Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0993620	02/06/2024
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Associates Of Georgia Llc	201 Michael Etchison Road, Monroe, GA	

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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on February 06, 2024. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of the Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing (PT), it was revealed there was no peer reviews performed twice annually or proficiency testing (PT) from a CMS approved agency to test the competency of PPM testing personnel in 2022 - January 2024. Findings: 1. A review of WSLH (PT) documents revealed the absence of (PT)s for PPM (KOH) testing or KOH peer reviews for testing personnel #s 4 - 9 (CMS 209) in 2022 - January 2024. 2. An interview with the lab lead, in the review room, at approximately 3:00 PM, on 02/06 /2024 confirmed the absence of PT records or peer review documentations for (TPs #s 4 - 9 CMS 209) 2022 - January 2024.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) document review and staff interview, the laboratory failed to document ALL quality assessment activities on a monthly or quarterly basis that cover pre-analytic, analytic and post analytic phases of laboratory testing in 2022 - January 2024 in the specialty of Histopathology. Findings: 1. Review of the daily maintenance logs revealed Quality Control (QC) and Plate Sterility logs for Dermatophyte Test Medium (DTM) testing were NOT reviewed by the Technical Supervisor (TS) in 2022 - January 2024. 2. An interview,with the lab lead, on 02/06 /2024, at approximately 3:30 PM, in the review room, confirmed the lack of standard quality oversite of the laboratory by the Technical Supervisor (TS) 2022 - January 2024.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on document review and interview with the lead MA , the Lab Director (LD) failed to ensure that Quality Assurance (QA) guidelines were followed to identify and fix problems in the laboratory from 2022 - January 2024, as required by the Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. Review of Standard Operating Procedures (SOP), Proficiency Testing (PT)/ Peer Review guidelines for KOH PPM testing and maintenance logs revealed the Lab Director falied to ensure ALL Quality Assurance (QA) activities were maintenaned 2022 - January 2024. 2. An interview with the laboratory's lead MA, in the review room, on 02/06/2024, at approximately 3:00 PM, confirmed the lab director failed to ensure proper oversight of the laboratory to solve problems as they occurred in 2022 - January 2024.