Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2170367	08/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Skin Cancer Center, Pllc	3209 24th Ave Nw, Norman, OK	

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	The recertification survey was performed on 08/07/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the office manager at the conclusion of the survey.
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 records and interview with the office manager, the laboratory failed to verify the accuracy of slide interpretations at least twice annually for two of three records reviewed during the period of January 2023 through July 2024. Findings include: (1) On 08/07/2024 at 10:00 am, the laboratory manager stated the laboratory performed microscopic interpretations of H&E (Hematoxylin and Eosin) stained slides from tissues removed during Mohs surgery. The tissue would then be observed microscopically; (2) A review of records from January 2023 through July 2024 identified that, for two of three cases (chosen from testing performed on 03/27/2023 and 06/13/2023), although they had been submitted to a reviewing physician, there was no date to show when the cases had been evaluated; (3) The records were reviewed with the office manager who stated on 08/07/2024 at 11:45 am the records had not been dated to prove the accuracy of the testing had been verified twice in 2023.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 a review of records, policy and procedure manual, manufacturer's instruction manual, and interview with the office manager, the laboratory failed to ensure the room temperature, relative humidity, and cryostat temperatures had been documented as observed for one of 11 days of patient testing reviewed from January 2023 through June 2024. Findings include: RT (ROOM TEMPERATURE) AND RH (RELATIVE HUMIDITY): (1) On 08/07/2024 at 10:00 am the office manager stated the laboratory performed slide interpretation of frozen sections of tissues obtained during Mohs surgical procedures using two Avantik QS12 cryostats (denoted by the laboratory as "L" and "R"); (2) A review of the manual titled, "Instruction Manual QS12 Cryostat" required an operating temperature range of 59 to 86 degrees F (Fahrenheit) and a maximum of 60% RH; (3) A review of the "Daily Room Temperature Logs" from 01/01/2023 through 06/30/2024 identified RT and RH readings had not been recorded on 09/27/2023 for "L" and "R" cryostats; (4) The records were reviewed with the office manager who stated on 08/07/2024 at 11:00 am, the RT and RH readings had not been documented as stated above. CRYOSTATS TEMPERATURE: (1) On 08/07/2024 at 10:00 am the office manager stated the laboratory performed slide interpretation of frozen sections of tissues obtained during Mohs surgical procedures using two Avantik QS12 cryostats (denoted by the laboratory as "L" and "R"); (2) A review of the manual titled, "Laboratory Procedure Manual" under "Quality Control Manual" in the section titled, "Equipment Quality Control-Cryostat" on page 4. stated: (a) "1. Temperature is recorded each day of use and documented."; (b) "2. Temperature range is -20 degrees to -30 degrees.". (3) A review of the cryostat temperature logs from 01/01/2023 through 06/30/2024 identified the temperature readings had not been recorded on 09/27/2023 for "L" and "R" cryostats; (4) The records were reviewed with the office manager who stated on 08 /07/2024 at 11:00 am, the cryostat temperatures had not been documented as shown above.