

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D2010033	<b>(X3) Date Survey Completed</b>  10/16/2019
<b>Name of Provider or Supplier</b>  Salerno Complementary Medicine Pllc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2016</b>	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a proficiency testing (PT) desk review of the Center for Medicare and Medicaid Services (CMS) PT reports and PT records from the American Proficiency Institute (API) PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the sub-specialty Endocrinology and the test analytes Free Thyroxine (FT4) and Thyroid Stimulating Hormone (TSH) The following scores were assigned: sub-speciality Endocrinology 2019 first event = 0% [non-participation] 2019 second event = 100% 2019 third event = 60% FT4 2019 first event = 0% [non-participation] 2019 second event = 100% 2019 third event = 0% TSH 2019 first event = 0% [non-participation] 2019 second event = 100% 2019 third</p>

	<p>event = 20% This is considered unsuccessful PT performance. Refer to D2107 and 2108.</p>
<b>D2075</b>	<p><b>GENERAL IMMUNOLOGY</b> CFR(s): 493.837(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a PT desk review of the CMS PT reports and PT records from the API PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the test analyte AFP (Tumor Marker). The following scores were assigned: 2019 first event = 0% [non-participation] This is considered unsatisfactory PT performance</p>
<b>D2076</b>	<p><b>GENERAL IMMUNOLOGY</b> CFR(s): 493.837(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on a PT desk review of the CMS PT reports and PT records from the API PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the test analytes specialty General Immunology. The following scores were assigned: 2019 first event = 50% This is considered unsatisfactory PT performance</p>
<b>D2093</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a PT desk review of the CMS PT reports and PT records from the API PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the speciality Chemistry and the test analytes Creatine Kinase Isoenzyme (CK-MB) and Total Iron (T Fe),. The following scores were assigned: 2019 first event = 0% [non-participation] This is considered unsatisfactory PT performance.</p>
<b>D2104</b>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p>

	<p>This STANDARD is not met as evidenced by: Based on a PT desk review of the CMS PT reports and PT records from the API PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the test analytes Cortisol and HCG. The following scores were assigned: 2019 first event = 0% [non-participation] This is considered unsatisfactory PT performance</p>
<p><b>D2107</b></p>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) desk review of the Center for Medicare and Medicaid Services (CMS) PT reports and PT records from the American Proficiency Institute (API) PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the test analytes Free Thyroxine (FT4) and Thyroid Stimulating Hormone (TSH) The following scores were assigned: FT4 2019 first event = 0% [non-participation] 2019 second event = 100% 2019 third event = 0% TSH 2019 first event = 0% [non-participation] 2019 second event = 100% 2019 third event = 20% This is considered unsuccessful PT performance.</p>
<p><b>D2108</b></p>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) desk review of the Center for Medicare and Medicaid Services (CMS) PT reports and PT records from the American Proficiency Institute (API) PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the sub-specialty Endocrinology. The following scores were assigned: sub-speciality Endocrinology 2019 first event = 0% [non-participation] 2019 second event = 100% 2019 third event = 60% This is considered unsuccessful PT performance.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> 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> <p>This CONDITION is not met as evidenced by:</p>

Based on PT desk review of the PT CMS data reports and API PT program records, the laboratory director failed to fulfill the laboratory director's responsibilities and ensure that the laboratory achieved a satisfactory performance and successfully participate in a PT program, for the specialties General Immunology, Chemistry and sub-specialty Endocrinology and the test analytes FT4, TSH, Cortisol, HCG, AFP (Tumor Marker), TIBC, T Fe and CK-MB. 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 PT desk review of the PT CMS data reports and API PT program records, the laboratory director failed to fulfill the laboratory director's responsibilities and ensure that the laboratory achieved a satisfactory performance and successfully participate in a PT program, for the test analytes FT4, TSH, Cortisol, , HCG, CK-MB, T Fe, TIBC, AFP (Tumor Marker) and the specialties General Immunology, Chemistry and sub-specialty Endocrinology. The following scores were assigned: sub-specialty Endocrinology 2019 first event = 0% [non-participation] 2019 second event = 100% 2019 third event = 60% FT4 2019 first event = 0% [non-participation] 2019 second event = 100% 2019 third event = 0% TSH 2019 first event = 0% [non-participation] 2019 second event = 100% 2019 third event = 20% This is considered unsuccessful PT performance. General Immunology 2019 first event = 50% AFP (Tumor Marker) 2019 first event = 0% [non-participation] Cortisol and HCG 2019 first event = 0% [non-participation] Chemistry and CK-MB, T Fe and TIBC 2019 first event = 0% [non-participation] This is considered unsatisfactory PT performance