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.:Nicole Li Telephone: 240-402-8562 Industry Information: www.fda.gov/oc/industry	May 12 - 14, 2025 FEI NUMBER 3006369552

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Elizabeth A. Chipala, Laboratory Manager

FIRM NAME	STREET ADDRESS
Premier Laboratory, LLC	1567 Skyway Drive, Unit E
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Longmont, CO 80504	Contract testing facility

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. Management of deviations, out-of-specifications (OOS), and corrective and preventive actions (CAPAs) is inadequate. For example:

   a. In Section 12.7 of (b) (4)-0013.11, client (b) (4) is to be notified as soon as possible of any issues with staining events through email or fax. However, DEV-24-006 indicates that the deviation was notified to client (b) (4) 14 days after discovery. This deviation was related to use of an incorrect antibody concentration that affected 27 of client (b) (4)'s studies initiated from January 17, 2024 to May 23, 2024. Client (b) (4) classified the deviation as (b) (4).

   b. Written procedures are not established to monitor or trend OOS to re-initiate a CAPA. For example, QA-0018.5.01, CAPA Effectiveness and Deviation Trend Review performed on August 27, 2024, indicates corrective action performed by CAPA-23-002 to address OOS-23-001 for non-specific staining during (b) (4) staining did not resolve the issue as the same root cause was identified in OOS-23-005, and the CAPA effectiveness proposed to monitor the issue for further action.

   c. The entries in logbooks are not in chronological order and predate the issuance of the logbooks. For example:
      i. QA-0018.4.01, Corrective and Preventative Action Log, Volume 2 was issued on October 25, 2023. The second CAPA entry in the logbook was for CAPA-23-010 that was opened on October 20, 2023, which predates the logbook's date of issuance.
      ii. The initial entry of QA-0018.4.01, Corrective and Preventative Action Log, Volume 2 was for CAPA-23-009 and the date opened was identified as February 22, 2024, for an internal equipment audit. However, the subsequent entry of CAPA-23-010 was opened on October 20, 2023, for an audit of Premier Laboratory. Therefore, the second entry predates the first entry by four months. On May 13, 2025, Quality Assurance (QA) discovered an operator had input the wrong open date for CAPA-23-009, which was actually opened on December 20, 2023. The second entry still predates the first entry by two

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months, and the entries are not in chronological order.

d. QA-0018.02, Deviations and CAPAs states to initiate a deviation no more than (b) (4) from the date of discovery. However, initiation of deviations occurs beyond the (b) (4) from the date of discovery. For example:
   i. DEV-23-006 was initiated seven days after awareness on March 30, 2023, following email notification on March 23, 2023 from client (b) (4) that the wrong lot number for the (b) (4) was used to label the file.
   ii. DEV-24-006 was initiated on May 28, 2024, which was seven days after the awareness date of May 21, 2024, that related to the use of an incorrect (b) (4) antibody concentration.
   iii. DEV-23-003 was initiated on March 15, 2023, for failing to complete preventive maintenance (PM) within the due date for the (b) (4) Slide Scanner and Dako Autostainer (b) (4) The March 15, 2023 deviation initiation date occurred after the PM for the slide scanner was performed late. Specifically, the slide scanner's PM was due on December 23, 2022 but was performed on February 23, 2024, two months later. Additionally, the autostainer's PM was due on January 19, 2023 but was performed on April 6, 2023, three months later.

e. QA-0018.02, Deviations and CAPAs states that a deviation or CAPA target due date can be extended. However, the procedure does not specify the extension process including the duration and number of extensions. For example, CAPA-23-004 included an extension, but the request for the extension on August 17, 2023 occurred after the initial target date of July 31, 2023, and the CAPA was closed on January 24, 2024, after the extended due date of January 5, 2024.

f. QA-0018.02, Deviations and CAPAs specifies that (b) (4) QA reviews the CAPAs to assess the effectiveness of CAPAs. However, the (b) (4) timeframe is inadequate. For example, during the nine months CAPA-23-004 remained open, OOS-23-003 and OOS-23-004 occurred and were closed for non-specific staining during (b) (4) staining for purity testing of (b) (4) and the same root cause was attributed to both OOS.

g. QA-0018.02, Deviations and CAPAs specifies that (b) (4) QA reviews unplanned deviation logs to identify deviation trends. However, written procedures are not established to define the number of

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deviations that would be considered a trend.

2. Quality oversight is inadequate to assure (b) (4) has the identity and purity it purports or is represented to possess. For example:

   a. Written procedures for QA's final review of documentation associated with batches for histology sample preparation, staining, and scanning for the identity and purity tests for (b) (4) are not established.

   b. Quality does not have control of work instructions (WIs). For example,
      i. No document control is performed on WIs. There are five work instructions (WI(b) (4)-0017.00, WI-(b) (4)-0019.00, WI-(b) (4)-0021.00, WI-(b) (4)-0025.01, and WI-(b) (4)-0026.01) that are associated with client (b) (4) 's study, but none of the work instructions have been reviewed or approved by QA.
      ii. No documentation for revision history is performed for revised WIs. For example, procedure #16 of WI-(b) (4)-0026.01 was inserted with yellow highlights without a revision history to include timing of preparation and equilibrium time for reagents based on (b) (4), which was related to non-specific binding of (b) (4) antibody.
      iii. On May 13, 2025, the Laboratory Manager stated that an operator can change WI-(b) (4)-0026.01 without any quality oversight. Additionally, the operator overwrote the previous version of WI-(b) (4)-0026.01.
      iv. WI-(b) (4)-0026.01 is not referenced by the corresponding standard operation procedure, (b) (4)-0008.14.

   c. (b) (4) Schedule, which is a spreadsheet used to track all studies including testing of (b) (4) (b) (4) is accessible to operators, and new entries can remain uncontrolled for approximately (b) (4).

3. Good manufacturing practice training is not conducted on a continuing basis to assure employees remain familiar with Current Good Manufacturing Practice (CGMP) requirements applicable to them. For example:

   a. As of May 12, 2025, "GLP, GMP, QSR Training" has not been completed according to (b) (4)-0010.1.01 Employee Training Plan, established for the Laboratory Aide/Archivist who was hired in (b) (6), (b) (7)(C)

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b. Annual CGMP is not provided nor required for all analysts who conduct identity and purity release tests for (b) (4)

4. Management of suppliers and service providers is deficient. For example:

a. Suppliers of critical materials (e.g., laminin antibody for the identity release test for (b) (4) (b) (4) have not been qualified, and the critical materials continue to be used for identity and purity release tests for (b) (4) Planned deviation PD-24-004 was opened on February 19, 2024, to track and ensure supplier approvals occur over time. PD-24-004 had a target closure date of January 3, 2025, which is an 11-month duration. However, PD-24-004 remained open as of May 14, 2025, which has an approximately 15-month opening period from initiation, and no extensions were documented.

b. The (b) (4) spreadsheet provided on May 11, 2025, for current suppliers associated with identity and purity testing of (b) (4) did not include the service provider for the preventive maintenance of the (b) (4) that are used for (b) (4) sample thaw and (b) (4).

c. (b) (4)-0001.01, Purchase Controls and Management specifies that suppliers will be reassessed every (b) (4) (b) (4) However, the frequency or extent of control and reassessment is not based on criticality, or the products or services provided.

5. Equipment is not qualified or monitored for its intended use. Specifically, refrigerators/freezers system numbers (b) (4) and (b) (4) and ultra-low (UTL) freezer system number (b) (4) were not qualified and are not continuously monitored. Critical reagents used for the identity and purity release tests for (b) (4) (b) (4) are stored in refrigerators/freezers system numbers (b) (4) and (b) (4) samples and antibody aliquots for the identity and purity release tests for (b) (4) are stored in UTL freezer system number (b) (4).

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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 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."