Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2272473	**(X3) Date Survey Completed** 04/09/2024
Name of Provider or Supplier Texoma Associated Dermatologists	**Street Address, City, State** 230 E Sycamore Suite 305, Sherman, 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 found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory environmental logs, Centers for Medicare and Medicaid Services (CMS)-116 form, and confirmed in interview with staff, the laboratory failed to have a system in place to ensure Mohs patient slides were maintained under proper preservation conditions for 337 of 337 days in 2023 and 2024 (05/08/2023-04/09/2024). Findings included: 1. During a tour of the facility on 04/09/2024 at 1:15 PM, two boxes of previous patient slides were observed stored in an employee office. There was no mechanism observed to monitor patient slide storage conditions in the office. The surveyor requested documentation of environmental monitoring in the employee office to ensure preservation of patient slides, and none was provided. 2. Review of laboratory environmental logs from 2023 and 2024 revealed no documentation of the employee office environment in which patient slides were stored. 3. Review of CMS-116 form submitted at time of survey, 04/09/2024, revealed the laboratory began patient testing on 05/08/2023 and performed 800 Mohs patient tests annually. 4. During an interview on 04/09/2024 at 1:16 PM, the laboratory regulatory compliance director confirmed the laboratory failed to have a system in place to ensure Mohs patient slides were maintained under proper preservation conditions for 337 of 337 days in 2023 and 2024 (05/08/2023-04/09/2024).
D5781	CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(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.

This STANDARD is not met as evidenced by:
Based on review of laboratory policy, random review of environmental logs (01/15/2024-04/09/2024), and confirmed in interview with staff, the laboratory failed to document corrective actions taken when room temperatures were not within the acceptable range for 7 of 14 days reviewed in 2024. Findings included: 1. Review of laboratory policy, "Texoma Associated Dermatologists Sherman-Laboratory Corrective Action Policy" (Approved by the Laboratory Director on 01/15/2024) revealed the following: " ...Procedures: A. For every deficiency found in the laboratory process, including equipment failure, a Request for Corrective Action will be prepared outlining the deficiency, the correction, and the procedure to prevent the recurrence of the deficiency. B. Request for Corrective Action must be completed with all pertinent information by the person involved, supervisor, manager, or laboratory director. ...D. All corrective actions will be retained for at least three (3) years with longer retention if it has been more than two (2) years since the last CLIA inspection." 2. Random review of laboratory environmental logs (01/15/2024-04/09/2024) revealed the following days the laboratory temperature was not within the acceptable temperature range: Laboratory Room Temperature Range: (68 F to 78 F) Date: Temperature Recorded a. 02/19/2024: 65 F b. 02/26/2024: 65 F c. 03/11/2024: 66 F d. 03/18/2024: 65 F e. 03/25/2024: 66 F f. 04/01/2024: 66 F g. 04/08/2024: 66 F The surveyor requested corrective action documentation for the above days when the laboratory temperature failed to fall within the acceptable temperature range, and none was provided. 3. During an interview on 04/09/2024 at 1:58 PM, the laboratory regulatory compliance director confirmed the laboratory failed to document corrective actions taken when room temperatures were not within the acceptable range for 7 of 14 days reviewed in 2024. Word Key CLIA- Clinical Laboratory Improvement Amendments F- Fahrenheit