

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1098830	(X3) Date Survey Completed 09/28/2021
Name of Provider or Supplier Northeast Dermatology Associates PLLC	Street Address, City, State 138 Conant St, Beverly, 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 Northeast Dermatology Associates, PLLC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to follow policies and procedures for twice annual verification of testing it performs that is not included in subpart I of this part as evidenced by the following: a) A review of the laboratory's policies for histopathology skin slide case reviews for accuracy of diagnoses indicated that the laboratory performs semiannual case reviews of 3 randomly selected cases. b) A review of histopathology skin slide case reviews performed for calendar year 2019 and 2020 revealed that skin slide case reviews for accuracy verification were not performed semiannually during calendar years 2019 and 2020. Record review further revealed that the case reviews for the latter part of 2019 and all of 2020 were performed on 3/19/21. c) The histotechnologist interviewed on 9/28/21 at 11:15 AM confirmed that twice annual accuracy verification for histopathology cases had not been performed semiannually during calendar years 2019 and 2020. The laboratory performs approximately 1,200 histopathology skin slide exams annually.</p>