DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	5/12/2026-5/15/2026 FEI NUMBER 1316257

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christopher J. Dietz, General Manager

FIRM NAME	STREET ADDRESS
Canyon Rush, LLC	7500 W Henrietta Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Rush, NY 14543-9790	Contract Laboratory

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 data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

Specifically,

Your firm failed to maintain contemporaneous, complete laboratory records for sterility testing, bioburden testing, and environmental monitoring. Three consecutive high-risk deviations were initiated within eleven (11) days in December 2025, all assigned to the same CAPA (CAPA-26-001), due to data integrity issues. For example:

1. DEV-25-050 (Initiated December 12, 2025): Documentation of sample preparation and transfer was not recorded contemporaneously for eleven (11) sterility tests across two testing sessions (December 5 and December 10, 2025), affecting (b) (4) pharmaceutical clients. Five (5) tests could not be reconstructed and were invalidated with no results issued; the affected lots included (b) (4) lots ((b) (4) , (b) (4)) and (b) (4) (lot (b) (4)). Six (6) additional tests were reconstructed using (b) (4) and secondary data forms rather than contemporaneous records.

2. DEV-25-051 (Initiated December 15, 2025): Bioburden testing contract review through incubation start was not documented contemporaneously for two (2) tests: M25-(b) (4) ((b) (4) , lot (b) (4)) and M25-(b) (4) ((b) (4) lot (b) (4)). Neither test could be reconstructed. No results were or will be issued. Both tests represented the sponsors' November (b) (4) manufacturing bioburden monitoring, and no replacement samples were available, resulting in a permanent gap in required monitoring data.

3. DEV-25-052 (Initiated December 15, 2025): Your firm explicitly characterized this deviation as recurrent, encompassing all failures from DEV-25-050 and DEV-25-051, plus (b) (4) of incomplete

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(b) (4) environmental monitoring documentation ((b) (4) –) on form MD-326. Required data fields including equipment used, work instruction revision, and results (including zero counts) were not recorded contemporaneously.
Your firm's risk assessment acknowledged a resulting gap in environmental trending data and risk to room control, however, you have not taken any steps to correct this issue.
Supporting Pattern of Recurrence (2024–2025):
Your firm's deviation logs document prior recurring documentation failures that prior CAPAs failed to prevent, including:

- DEV-24-034 (May 2024): EM/PM negative control results not recorded; results unable to be confirmed
- DEV-24-050 (July 2024): Twelve (12) EM alert limit excursions not reported to management over a three-month period
- DEV-24-055 (August 2024): Bioburden plates not retained; required gram stain/morphology data unable to be provided to sponsor
- DEV-24-058 (September 2024): Negative control counts not recorded for four consecutive days following a form revision
- DEV-24-082 (December 2024): Sterility incubation ended prior to completion of required (b) (4) period
- DEV-25-068 (October 2024): Sterility incubation ended two days early, affecting multiple customers

This pattern spans from at least 2024 through December 2025, affecting major pharmaceutical clients.

OBSERVATION 2
Established laboratory control mechanisms are not followed.

Specifically,

Your firm failed to follow Laboratory Investigation Procedure (SRP-12, v14.0), which requires that Laboratory Investigation Reports (LIRs) be completed and approved within (b) (4) that any due date extensions include documented justification and QA approval (form QA-378), and if due date is without an approved extension, a risk assessment must be documented by the investigation owner and approved by department management and QA. For example:

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1. LIRs Completed Past Self-Established Extension Due Dates Without a Documented Risk Assessment
Review of LIR records from 2023-present revealed at least 19 LIRs were completed past your firm-established extension due dates up to 36 days, 2 of which with no documented risk assessment and no adequate justification for the delays.

- For example, LIR-24-035, LIR-24-036, and LIR-24-037 were initiated on June 13, 2024, following the observation of particulate matter in sterility test media ((b) (4) and (b) (4)) for three lots of sterile (b) (4) drug products tested in the same session on June 10, 2024 — (b) (4) (Lots (b) (4) and (b) (4)) and (b) (4) (Lot (b) (4)). Two extensions were requested and approved for each LIR, extending the due dates to (b) (4), 2024. Despite this, all three LIRs were completed past the final approved extension date, with LIR-24-035 closed 26 days late, LIR-24-036 closed 36 days late, and LIR-24-037 closed 26 days late. As a result, a risk assessment memorandum was prepared on (b) (4), 2024, after the second extension due date of (b) (4), 2024, had already been exceeded as required by SRP-12, Section 5.3.7.2.

2. LIRs Completed Past Due Dates Without Any Risk Assessment
The following 2 LIRs were completed past their due dates with no risk assessment documented as expected by SRP-12, Section 5.3.7.2:

- LIR-24-012 (5 days late): Personnel monitoring (PM) samples collected following the 1/26/2024 sterility session were over the action limit.
- LIR-25-006 (21 days late): (b) (4) and (b) (4) samples were positive for growth on day 3 for Sterility Natural Product.

No documentation was identified in either file to demonstrate that the investigation owner, department management, or QA acknowledged or assessed the risk associated with completing these investigations beyond their established due dates.

OBSERVATION 3

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Laboratory controls do not include the establishment of scientifically sound and appropriate specifications designed to assure that components conform to appropriate standards of identity, strength, quality and purity.

Specifically,

Your firm has failed to ensure that incubation conditions used for environmental monitoring samples associated with sterility testing are scientifically sound and appropriate to support optimal incubation conditions for microbial recovery. For example:

Microbiology Incubator #(b) (4), used to incubate microbiological samples, including (b) (4)-based plates for environmental monitoring (EM), sterility, and bioburden testing, is neither equipped with humidity control nor qualified to monitor or maintain humidity. Equipment assessment documentation records the humidity controller, humidity (b) (4) input, and all associated humidity parameters as "N/A" throughout Parts II and IV of the assessment. No humidity setpoints, alarm limits, or monitoring data are established or recorded for this unit. The absence of humidity control creates conditions that can lead to (b) (4) desiccation, directly compromising the integrity of any (b) (4)-based plate incubated in this unit and undermining the firm's ability to reliably recover microorganisms. This impact was demonstrated in the following example:

During a review of sterility data release procedures on 05-13-26, EM plates composed of (b) (4) media (Lot No. (b) (4)) were observed to be cracked and desiccated following incubation in Microbiology Incubator #(b) (4). These plates had been used to assess microbial contamination during biological indicator (BI) sterility testing (Test Nos. M26-(b) (4), M26-(b) (4), M26-(b) (4); BI Lots (b) (4) and (b) (4)).

Work Instructions S-2 (*Product and Biological Indicator Sterility Testing*, v36.0) and M-8 (*Bioburden Determination Procedures*, v16.0) require that media be inspected for integrity and that only acceptable, undamaged containers be used. However, neither procedure establishes humidity requirements for incubation equipment used with (b) (4)-based plates, nor do they define corrective actions when media desiccation is observed during incubation.

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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."