

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0067526	(X3) Date Survey Completed 02/07/2023
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. Please refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 493. .
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual review and interview, the laboratory director failed to approve, sign, and date laboratory procedures as evidenced by the following: a) A review of the clinical laboratory procedure manual for Physician Performed Microscopy Procedures (PPMP) revealed that the current laboratory director had not reviewed and approved the laboratory policy and procedure manual. b) The Director of Operations confirmed in an interview on 2/7/23 at 11:38 a.m. that documentation was not available to verify that the current laboratory director had reviewed and approved of laboratory procedures. c) Based on the lack of procedure review by the laboratory director there was no assurance that laboratory personnel were following established policies and procedures (refer to D6175). The laboratory performs approximately 374 PPMP procedures annually.</p>
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with</p>

each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to document a control slide of known reactivity with each patient slide or group of patient slides when special staining was performed as evidenced by the following: a) A review of fifteen (15) histopathology skin slide final reports was performed for slide examinations performed between 1/14/22 and 1/19/23. b) The review revealed that for two (2) of the fifteen (15) patient reports special and immunostains were performed on the following slide specimens: 1. Case number NED22-11074 - Melan A immunostain and Fontana Mason and Iron special stains - reported on 10/19/22. 2. Case number NED22-12916 - Brown and Benn special stain - reported on 12/6/22. c) There was no documentation in the facility's record system of the reactions of the control slide with each immunostain or special stain for slides prepared at a reference laboratory and read at this laboratory site. d) The Director of Operations confirmed in an interview on 2/7/23 at 12:15 p.m. that the results of the immunostain control portion of patient slides were being reviewed by the doctors and the reference lab where the slides were prepared but the results of the control slide exams were not being documented in the laboratory's record system. The laboratory performs approximately 14,863 histopathology slide exams annually.

D6175

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1495(b)(1)

Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:

Based on record and procedure review and interview, laboratory personnel failed to follow the laboratory's procedures for test reporting as evidenced by the following: a) A review of the laboratory's procedure for Physician Performed Microscopy Procedures (PPMP) for reporting indicated that results are reported either positive or negative. 2) A review of six (6) patient charts for Potassium Hydroxide (KOH) procedures performed between 3/16/22 and 12/30/22 revealed that for two (2) of the six (6) results reported the results were documented as "+/-" in the patient's electronic medical records (medical records 20244 and 132098 for KOH exams performed on 5/30/22 and 12/30/22 respectively). c) The Director of Operations indicated in an interview on 2/7/23 at 11:55 a.m. that the +/- entries indicated that the results were equivocal (no definitive result) and that the patient would be treated as if the results were positive. However, this type of reporting was not indicated in the laboratory's procedure manual. The laboratory performs approximately 374 PPMP procedures annually.