DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	7/14/2025-7/30/2025* FEI NUMBER 3000233845

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David W. Bryant, SVP North America

FIRM NAME	STREET ADDRESS
Nelson Laboratories, LLC	6280 S Redwood Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Salt Lake City, UT 84123-6600	Testing 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 WE OBSERVED:

OBSERVATION 1

Specified requirements for in-process controls were not met.

Specifically, while reviewing amended test results, the following studies were not properly resulted ensuring that in-process controls were met:

Bioburden Testing

- (b) (4) had ten human tissue samples submitted for bioburden testing. Sample three (3) showed 4 cfu in the aerobic material, sample four (4) showed 12 cfu and sample one (1) showed 4 cfu growth in the anaerobic media. The client was contacted and confirmed that they wanted the organisms identified. The samples were transferred internally to the organism identification department. The department was unable to recover cells from the samples. As a result, the final bioburden report was amended to reflect that samples one (1) four (4) and three (3) showed no growth for their respective medias. The original report showed a bioburden average of <4.0 for the aerobic media and <8.1 for the anaerobic media. The amended report showed a bioburden average of <4.0 for aerobic media and a lower average of <7.3 for anaerobic media.

Sterility Testing

- (b) (4), human tissue rinsate (wash), had an amended test result from growth to no growth. The following was observed:
  - The test was initiated on August 14, 2023

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- A preliminary read was conducted on August 21, 2023. A secondary review was required. A secondary review stating that growth was visible in all (b) (4) was documented on August 30, 2023
- A final reading with one (b) (4) media showing positive, and the rest negative was documented on September 19, 2023.
- The final report with a positive result for the (b) (4) was sent to the client and the positive (b) (4) was internally transferred for organism identification on October 2, 2023
- The final report for gram stain and genetic testing showing that cells could not be recovered was reported on October 17, 2023
- A media transfer from the original positive (b) (4) of (b) (4) containing the sample was conducted on October 18, 2023
- The results stating the media transfer showed no growth was documented on October 23, 2023
- An amended report stating that the (b) (4) sample had no growth was sent to the client on October 30, 2023

- (b) (4), human tissue rinsate (wash), had an amended test result from growth to no growth. The following was observed:
  - The test was initiated on July 3, 2024
  - A preliminary read was conducted on July 10, 2024. A secondary review was required. A secondary review stating that growth was visible in all (b) (4) was documented on July 11, 2024

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- A final reading with one (b) (4) media showing positive, and the rest negative was documented on July 18, 2024.
- The final report with a positive result for the (b) (4) was sent to the client and the positive (b) (4) was internally transferred for organism identification on July 22, 2024
- The final report for gram stain and genetic testing showing that cells could not be recovered was reported on August 5, 2024
- An amended report stating that the (b) (4) sample had no growth was sent to the client on September 9, 2024.

Since 2023 your firm has conducted approximately:
- (b) (4) Bioburden tests on (b) (4) samples
- (b) (4) Sterility Assurance tests on (b) (4) samples

OBSERVATION 2
Records were not detailed as necessary to provide a complete history of work performed.

Specifically, during the review of SOP NEL-STP-0077 Product Sterility, dated November 7, 2024, we noted that section 19.3.4 states (b) (4) . During the review of (b) (4) data for (b) (4) , it was noted that one unit was marked for secondary review, (b) (4) . The (b) (4) data contained result comments for the secondary review ((b) (4)), however no result comments were documented for the initial preliminary review ((b) (4)) or the final review((b) (4)).

Since 2023, your firm has conducted approximately (b) (4) Sterility Assurance tests on (b) (4) samples.

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OBSERVATION 3

HCT/Ps were not processed in a way that does not cause contamination or cross contamination during processing and that does not increase the risk of introduction, transmission, or spread of communicable disease.

Specifically, while observing a testing procedure, the test was not performed in such a way as to prevent potential contamination of the article. The following was observed:

- On 7/16/2025, Lab Technician (b) (6), (b) (7)(C) conducted product sterility testing on 20 bone family samples received under (b) (4). During the process, Technician (b) (6), (b) (7) was observed performing the following:
  - Dropping bone pieces onto the surface of the Biological Safety Cabinet (BSC) hood during processing. (b) (4) In accordance with best practices, the technician (b) (4) (b) (4) BSC (b) (4), which included 20 samples. (b) (4) BSC (b) (4).
  - During this observation, your lab technician had to exit the clean room multiple times to (b) (4). At no point during the processing of 20 tissue samples did the technician (b) (4).

Since 2023, your firm has conducted approximately (b) (4) Sterility Assurance tests on (b) (4) samples.

OBSERVATION 4

The quality program has not established and maintained appropriate monitoring systems.

Specifically, procedures have not been established or maintained to ensure proper monitoring and control of Human Cells, Tissues, and Cellular and Tissue-Based Product (HCT/P) lot identification

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during testing. Your firm has failed to implement written procedures that are adequate to ensure accurate traceability of HCT/P lots. As a result, traceability was lost in Bioburden (b) (4), and Sterility (b) (4), compromising the ability to link test results to their corresponding tissue lots.

This lack of procedural control undermines the reliability of product release decisions and poses a risk to product quality and patient safety.

Since 2023, your firm has conducted approximately:

- (b) (4) Bioburden tests on (b) (4) samples
- (b) (4) Sterility Assurance tests on (b) (4) samples
- (b) (4) Endotoxin tests on (b) (4) samples

OBSERVATION 5

Procedures were not designed to prevent circumstances that increase the risk of communicable disease introduction, transmission and spread through the use of HCT/Ps.

Specifically, your firm receives tissue from (b) (4) tissue manufacturing facilities to include but are not limited to powders, gels, liquids, and whole tissue pieces. Incoming tissue type is not required on the sample submission form that accompanies the tissue to the laboratory. The disposition of tissue received is also not included on the incoming sample submission forms. During the review of SOP NEL-STP-0077 Product Sterility, dated November 7, 2024, we noted that the procedure lacks tissue-specific instructions for sterility testing performed by the firm. Neither the (b) (4) nor the NEL-STP-0077 Product Sterility procedure describe in detail how to complete sample transfer into the media for the different tissue types. These additional steps, which are inherent to tissue sample handling, are not addressed in any current Standard Operating Procedures or (b) (4).

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As a result of not having these additional steps, on 07/16/2025 we observed technician (b) (6), (b) (7)(C) use different types of sterile instruments when processing multiple samples of (b) (4), in a seeming attempt to adequately perform the assay.

Incoming tissue type and disposition is unknown – your firm receives multiple tissue types.

Since 2023, your firm has conducted approximately:

- (b) (4) Bioburden tests on (b) (4) samples
- (b) (4) Sterility Assurance tests on (b) (4) samples
- (b) (4) Endotoxin tests on (b) (4) samples

OBSERVATION 6

Environmental conditions existed in which contamination or cross contamination of HCT/Ps or equipment could occur, and environmental conditions were not adequately controlled.

Specifically, during the review of (b) (4), your firm identified an action level excursion in the (b) (4) floor on May 1, 2023, associated with the recovery of *Bacillus cereus*. The investigation, which spanned from May to October 2023, documented a progressive contamination event of a spread of *Bacillus cereus* throughout multiple classified cleanroom areas.

Although your firm implemented enhanced cleaning activities and modified disinfection procedures in response to repeated alert and action level excursions, environmental monitoring data continued to yield positive results for *Bacillus cereus* in critical areas. These included the ISO Class (b) (4) (b) (4) ISO Class (b) (4). The persistence of contamination suggests the cleaning and disinfection methods employed were ineffective in eradicating the microorganism or preventing its spread.

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While *Bacillus cereus* continued to be detected in environmental samples through July 2023, on June 2, 2023, internal email communication from staff member (b) (6), (b) (confirmed *Bacillus cereus* was also recovered from product samples. Despite these findings, sterility testing of products continued across cleanroom areas until corrective actions were completed on October 10, 2023.

In addition, internal communications included in the investigation identified significant personnel training deficiencies. (b) (4)

Since 2023, your firm has conducted approximately (b) (4) Sterility Assurance tests on (b) (4) samples.

OBSERVATION 7

The quality program has not ensured the proper training and education of personnel involved in core GTP activities.

Specifically, personnel responsible for performing sterility testing and cleaning were observed to lack documented, tissue-specific training related to the proper handling of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).

During review of records and observational walk-throughs, deficiencies were noted in employees' ability to carry out routine duties for which they were reportedly trained, including the incomplete cleaning of spills in classified cleanroom areas and improper handling of quarantined media lots. These gaps indicate that the firm has not ensured personnel possess the education, training, and experience necessary to perform their functions in compliance with established procedures and current good tissue

practices.

Since 2023, your firm has conducted approximately:

- (b) (4) Bioburden tests on (b) (4) samples
- (b) (4) Sterility Assurance tests on (b) (4) samples
- (b) (4) Endotoxin tests on (b) (4) samples

OBSERVATION 8

In-process inspections, tests, or other verification activities and approvals were not documented.

Specifically, while reviewing test results the following was observed:

Endotoxin Testing

- On 05/21/2025, Bacterial Endotoxin Test (BET) (b) (4) had two samples from (b) (4) (b) (4) and one sample from (b) (4) that resulted with the %CV values above the acceptability limit (b) (4). Procedure NEL-STP-0046 "Bacterial Endotoxins Test" states, (b) (4)

  A new test was not performed. The data was reviewed and accepted by the study director on 05/27/2025 and the results were sent to the clients on the same day.

- (b) (4), two devices were combined and tested in a (b) (4) solution during Bacterial Endotoxin Testing, however, the validation test method specifies the use of one device per (b) (4). The pooling of two devices in the (b) (4), violating the established test parameters. Despite this deviation, the results were reported to the client and considered valid.

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Bioburden

- (b) (4), during bioburden testing for (b) (4), unique donor identifiers were not tracked in the raw data. As a result of this loss of traceability, test results were reported using only the unit numbers assigned by the laboratory, rather than the original donor identifiers. Growth was observed in one of the ten units tested, but this positive result could not be tied back to a specific donor. You concluded that this traceability issue does not affect the overall validity of the bioburden results.

Since 2023, your firm has conducted approximately:
- (b) (4) Bioburden tests on (b) (4) samples
- (b) (4) Endotoxin tests on (b) (4) samples

OBSERVATION 9

Each lot of components was not appropriately identified as to its status in terms of being quarantined, approved or rejected.

Specifically, on 7/23/2025, during review of NEL - FRM-0211 (Steam Sterilizer Log and Cycle Review) the following was observed:

- (b) (4) underwent an out-of-specification (OOS) sterilization cycle on (b) (4), which exceeded the validated cycle duration by 33 minutes and 11 seconds. Upon inquiry, (b) (6), (b) (6), (b) (7)(C) indicated that this lot was in quarantine pending QC review and release. However, the media was found (b) (4) —not in a designated, clearly labeled quarantine area, nor secured in a (b) (4) to prevent premature access or use. The lack of appropriate labeling and physical controls compromised the integrity of the quarantine process.

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- (b) (4) underwent an out-of-specification (OOS) sterilization cycle on (b) (4), exceeding the chamber temperature limit by 2.4°C. Upon inquiry, (b) (6), (b) (7)(C) stated that the lot was in quarantine pending QC review and release. The lot was observed (b) (4) however, no documentation was available, as required by procedure, to indicate the quarantine status of the lot. The absence of proper documentation and reliance solely on physical labeling compromised the integrity and control of the quarantine process.

Since 2023, your firm has conducted approximately:
- (b) (4) Bioburden tests on (b) (4) samples
- (b) (4) Sterility Assurance tests on (b) (4) samples

OBSERVATION 10
Laboratory records are deficient in that they do not include a complete record of all data obtained during testing.

Specifically, during the review of (b) (4) data for (b) (4) (human amniotic fluid), it was noted that two units were marked for secondary review, unit (b) (4). The (b) (4) data contained result comments from the initial reviewer for unit (b) (4)). No result comments from the initial reviewer were documented for unit (b) (4) as required by the firm's sterility procedure (SOP NEL-STP-0077 Product Sterility).

Since 2023, your firm has conducted approximately (b) (4) Sterility Assurance tests on (b) (4) samples.

OBSERVATION 11
Deviations from written production and process control procedures are not justified.

Specifically, during the review of SOP NEL-STP-0077 Product Sterility, dated November 7, 2024, we

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noted that section 19.3.4 states (b) (4) . The following was observed during document review:

(b) (4) had a human amniotic fluid product (unit [b]) test show a potentially positive result for the (b) (4) media. A secondary review was required for the media type. The initial read for the (b) (4) by the technician requesting the secondary review stated, "media is clear but has floaties." The secondary reviewer stated, "media is not turbid and does not have sediment or other signs of growth." The secondary review did not address the "floaties" that the initial reviewer saw, and a media transfer was not performed. The (b) (4) result was reported out as negative.

Since 2023, your firm has conducted approximately (b) (4) Sterility Assurance tests on (b) (4) samples.

***DATES OF INSPECTION**

7/14/2025(Mon), 7/15/2025(Tue), 7/16/2025(Wed), 7/17/2025(Thu), 7/18/2025(Fri), 7/21/2025(Mon), 7/22/2025(Tue), 7/23/2025(Wed), 7/25/2025(Fri), 7/28/2025(Mon), 7/30/2025(Wed)

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: Not annotated

Observation 4: Not annotated

Observation 5: Not annotated

Observation 6: Not annotated

Observation 7: Not annotated

Observation 8: Not annotated

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Annotations to Observations

Observation 9: Not annotated

Observation 10: Not annotated

Observation 11: Not annotated

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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."