Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2046579	08/21/2025
Name of Provider or Supplier	**Street Address, City, State**	
Southern Skies Dermatology & Surgery	48 Medical Park Drive East Suite 458, Birmingham, AL	

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
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 a review of the Bi-Annual Quality Control (QC) Peer Review (PR) Proficiency Testing (PT) records, the Policy and Procedure Manual and an interview with the MOHS Technician, the laboratory failed to document one of the two accuracy verification reviews due in 2023, as per laboratory policy. The findings include: 1. A review of the 2023 Bi-Annual QC PR PT records revealed no documentation of MOHS surgery accuracy verification the last six months of 2023. 2. A review of the PT Procedure revealed twice per year the laboratory will submit 10 slides per surgeon per location to Skin Pathology Group for accuracy verification of the MOHS surgeons' diagnoses. 3. The MOHS Tech and the Laboratory Director confirmed the above findings during the exit conference on 08-21-2025 at 12:00 PM.
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: Based on reviews of the Daily Room Temperature (RT) and Humidity logs, the Policy and Procedure (P&P) manual, patient testing logs and an interview with the MOHS Technician, the laboratory failed to document the corrective action when the RT was outside the specified range indicated on the log. The surveyor noted temperatures were out of range for 66 out of 102 testing days in 2024 and 34 out of 67 testing days from January - July 2025. The findings include: 1. A review of the RT and Humidity logs revealed room temperature range requirements of 60-75 degrees Fahrenheit (F). However, on the days when temperatures were above 75 degrees F, no corrective actions were documented. The laboratory did not provide the Leica Cryostat operator's manual for verifcation of the manufacturer's established environmental operating requirements. 2. A review of the Daily Laboratory Documentation procedure on page 9 of the P&P manual revealed, "Room Temperature and Humidity - Any concerns or discrepancies are to be documented in the comment section of this form along with the corrective action". 3. A review of the patient logs revealed 946 patients were performed when temperatures were outside the specified range in 2024-2025. 4. The MOHS Tech and the Laboratory Director confirmed the above findings during the exit conference on 08-21-2025 at 12:00 PM.