Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0922573	(X3) Date Survey Completed 02/08/2019
Name of Provider or Supplier Northeast Dermatology Associates, Pllc	**Street Address, City, State** 538 Turnpike Street, North Andover, 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.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (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 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 differential or special staining was performed as evidenced by the following: Surveyors reviewed Mohs histopathology quality control (QC) records for calendar years 2017 and 2018. The review revealed that the laboraory failed to document the hematoxilyn and eosin (H&E) stain QC on five (5) days of testing, 10/10/17, 10/16 /17, 10/17/17, 10/23/17, and 10/24/17. The histopathology technician confirmed in an interview on 2/8/19 at 10:20 AM that the H&E stain QC was not documented for five (5) days in 2017. Twenty-seven (27) Mohs surgeries were performed between 10/10 /17 and 10/24/17.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification,

	either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to indicate on the test report the name of the laboratory where the test was performed as evidenced by the following: Surveyors reviewed eight (8) Mohs test reports between 3/21/17 and 11/20/18. The review revealed the name of the laboratory on the test reports was NEDA - North Andover- Turnpike. The laboratory's name is Northeast Dermatology Associates, PLLC. The training manager confirmed on 2/8/19 at 12:15 PM that the test report did not indicate the name of the laboratory where the test was performed.