Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2288145	05/29/2025
Name of Provider or Supplier	**Street Address, City, State**	
Georgia Dermatology Specialists Of Coweta	4360 Chamblee Dunwoody Road, Ste 280, Atlanta, 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 May 29, 2025. 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:
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: A review of 2023 - 2025 Proficiency Records confirmed that the laboratory was not enrolled in an approved proficiency program for KOH preparations. THE FINDINGS INCLUDE: 1. A review of the 2023 - 2025 Proficiency Records confirmed that Peer-to-peer reviews were completed for the MOHS Histopathology testing only. There were no peer-to-peer reviews completed for the KOH preparation procedure. 2. An exit interview, with Lab Manager, on May 29, 2025, at 2:30pm, in the conference room, confirmed that the laboratory failed to enroll in an approved proficiency program for KOH preparations.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: A review of the 2023 - 2025 Temperature Records confirmed that the laboratory failed to perform corrective actions for the lack of temperature monitoring and temperature failures. THE FINDINGS INCLUDE: 1. A review of the 2023 - 2025 Refrigerator Temperature Records revealed temperature failures for the period of January 2024 - December 2024 (95 failures out of 152 recorded temperatures points) and for the period of January 2025 - May of 2025 (59 failures out of 87 recorded temperature points). 2. A review of the temperature logs revealed a temperature range of 2C - 8C (35.6F - 46.4F). 3. Observation of the refrigerator temperature logs revealed there were no temperatures recorded for the period of May 16 - July 10, 2024. 4. Observation during the laboratory tour revealed that the small refrigerator/ freezer cooling system, containing reagents and supplies in the freezer section, required storage at -20C. The reagents and supplies stored in the refrigerated section had a storage requirement of 2C - 8C. There was no evidence of monitoring of the freezer temperatures. 5. Observation of the Hot Plate/ Oven Temperature log revealed an established range for the Hot Plate (25C - 70C) and for the Oven (25C - 70C). There were no numerical temperatures documented for the January 2023 - May 2025 period. 6. An exit interview, with the Lab manager, on May 29, 2025, at 2:30pm, in the conference room, confirmed that the laboratory failed to perform corrective actions for failures in temprature monitoring.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: A review of current Procedure Manual (SOP) confirmed that the laboratory failed to perform the Quality Assurance protocols established for the facility to assure that the laboratory delivered quality laboratory results. THE FINDINGS INCLUDE: 1. A review of the SOP revealed that each procedure contained an established quality assurance component. 2. A review of the 2023 - 2025 QC Temperature, and Maintenance Records confirmed the laboratory had not performed the quality assurance reviews as documented in the SOP. 3. An interview with of the laboratory representative confirmed that audits were not performed in the transfer of data from the instrument into the electronic database to assure the accurate delivery of results to patients' records. 4. An exit interview, with Laboratory Representative, on May 29,

	2025, at 2:30pm, in the conference room confirmed that the laboratory failed to follow the Quality Assurance protocols, established for the facility, to assure that the laboratory delivered quality laboratory results.