

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0067526	(X3) Date Survey Completed 04/09/2021
Name of Provider or Supplier New England Dermatology, Pc	Street Address, City, State 3455 Main St, Springfield, MA	
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
D0000	A CLIA recertification survey was conducted for the New England Dermatology, PC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing review and interview, the laboratory failed to properly document the handling of proficiency testing samples as evidenced by the following: a) The laboratory is enrolled in a Physician Performed Microscopy Procedure (PPMP) module through the American Association of Bioanalysts (AAB). A review of proficiency testing records for calendar years 2019 and 2020 (6 testing events) revealed the fact that the program report forms and the attestation statements provided by the proficiency testing program were not maintained for five (5) of the six (6) proficiency testing events reviewed (testing events 1, 2, 3 for 2019 and testing events 1 and 3 for 2020). In addition a copy of the program reports for each testing event was not available for three (3) of six (6) testing events (testing event 3 for 2019 and testing events 2 and 3 for 2020). b) The executive director interviewed on 4/9/21 at 11:20</p>

	<p>AM confirmed that the program report forms and the attestation statements for the above events were not completed by the laboratory director and the laboratory technologist. .</p>
<p>D3037</p>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing review and interview, the laboratory failed to retain all proficiency testing records for at least 2 years as evidenced by the following: a) The laboratory is enrolled in a Physician Performed Microscopy Procedure (PPMP) module through the American Association of Bioanalysts (AAB). A review of proficiency testing records for calendar years 2019 and 2020 (6 testing events) revealed the fact that the final PT report issued, by the PT service, evaluating the submitted test results was not available for three (3) of six (6) testing events (testing event 3 for 2019 and testing events 2 and 3 for 2020). b) The executive director interviewed on 4/9/21 at 11:20 AM confirmed that the final PT reports were not available.</p>
<p>D5211</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: . Based on proficiency testing (PT) review and interview, the laboratory failed to maintain documentation to verify that a review and evaluation of PT results was performed as specified in subpart H of this part as evidenced by the following: a) The laboratory is enrolled in a Physician Performed Microscopy Procedure (PPMP) module through the American Association of Bioanalysts (AAB). A review of proficiency testing records for calendar years 2019 and 2020 (6 testing events) revealed the fact that the laboratory failed to document a review of three (3) of three (3) proficiency testing reports. The other three (3) reports were not available in the record to review. b) The executive director interviewed on 4/9/21 at 10:00 AM confirmed that the proficiency testing reports had not been signed off as being reviewed by the technical supervisor. .</p>
<p>D6127</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review interview and interview, the technical supervisor failed to evaluate and document the performance of individuals responsible for high</p>

complexity testing at least semiannually during the first year the individual tested patient specimens as evidenced by the following: a) Review of the CMS 209 Laboratory Personnel Report on 4/9/21 revealed that there was one (1) new histotechnician hired and performing tissue inking since the last CLIA recertification survey on 11/30/18. b) Review of personnel competencies for calendar years 2019 and 2020 revealed that there was no documentation of semiannual competency evaluations for the one (1) new histotechnician who had been working for over a year. c) Histotechnician number 2 confirmed in an interview on 4/9/21 at 11:45 AM that no semiannual competency evaluations had been performed on the one (1) new histotechnician.