

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

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| DISTRICT ADDRESS AND PHONE NUMBER<br>US Customhouse Rm900 200 Chestnut St<br>Philadelphia, PA 19106<br>(215) 597-4390 Ext:4200 Fax: (215) 597-0875 | DATE(S) OF INSPECTION<br>4/8/2026-4/14/2026*<br><br>FEI NUMBER<br>3006799640 |
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| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED<br>Zhongping (John) Lin, Ph.D., Co-CEO |
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|--------------------------------------------------------|-------------------------------------------------------------|
| FIRM NAME<br>Frontage Laboratories, Inc.               | STREET ADDRESS<br>700 Pennsylvania Dr                       |
| CITY, STATE, ZIP CODE, COUNTRY<br>Exton, PA 19341-1129 | TYPE ESTABLISHMENT INSPECTED<br>Contract 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 I OBSERVED:**

**OBSERVATION 1**

Written records of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

Specifically, laboratory investigations into aberrant or Out of Specification (OOS) results were not conducted thoroughly to identify root cause(s). Investigations failed to identify potential sources of the OOS results and insufficient justifications were provided to explain the observed aberrant test results. For example, laboratory OOS investigation #02LINV-166 was initiated for observed (b) (4) assay value of 112.5%, outside the specification limit of (b) (4) %. Retesting performed by (b) (4), (b) (4) reported (b) (4) values of 96.0% and 102.1%. The laboratory OOS investigations did not identify potential root causes for the initial OOS result and no justifications were provided for the high (~6%) testing variabilities observed during the retesting by the (b) (4). As no root cause(s) were identified, no CAPAs were implemented to prevent reoccurrence.

**OBSERVATION 2**

Laboratory records do not include a complete record of all data secured in the course of each test, including all charts and spectra from laboratory instrumentation, properly identified to show the.

Specifically, generated electronic data from your (b) (4) laboratory instruments are not controlled to ensure security and integrity. For example,

A. Original electronic data stored on the (b) (4) of the (b) (4) instrument was able to be modified and deleted with the Windows File Explorer. During the data integrity demonstrations on the instrument computer, analytical data file names for previously analyzed samples were able to be modified with the Windows File Explorer. Additionally, the demonstrations revealed original data files could be deleted from the instrument file folders by the manager level users. Deleted files were recovered in the system Recycle Bin and restored. As per the site management, the instrument software "(b) (4)" was identified as 21 CFR Part-11 Compliant.

B. (b) (4) Analyzer instrument (b) (4) was not configured to maintain security and integrity of the generated electronic data. Electronic data on the instrument computer was not restricted to prevent modifications and the

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| <b>SEE REVERSE<br/>OF THIS PAGE</b> | EMPLOYEE(S) SIGNATURE<br>Junho Pak, Investigator | Junho Pak<br>Investigator<br>Signed By: 2000578589<br>Date Signed: 04-14-2026<br>14:02:11<br><br>X | DATE ISSUED<br>4/14/2026 |
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previously analyzed data on the instrument computer and the data was able to be modified with the instrument software, (b) (4) During the demonstration, file name on the instrument computer was changed by a standard user, using the instrument software, (b) (4)

**OBSERVATION 3**

Failure to maintain a backup file of data entered into the computer or related system.

Specifically, (b) (4) system backup of electronic data from the (b) (4) UV-VIS Spectrophotometer was not executed for (b) (4) and the firm's IT group failed to take corrective actions for the identified data backup failures, as defined in the written procedure. According to the system logs, the last successful (b) (4) data backup was executed on March 30, 2026. At time of the facility walkthrough on April 8, 2026, the instrument computer was observed to have been powered off, in contrary to the label on the instrument, "DO NOT TURN OFF THIS COMPUTER".

**OBSERVATION 4**

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

Specifically, the (b) (4) Microbial Limits/Bioburden testing procedure do not contain sufficient control to ensure (b) (4) have reached the required (b) (4), prior to use. There are no defined methods to identify the (b) (4) of the (b) (4) and insufficient controls to ensure sufficient (b) (4). Exceeding the (b) (4) requirements could destroy/attenuate the microorganisms on test, resulting in reduced or false negative test results.

**\*DATES OF INSPECTION**

4/08/2026(Wed), 4/09/2026(Thu), 4/10/2026(Fri), 4/13/2026(Mon), 4/14/2026(Tue)

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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."