DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	3/18/2026-3/20/2026
	FEI NUMBER 3009255642

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David L. Exline, President

FIRM NAME	STREET ADDRESS
Gateway Analytical, LLC	2009 Kramer Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Gibsonia, PA 15044-9631	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

Written procedures are not followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

Your firm failed to maintain critical storage equipment including your (b) (4) freezer, ID (b) (4), which is used to store analytical samples provided by your customers. (b) (4) preventative maintenance for - (b) (4) freezer, ID (b) (4), was not completed by the required due date of December 31, 2025. Your firm's deviation, DEV-25-008-GA, postponed the required maintenance until April 30, 2026. To date, there have been multiple temperature excursions exceeding the acceptable limits (b) (4) with freezer (b) (4) reaching temperatures as high as -59.00°C for an excursion lasting over 55 minutes per Alarm Report from September 2025 – December 2025. Your firm has no scientific justification for the delay in the preventative maintenance or failing to replace or use working critical storage equipment for the storage of test samples.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Kara J Wright, Investigator X Kara J Wright Investigator Signed By: 2004338119 Date Signed: 03-20-2026 15:13:29	3/20/2026

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."