Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0685800	10/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Of Athens	1220 Langford Drive, Bldg 100, Suite 103, Watkinsville, 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 October 20, 2022. 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 staff interview, the laboratory failed to document quality assessment activities on a monthly or quaterly basis per their QA guidelines as required from 2021 to 2022. The Findings include: 1. Laboratory QA documents review revealed the laboratory did not have a monthly or quarterly quality checklists from March 2021 through date of survey (10/20/2022). 2. Daily maintenance logs including: Room Temperature, Humidity, Cryostat, Eye wash, Microscope, Slide Stainer maintenance and Refrigerator logs were not reviewed and signed by the Lab director from March 2021 through Survey date (10/20/2022). 3. An interview with the Clinic Manager, on 10/20/2022, at 11:35 AM in the Lab review room confirmed the lack of adequate QA checklist and no laboratory director review and oversite from March 2021 through date of survey (10/20/2022).
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 Quality Assurance(QA) documents review and staff interview, the Lab Director(LD) failed to ensure that proper QA guidelines were followed including regular review of (QA) and maintenance data to identify and fix problems in the laboratory as required by Clinical Laboratory Improvement Amendments (CLIA). Findings include: 1. Laboratory maintenance logs and (QA) documents review revealed the laboratory director did not review maintenance or (QA) logs to identify and correct problems in the laboratory as they occur from March 2021 through date of survey (10/20/2022). 2. An interview with the Clinic Manager in the lab review room on 10/20/2022, at approximately 12:50 AM, confirmed the LD did not review the aformentioned maintenance and (QA) data from March 2021 through the date of survey (10/20/2022).