

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2026119	(X3) Date Survey Completed 09/04/2025
Name of Provider or Supplier Texas Dermatology & Skin Cancer Center, Pllc	Street Address, City, State 6751 Horizon Road, Heath, 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	An announced routine recertification survey of the laboratory was completed on 09/04/2025. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. Standard level deficiencies were cited.
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's environmental logs, and confirmed in interview, the laboratory failed to document corrective action for temperatures outside of the laboratory's acceptable limits for 29 of 29 days from January 2025 to February 2025. Findings include: 1. Review of the laboratory's policy titled "Quality Assurance Program" stated: "Temperatures will be taken by an employee in the laboratory and recorded. If a temperature is outside the desired range, the Laboratory Director will be notified as soon as possible, and before any patient test is reported. Appropriate corrective action will be taken and documented ..." Review of the laboratory's policy titled "Histopathology - Mohs Surgery", approved by the laboratory director on 07/01/2019 stated: "Test Procedure 1. Sectioning specimens: ...The tissue is then cut into 4 to 10 micron sections in a cryostat, which is</p>

kept within a range of -20 C to -30 C." 2. Review of the laboratory's environmental logs from January 2025 to February 2025 determined the laboratory documented temperatures that were outside of the laboratory's acceptable range for 29 of 29 days from January 2025 to February 2025: Title: CRYOSTAT TEMPERATURE LOG - HEATH Serial Number: 56227 January 2025: Day 13: -19 C Day 14: -19 C Day 15: -18 C Day 16: -18 C Day 17: -19 C Day 20: -19 C Day 21: -19 C Day 22: -18 C Day 23: -18 C Day 24: -18 C Day 27: -17 C Day 28: -17 C Day 29: -17 C Day 30: -17 C Day 31: -17 C February 2025: Day 3: -17 C Day 4: -17 C Day 5: -17 C Day 6: -17 C Day 7: -17 C Day 10: -17 C Day 11: -17 C Day 12: -17 C Day 13: -17 C Day 20: -17 C Day 24: -17 C Day 25: -17 C Day 26: -16 C Day 27: -19 C The laboratory was asked to provide documentation of performing corrective action for temperatures recorded outside of the laboratory's acceptable range. No documentation was provided. 3. The office manager confirmed the findings in an interview on 09/04/2025 at 1220 hours in the laboratory. Key: C - Celcius