Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0922573	(X3) Date Survey Completed 04/09/2025
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 recertifiaction survey was conducted on April 09, 2025 for the Northeast Dermatology Assocaites, PLLC laboratory pursuant to the Clinical Laboratory Improvement Act (CLIA) of 1988 and CLIA regulations at 42 CFR CFR 493.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: . Based on record review and interview with the Histotech (HT) the Laboratory Director (LD) failed to attest that Proficiency Testing (PT) samples are routinely integrated into the laboratory workload. Findings include: 1. Review of American Proficiency Institute (API) results for 2023, 2024 and 2025 to date on 04/09/2025 revealed attestation sheet was not signed by the LD for the 2025 Microbiology module Event 1 (KOH). 2. Staff interview with the HT on 04/09/2025 at 10:30 AM confirmed the above PT attestation sheet was not signed by the LD. 3. The laboratory performs 5 KOH tests annually.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (b)(7) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: . Based on proficiency testing (PT) review and interview with Histotech (HT) and

	Practice Manager (PM) on 4/09/2024, the laboratory failed to document and maintain a copy of all PT records as evidenced by the following: 1. The surveyors reviewed the American Proficiency Institute (API) PT records for calendar years 2023, 2024 and 2025 to date. The review revealed: 1. The coding report was not available for a. API Chemistry 2023 (Urinary Human Chorionic Gonadotropin - UHCG) Event 3 b. API Chemistry 2024 (UHCG) Events 1, 2 and 3 c. API Microbiology (KOH) 2025 Event 1. 2. The final reports were not present and not signed by the Laboratory Director for API Chemistry Module for 2024 Events 1, Event 2 and Event 3. 2. TP1 and TP2 confirmed in an interview on 4/9/2025 at 11:00 AM that the coding reports and final result reports were not present or reviewed and signed by the laboratory director /designee. 3. The labratory performs 342 UHCG tests and 5 KOH tests annually.