DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900	5/18/2026-5/21/2026
	FEI NUMBER 2246393

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Patricia O. Griffin, Laboratory Director

FIRM NAME	STREET ADDRESS
EMSL Analytical, Inc. DBA MPL Laboratories	12 Wilson Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sparta, NJ 07871-3400	Control 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

The accuracy, sensitivity, specificity and reproducibility of test methods have not been established and documented.

Specifically,

A. Specifically, suitability testing was not performed as required by USP General Chapters <60>, <61>, <62> for test methods used to test drug products, such as: (b) (4) (b) (4) . You did not establish and document that the test methods are suitable for their intended use prior to testing drug products, as required by the referenced USP chapters.

B. Specifically, method transfer was not performed or documented for client-specific test methods used to test unidentified drug products. No method transfer protocol, acceptance criteria, or completed method transfer report was available for review for Method MP 035, Microbiological Examination of Cosmetic Products, and there is no documented evidence that these methods were verified to perform equivalently at this laboratory prior to use in testing drug products.

OBSERVATION 2

Routine calibration, inspection and checking of automatic, mechanical and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Anthony J Donato, Investigator Emmanuel T Donyina, Investigator Jenny Sung, Investigator	X Anthony J Donato Investigator Signed By: 2003042872 Date Signed: 05-21-2026 15:41:58	5/21/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900	5/18/2026-5/21/2026
	FEI NUMBER 2246393

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Patricia O. Griffin, Laboratory Director

FIRM NAME	STREET ADDRESS
EMSL Analytical, Inc. DBA MPL Laboratories	12 Wilson Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sparta, NJ 07871-3400	Control Testing Laboratory

A. Your firm uses (b) (4) a computerized software system, to design and print labels for incoming samples received by the microbiology laboratory. As of the date of this inspection, your firm has not established a written program to assure the proper performance of this system. No validation or software assurance activities have been conducted to demonstrate that (b) (4) consistently and accurately produces labels that conform to required sample identification specifications, including correct sample name, lot number, date of receipt, and other required identifying information. No documentation was available for review to demonstrate that (b) (4) is fit for its intended use in microbiology laboratory sample labeling operations.

B. The Performance Qualification (PQ) for Incubator 808 is inadequate in that loading configuration parameters were not established. Specifically, the PQ documented the number of plates used during the load study; however, plate spacing was not defined. During the inspection, a firm investigation was reviewed documenting a temperature excursion that occurred during routine use of Incubator 808. The firm's investigation determined that the temperature excursion was attributed to plates being placed too close together during loading. The qualification does not address plate spacing requirements necessary to ensure temperature uniformity under actual production loading conditions.

OBSERVATION 3

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

A. Your firm uses an unvalidated Microsoft Excel spreadsheet as an active, controlled record to manage the Receiving Sample Log for the microbiology laboratory. As of the date of this inspection, this spreadsheet is not validated for its intended use, contains no audit trail, and is not secured against unauthorized alteration, erasure, or loss. Any user with access to this file can add, modify, or delete

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900	5/18/2026-5/21/2026
	FEI NUMBER 2246393

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Patricia O. Griffin, Laboratory Director	
FIRM NAME EMSL Analytical, Inc. DBA MPL Laboratories	STREET ADDRESS 12 Wilson Dr
CITY, STATE, ZIP CODE, COUNTRY Sparta, NJ 07871-3400	TYPE ESTABLISHMENT INSPECTED Control Testing Laboratory

entries without detection, as there is no mechanism to record who made changes, what was changed, or when changes occurred. Your firm has not established appropriate controls over this computerized system to assure that records are accurate, complete, and protected from unauthorized modification.

Furthermore, entries into the Receiving Sample Log are not recorded contemporaneously at the time of sample receipt. Instead, entries are made at (b) (4) after all samples have been received. Additionally, completed Receiving Sample Log pages are printed and stored in an unbound notebook, which does not prevent the removal, replacement, or substitution of pages.

X Jenny Sung
Investigator
Signed By: 2003619391
Date Signed: 05-21-2026 15:43:00

X Emmanuel T Donyina
Investigator
Signed By: Emmanuel T. Donyina -S
Date Signed: 05-21-2026 15:44:00

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."