Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2026119	**(X3) Date Survey Completed** 05/18/2023
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 recertification survey conducted 05/18/2023 found the facility in substantial compliance with CLIA regulations (42 CFR Part 493). Standard level deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, patient Mohs maps, and confirmed in interview, the laboratory failed to follow their own written policy for documenting the intended reactivity of Hematoxylin & Eosin (H&E) stain for Mohs histopathology slides on the patient Mohs maps for 4 of 10 patients from January to April of 2023 (random sampling). The findings include: 1. Review of the laboratory policy titled "Histopathology- Mohs Surgery" revealed: "Quality Control Procedures ... The quality of the H&E stain is documented on the patient's Mohs Map form as a Yes or No. If "No" is circled the corrective measures are documented on the Quality Control Log for the H&E stain ..." 2. A random sampling of patient Mohs maps from January to April 2023 revealed the following Mohs maps that did not have documentation of H&E quality control: 01/19/2023 Mohs #: H23-0036 02/07/2023 Mohs #: H23-0055 04/03/2023 Mohs #'s: H23-0147, H23-0148 The laboratory failed to follow their own written policy for documenting the intended reactivity of Hematoxylin & Eosin (H&E) stain on the patient Mohs maps. 3. During the exit interview on 05/18/2023 at 01:41 p.m., the Practice Manager confirmed the above findings.
D5801	TEST REPORT

	CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of laboratory records, patient records, and confirmed in interview, the laboratory failed to ensure 1 of 4 patient Tzanck smear results were transcribed accurately to the final test report in 2023 (February to April). The findings include: 1. Review of the laboratory's "Tzanck Smear Requisition and Report Log" and corresponding patient final reports revealed the following: 03/31/2023 Path #: T23-0002 Tzanck Log: "(+)" Final report: "(- Tzank smear performed today, negative, patient notified in office also)" The laboratory failed to accurately transcribe results of Tzanck smears to the final report. 2. During the exit interview on 05/18/2023 at 01:41 p.m., the Practice Manager confirmed the above findings.