Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2167858	(X3) Date Survey Completed 03/20/2025
Name of Provider or Supplier Lubbock Dermatology & Skin Cancer Center	**Street Address, City, State** 5103 98th St Suite 200, Lubbock, 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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, slides, Mohs log, appointment log, interview, and pre-survey paperwork, the laboratory failed to identify and correct slides and Mohs log for one of five Mohs cases reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Laboratory Procedure Manual- Mohs Surgery, approved 07/25/2019, under 3.3 Slide/Specimen Rejection stated, "Incorrectly labeled specimen eg. wrong patient." And under 3.4 Specimen Handling, Storage, Preservation, and Identification stated, "3.4.5 Patient name, site, date, surgeon, and lab technician is written on the log, along with total number of slides processed" and "3.4.5 Laboratory technician will cut frozen sections and stains slides and labeled with accession number, patient's last name and first initial and date." B. Review of slides showed one case, S24-412, had two (for Stage III) out of six slides, were labeled with the name ((medical record number (MRN) 160495.0)) and date from test report S24-400 on 10/30/2024. C. Review of the Mohs log showed the name of the patient from case S24-400 (MRN 160495.0) seen 10/30 /2024 was also listed on the log for case S24-412 on 11/13/2024 (but dated 10/30 /2024). D. Review of the appointment log showed a different name of the patient (MRN 172367.0) and matched the name on the test report for S24-412 and seen on the appointment log. It was unclear as to whether the slides labeled as S24-412 dated

	10/30/2024 belonged to case S24-400 (MRN 160495.0) from 10/30/2024 or case S24-412 (MRN 172367.0) from 11/13/2024. E. Interview with the histotechnologist on March 20, 2025 at 1215 hours in the office confirmed the findings. F. Review of the presurvey paperwork titled Annual Test Volume & Proficiency Testing Programs Worksheets showed an estimated annual test volume of 1776 stages in Mohs.
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 review of manufacturer's instructions, laboratory policy and procedure, temperature logs, observation, pre-survey paperwork and interview, the laboratory failed to document the temperatures of the Thermo Scientific CryoStar NX and the Leica CM 1510 cryostats for 26 of 26 months reviewed. Findings follow. A. 1. Review of the Thermo Scientific CryoStar NX50 Operator's Guide, 2013, under Chapter 4- Operation for Chamber Temperature stated, "The CryoStar NX50 provides good sectioning quality with a variable controlled temperature down to -45 degrees Celsius (C) +/- 2C and a uniform chamber temperature of -25C +/- 2C at ambient temperature of +20C. The compressor runs continuously to maintain the chamber temperature and the evaporator ensures good air flow through the chamber. Both the maximum temperatures for the object head temperature and the chamber temperature will be influenced by ambient temperature by -0.7C increase for every 1C ambient temperature increase. For example, at +25C ambient the maximum specimen temperature would be -41C +/- 2C and the chamber temperature -21C +/- 2C. Note The user sets the desired specimen temperature depending on type of specimen." At 7.3.1 for Mains switch stated, "The display of the temperature control unit will read the actual temperature of the cryochamber." 2. Review of the Leica CM 1510 Cryostat Instruction Manual, 06/97, under 7.3.3 Control Unit stated, "During normal operation, the display indicates the actual temperature of the cryochamber." B. Review of the laboratory's policy and procedure titled Laboratory Procedure Manual - Mohs Surgery, approved 07/25/2019, under Calibration stated, "5.1.2 Daily temperature charts of all temperature sensitive equipment are maintained. Examples: Refrigerators, freezers, tissue, processing equipment, cryostat. 5.1.3 While cutting frozen sections, the cryostat will be kept in the range of -20C to -30C." C. Review of the Daily Maintenance Log from 01/2023 - 02/2025 stated "Unless otherwise indicated, Cryostat temperature is always at -22C." D. During a tour of the laboratory on March 20, 2025 at 1135 hours showed the Thermo Scientific cryostat was at -20C and the Leica cryostat was at -26C. E. Review of the presurvey paperwork titled CMS Form 116 showed an estimated annual test volume of 5276 blocks in Mohs, frozens, and permanents. F. Interview with the Mohs histotech on March 20, 2025 at 1140 hours in the office stated it fluctuated during the day but was set at -22[C].