Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2141623	05/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology And Skin Cancer Assoc, Pllc	5349 Airline Rd, Arlington, TN	

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
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 observation of the laboratory, review of the manufacturer instruction manuals, review of the laboratory procedure manual, patient records, the Centers for Medicare & Medicaid Services Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), lack of records and staff interview, the laboratory failed to monitor humidity in the area where the Advantik QS12 cryostat and Linistat stainer was in use for processing patient tissue removed during Mohs procedures in 2021, 2022, and 2023 with approximately 300 patient cases performed annually, and failed to define temperature ranges for the use of the cryostat. The findings include: 1. Observation of the laboratory on 05/15/23 at 8:10 am revealed the Advantik QS12 cryostat and Linistat stainer in use for processing patient tissue removed during Mohs surgery. 2. Review of the manufacturer's instruction manuals revealed the following operating environmental conditions: Advantik QS12 Relative Humidity Maximum of 60% up to 35C Linistat Stainer Relative Humidity Maximum of 80% up to 31C. Decreasing linearly to 50% at 40C 3. Review of the laboratory's procedure manual revealed discrepancies between the acceptable temperature for the cryostat. The cryostat maintenance procedure indicated to maintain temperature of -22 to -30C; the quality control policy indicated a

	temperature range of -20 to -30C, the Mohs procedure indicated a cryostat temperature of -24 to -29C. 4. Review of randomly selected patient cases revealed testing performed on 04/26/21 - case #908, 05/09/22 - case #1211, 10/10/22 - case# 1323, and 03/27/23 - case #1471. 5. Review of the Form CMS-116 revealed the laboratory performs approximately 300 Mohs cases per year. 6. There were no records documenting monitoring of humidity for 2021, 2022, or 2023. 7. Interview with the lead histotech on 05/15/23 at 10:45 am confirmed the laboratory did not monitor humidity in the area where the Advantik QS12 cryostat and Linistat stainer were being used to process patient tissue removed during Mohs surgical procedures in 2021, 2022, and 2023 with patient testing performed. She also confirmed the laboratory did not clearly define the acceptable temperature range to use for the Advantik QS12 cryostat.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, external proficiency testing documents, and interview with the lead histotech, the laboratory director failed to review the external proficiency testing documents for seven of seven case reviews from 2020, 2021, 2022 and 2023. The findings include: 1. Review of the laboratory's quality assurance plan revealed the laboratory sends Mohs cases to an outside pathologist twice a year as an external quality control/proficiency testing program. Additionally, it was noted in the "Proficiency Testing" policy that if there is a diagnosis discrepancy, an identical slide will be sent, by the tech or risk manager to another outside laboratory to be evaluated. 2. Review of the twice a year verification of accuracy documents revealed the following: No review of the quality assessment documents performed on 05/18/20, 10/12/20, 05/10/21, 09/27/21, 06/06/22, 11/07/22, 05/01/23 was performed by the laboratory director. The case review performed on 09 /27/21 for patient case #1035 revealed a disagreement with a comment of "BCC present." There was no evidence of case review and no corrective action performed. 3. Interview with the lead histotech on 05/15/23 at 10:45 am confirmed the lab director did not review the proficiency testing quality assessment verification documents from 2020, 2021, 2022 or 2023 (seven of seven cases sent for review).