/2025(Tue), 8/13/2025(Wed), 8/14/2025(Thu)

Alan L Truong
 Investigator
 Signed By: 2002619229
 Date Signed: 08-14-2025 15:20:47

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Alan L Truong, Investigator Lewis K Antwi, Investigator	<input checked="" type="checkbox"/> Lewis K Antwi Investigator Signed By: 2001796124 Date Signed: 08-14-2025 15:20:03	DATE ISSUED 8/14/2025

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."