Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2206539	**(X3) Date Survey Completed** 10/18/2022
Name of Provider or Supplier Dermatology & Skin Cancer Surgery Center	**Street Address, City, State** 2548 Lillian Miller Parkway Suite 120, Denton, TX	
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	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Southern Operations Branch-Dallas for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 review of the laboratory policy, laboratory environmental logs, and confirmed in interview, the laboratory failed to accurately monitor, and document Cryostat temperatures used to process patient specimens for 8 of 14 days in 2021

	(September and October) for Leica Cryostat #1 and Leica Cryostat #2. The findings include: 1. Review of the laboratory policy titled "Equipment Quality Control-Cryostat" revealed: "1. Temperature is recorded daily and documented. 2. Temperature range is -15C to -25C ..." 2. Review of laboratory environmental logs for the Leica Cryostat revealed the laboratory had an established acceptable temperature range for Cryostat #1 and Cryostat #2 as "-15C to -25C". 3. Further review of the laboratory's environmental logs for the Leica Cryostats from September to October 2021 revealed the following documented temperatures for Cryostat #1 and Cryostat #2 that were not within the defined range of "-15C to -25C: A. CRYOSTAT# 1 09/15 /2021; Temperature: "22" 09/16/2021; Temperature: "23" 09/21/2021; Temperature: "22" 09/22/2021; Temperature: "21" 09/29/2021; Temperature: "22" 09/30/2021; Temperature: "23" 10/05/2021; Temperature: "21" 10/13/2021; Temperature: "23" B. CRYOSTAT #2 09/15/2021; Temperature: "21" 09/16/2021; Temperature: "22" 09/21 /2021; Temperature: "23" 09/22/2021; Temperature: "23" 09/29/2021; Temperature: "22" 09/30/2021; Temperature: "23" 10/05/2021; Temperature: "23" 10/13/2021; Temperature: "23" The laboratory failed to properly monitor and document Cryostat temperatures. 4. During an interview on 10/18/2022 at 11:02 a.m., the Mohs Technician confirmed the above findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and confirmed in interview, the laboratory failed to include the facility address on 11 of 11 Mohs maps (random review) in October 2022. The findings include: 1. A random review of patient test reports from October 2022 revealed the following 11 Mohs maps missing the facility address: 10/05 /2022 Mohs case numbers: 420, 421, 422 10/06/2022 Mohs case numbers: 427, 428, 429, 430 10/11/2022 Mohs case numbers: 437, 438 10/12/2022 Mohs case numbers: 439, 440 2. During an interview on 10/18/2022 at 11:28 a.m., the Mohs Technician confirmed the above findings.