

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

DISTRICT ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900	DATE(S) OF INSPECTION 3/2/2026-3/17/2026* FEI NUMBER 2246907
--	---

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Bruce J. Gollob, Chief Executive Officer (CEO)

FIRM NAME Atlantic Analytical Laboratories LLC	STREET ADDRESS 291 UU Highway 22 East, Buiding 1 & 2
CITY, STATE, ZIP CODE, COUNTRY Whitehouse, NJ 08888	TYPE ESTABLISHMENT INSPECTED 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

The suitability of all testing methods is not verified under actual conditions of use.

- A. Your firm failed to complete Analytical Method Verification Studies for the following USP methods used to test (b) (4) :
- Assay: (b) (4)
 - Impurities ((b) (4)): *Impurities Testing in (b) (4)*
(b) (4)
 - Example: (b) (4) USP (b) (4) Lot#(b) (4)
- B. Your firm failed to complete Analytical Method Verification Studies for the following USP methods used to test (b) (4) :
- Assay: (b) (4)
 - Impurities ((b) (4) , and (b) (4)): *Impurities Testing in (b) (4)*
(b) (4)
 - Example: (b) (4) USP (b) (4) BN#(b) (4)
- C. Your firm failed to complete Analytical Method Verification Studies for the following compendial methods used to test (b) (4) ((b) (4))
- Assay: *Chromatography <621>*
 - Example: (b) (4) Tank# (b) (4) , QC# (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jessica S Estriplet, Investigator	DATE ISSUED 3/17/2026
	Jessica S Estriplet Investigator Signed By: Jessica S. Estriplet-S Date Signed: 03-17-2026 15:44:14 X	

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054
(973) 331-4900

DATE(S) OF INSPECTION

3/2/2026-3/17/2026*

FEI NUMBER

2246907

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Bruce J. Gollob, Chief Executive Officer (CEO)

FIRM NAME

Atlantic Analytical Laboratories LLC

STREET ADDRESS

291 UU Highway 22 East, Buiding 1 & 2

CITY, STATE, ZIP CODE, COUNTRY

Whitehouse, NJ 08888

TYPE ESTABLISHMENT INSPECTED

Contract Testing Laboratory

***DATES OF INSPECTION**

3/02/2026(Mon), 3/06/2026(Fri), 3/17/2026(Tue)

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Jessica S Estriplet, Investigator

Jessica S Estriplet
Investigator
Signed By: Jessica S. Estriplet -S
Date Signed: 03-17-2026
15:44:14

X

DATE ISSUED

3/17/2026

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."