Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2228809	03/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Spectrum Dermatology Of Atlanta, Llc	1725 Windward Concourse, Suite 120, Alpharetta, 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	An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on March 15, 2023. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) document review and laboratory director interview, the laboratory failed to document quality assessment activities on a monthly or quarterly basis per their QA guidelines for Dermatophyte Test Medium (DTM) and KOH testing as required. The Findings: 1. Laboratory QA documents review revealed the laboratory did not have a monthly or quarterly quality checklist in 2021 thru date of survey (03/15/2023). 2. Daily maintenance logs including: Room Temperature(RT), refrigerator and DTM incubation logs were unavailable during the time of survey (03/15/2023). 3. An interview with the laboratory director, on 03/15 /2023, at approximately 12:25 PM in the review room confirmed the lack of a QA checklist and standard maintenance logs for the laboratory at the date of survey (03/15 /2023).
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 documents review and interview with the owners, the Lab Director(LD) failed to ensure that Quality Assurance (QA) guidelines were followed to identify and fix problems in the laboratory in 2021 thru 2023 as required by Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. Standard Operating Procedures (SOP), QA and maintenance logs (Room Temperature, Refrigerator and QC) review revealed the lab director, who is also the Technical Supervisor (TS), did not review or sign Quality Assurance or maintenance logs in 2021 to 2023. 2. An interview with the laboratory owner and laboratory director in the review room on 03/15/2023, at approximately 12:00 PM, confirmed the LD failed to ensure proper oversight of the laboratory to solve problems as they occurred in 2021 thru 2023.