| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 22D0067526 | 11/30/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| New England Dermatology, Pc | 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 |
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| **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. |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory failed to verify at least twice annually procedures it performs that are not included in subpart I of this part as evidenced by the following: Potassium Hydroxide (KOH) and wet prep examinations: a) The laboratory director interviewed on 11/30/18 at 12:10 PM indicated that the laboratory was enrolled in the American Association of Bioanalysts (AAB) proficiency testing program to cover the performance of KOH and wet preps. b) No documentation could be provided at the time of the survey to confirm the laboratory's enrollment in the proficiency testing program. MOHS slide examinations: a) The laboratory's policy for MOHS slide case reviews is to have five cases reviewed two times per year for each MOHS surgeon b) A review of skin slide case reviews for calendar years 2016, 2017 and 2018 revealed that for 2017 and 2018 one (1) of two (2) MOHS surgeons only had case reviews performed once during the year. For 2017 the case review had been performed on 2/28/17 and for 2018 on 11/14/18. c) The histotechnician interviewed on 11/30/18 at 11:55 AM confirmed that one of the MOHS surgeons had not had case reviews performed twice annually for the years indicated. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d) |

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| | Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation and record review, the laboratory failed to ensure laboratory reagents were not used when they had exceeded their expiration date. The findings include: During a tour of the laboratory on 11/30/18 at 10:40 AM the surveyor observed the following expired item in the laboratory area where Physician Performed Microscopy Procedures (PPMP) are performed: 1. One (1) bottle of Wright Giemsa stain lot number K14B31, expiration date 11/17; There were no in-date reagents available in the laboratory. Based on this evidence the accuracy and reliability of microscopic examinations utilizing this stain could not be assured. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the technical consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually as evidenced by the following: a) Findings revealed that the technical consultant failed to evaluate the competency, at least annually, of seventeen (17) out of seventeen (17) mid-level practitioners performing provider performed microcopy procedures (PPMP) (potassium hydroxide (KOH) and wet preps) for calendar years 2017 and 2018. b) This was confirmed through an interview with the technical consultant on 11/30/18 at 12:00 PM. |
| **D6102** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(12)<br><br>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.<br><br>This STANDARD is not met as evidenced by:<br>Based on an interview, the laboratory director failed to ensure that documentation was maintained to verify that newly hired personnel were appropriately trained for the type and complexity of the services offered as evidenced by the following: a) One (1) new histotechnician had been hired since the last CLIA survey performed. The histotechnician performs high complexity inking and grossing of tissues. There was no documentation maintained to verify that she had received training in all aspects of the laboratory operation prior to performing high complexity procedures. b) Interview on 11/30/18 at 12:05 PM with the main histotechnician, responsible for training, |

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| | confirmed that there was no documentation maintained of the new histotechnician's initial training. |