

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2010033	(X3) Date Survey Completed 12/23/2024
Name of Provider or Supplier Salerno Complementary Medicine Pllc	Street Address, City, State 345 East 37th Street, Suite 208, New York, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of Centers for Medicare & Medicaid Services (CMS) Proficiency Testing (PT) Certification and Survey Provider Enhanced Reporting system (CASPER 0155D), Standard Operating Procedures (SOPs), lack of proficiency testing (PT) records as well as interview with Testing Personnel (TP), the laboratory failed to enroll in an approved PT program for the general immunology specialty. FINDINGS: 1. The laboratory performed on-site allergy panel laboratory testing and result reporting. 2. There was no documentation of general immunology PT performance or results for calendar years 2023 and 2024. 3. The current, approved SOPs did not include instructions for performing such activity. 4. The TP confirmed the findings on December 23, 2024, at approximately 3:30 P.M.</p>
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p>

This CONDITION is not met as evidenced by:
Based on review of CMS PT CASPER 0155D, SOPs, lack of PT records, and interview with the TP, the laboratory director (LD) failed to provide overall management and direction of the laboratory services. Refer to D6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on review of CMS PT CASPER 0155D, SOPs, lack of PT records, and interview with the TP, the LD failed to ensure successful participation in an HHS approved proficiency testing program.