

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1075485	(X3) Date Survey Completed 03/12/2024
Name of Provider or Supplier Skin Solutions Dermatology	Street Address, City, State 1040 N James Campbell Blvd Suite 101, Columbia, TN	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality assurance (QA) manual, quality assurance documentation, and staff interview, the laboratory failed to verify the accuracy of micrographically oriented histographic surgery (MOHS) testing at least twice annually in 2022 and 2023. The findings include: 1. A review of the policy titled "Quality Assurance Manual" revealed the following statement: -"Any test performed in the laboratory for which proficiency testing is not available will be verified at least twice a year, and the results will be reviewed by the Laboratory Director." 2. A review of quality assurance records revealed the laboratory performed verification of accuracy for MOHS testing on 5/5/2023 and 8/25/2022. Records of a second proficiency event in 2022 and 2023 were not available. 3. An interview with the MOHS Surgical Coordinator on 03/12/2024 at 10:30 a.m. confirmed the laboratory did not verify the accuracy of MOHS testing twice in either 2022 or 2023.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p>

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's Quality Assurance (QA) Manual, lack of documentation, and staff interviews, the laboratory failed to follow its policy for quality assurance when it did not conduct and document monthly quality assurance reviews with staff in 2022, 2023, and 2024 (26 of 26 months reviewed). The findings include: 1. A review of the QA manual revealed the following statement under the section titled "Quality Assurance Review with Staff": "The Laboratory Director will discuss with the staff, on a monthly basis, the results of quality assurance reviews and ways to which the laboratory can improve the quality of its work." 2. The laboratory did not have documentation of monthly QA reviews with staff from January 2022 through February 2024 (26 months reviewed). 3. An interview with the MOHS Surgical Coordinator on 03/12/2024 at 10:30 a.m. confirmed the laboratory did not have documented monthly QA reviews with staff for 2022, 2023, and 2024.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's micrographically oriented histographic surgery (MOHS) procedure manual and staff interview, the laboratory failed to ensure the procedures in use for MOHS testing and tissue processing were approved by the laboratory director. The findings include: 1. A review of the laboratory's MOHS procedure manual revealed no approval by the lab director. 2. An interview with the MOHS surgical Coordinator on 03/12/2024 at 10:30 a.m. confirmed the laboratory's procedures for MOHS testing and tissue processing did not indicate review and approval by the laboratory director.

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 observation of the laboratory, review of the manufacturer's instruction manual, environmental records, and staff interview, the laboratory failed to monitor ambient humidity where patient tissue processing occurred in 2022, 2023, and 2024. 1. Observation of the laboratory on 03/12/2024 at 8:10 a.m. revealed a Leica CM 1510 S (ID: 5946) cryostat instrument used for processing patient tissue samples removed during MOHS procedures. 2. A review of the Leica CM 1510 S cryostat instruction manual revealed a maximum air humidity requirement of 60%. 3. A review of the laboratory maintenance logs revealed no humidity records were available for the area where the laboratory processed tissues using the Leica CM 1510

S cryostat in 2022, 2023, or 2024. 4. An interview with the MOHS surgical Coordinator on 03/12/2024 at 10:30 a.m. confirmed the laboratory did not monitor laboratory humidity.