DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	5/26/2026-5/29/2026
	FEI NUMBER 3001452367

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Scott E Afton, Senior Director, Site Lead

FIRM NAME	STREET ADDRESS
Pace Analytical Life Sciences, LLC	1311 Helmo Ave N
CITY, STATE, ZIP CODE, COUNTRY Oakdale, MN 55128-6023	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 WE OBSERVED:

Facilities & Equipment

OBSERVATION 1

Input to and output from related systems of formulas and records or data are not checked for accuracy.

Specifically,

1. You failed to establish adequate backup systems and procedural controls to ensure the continued proper performance of your stability chambers and to prevent the loss, compromise, or exposure of pharmaceutical stability samples to unacceptable conditions. This was evidenced by a freezer compressor failure, the absence of a formal backup response procedure, and a second temperature excursion that occurred before corrective actions were fully implemented.

   Excursion Event Report (EER) 1706 dated February 9, 2026, resulting in the initiation of Deviation 7164 (March 13, 2026). Although a CAT 3911 (March 23,2026) was initiated, it remains in draft status. You stated that training was conducted "shortly" after the SOP and training procedure were revised as part of the immediate corrective action; however, no training records were available to demonstrate that this action was implemented.

   Since Feb 2026, you have had 8 freezer excursions as listed below:

DEV #	Date Opened	(b) (4)/Protocol Affected	Equipment	Status
DEV 7170	3/17/2026	(b) (4)	Chamber	Open
DEV 7128	2/23/2026		Freezer	Open
DEV 7126	2/23/2026		Freezer	Open

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	5/26/2026-5/29/2026 FEI NUMBER 3001452367

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Scott E Afton, Senior Director, Site Lead

FIRM NAME	STREET ADDRESS
Pace Analytical Life Sciences, LLC	1311 Helmo Ave N
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Oakdale, MN 55128-6023	Contract Testing Laboratory

DEV 7164	3/13/2026	(b) (4)	Freezer #5412	Open
DEV 7193	3/24/2026		Freezer	Open
DEV 7200	3/26/2026		Freezer	Open
DEV 7274	4/22/2026		Freezer	Open
DEV 7205	3/27/2026		PLS 4162	Open

Laboratory

OBSERVATION 2

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

Specifically,

1. From May 2024 through May 2026, of the 162 deviations recorded, over 100 deviations — including DEV-6744, DEV-6198, and DEV-6189 — were recorded for documentation related failures including but not limited to: accurately documenting data, time points, required information, or critical testing steps. At least three corrective actions (CATs 3687, 3664, and 3878) were implemented to address documentation errors from multiple different analysts during this time frame.

2. Laboratory records are not attributable to the person performing the GMP testing activity. Specifically, despite implementing CAT 3693 (opened August 6, 2024; training intervention completed December 3, 2024; closed as effective May 30, 2025), which trained analysts on ALCOA+ principles and SOP 41, "Network Security and Access Control," Version 13, effective February 7, 2022, deviations for unattributable laboratory records continued to be recorded.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	5/26/2026-5/29/2026
	FEI NUMBER 3001452367

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Scott E Afton, Senior Director, Site Lead	
FIRM NAME Pace Analytical Life Sciences, LLC	STREET ADDRESS 1311 Helmo Ave N
CITY, STATE, ZIP CODE, COUNTRY Oakdale, MN 55128-6023	TYPE ESTABLISHMENT INSPECTED Contract Testing Laboratory

DEV-6595, DEV-6686, DEV-6765, and DEV-6920 were recorded after CAT 3693 was closed as effective.

3. Multiple deviations were recorded for breaches in client data confidentiality and inadequate controls over the review, release, and distribution of laboratory records, without corrective action being taken. Only after receiving COMP-093 (opened September 25, 2025; closed January 14, 2026), in which a client method was revised and approved by another client, was corrective action (CAT 3887) initiated. CAT 3887 was closed on December 30, 2025. Subsequently, DEV-7162 (March 13, 2026), in which an unrelated project log was included in a client data packet identified during a client audit, and DEV-7166 (March 16, 2026), in which a data report file was made accessible to the wrong client, were recorded.

X Kelly M Bromley
Investigator
Signed By: Kelly M. Bromley -S
Date Signed: 05-29-2026 15:35:21

X Elizabeth R Bloom
Investigator
Signed By: ELIZABETH R. BLOOM -S
Date Signed: 05-29-2026 15:35:53

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Beatrix D Hippe, Investigator
Elizabeth R Bloom, Investigator
Kelly M Bromley, Investigator

X Beatrix D Hippe
Investigator
Signed By: BEATRIX D. HIPPE -S
Date Signed: 05-29-2026
18:34:51

DATE ISSUED
5/29/2026

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."