Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2040615	03/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
Skin Solutions Dermatology	6606 Charlotte Pk Ste 106, Nashville, 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	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Proficiency Testing (PT) policy, PT 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 "Proficiency Testing" revealed the following statements: -"Semi-annually, the tech or Risk Manager will send two cases containing the original slides, label it with only the surgical case number and send it for a microscopic examination by a Board Certified Dermatopathologist." -"Upon receipt of the pathology report from the Dermatopathologist, diagnosis of the slide specimen will be matched to the in-house diagnosis by the physician." -"The reports are attached and placed in "Proficiency Testing" located in the quality control manual." 2. A review of proficiency testing reports 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 03/13 /2024 at 11:00 a.m. confirmed the laboratory did not verify the accuracy of MOHS testing twice in either 2022 or 2023.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231

	through 493.1236. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Quality Assurance (QA) Program, QA policy, QA records, and staff interviews, the laboratory failed to follow its policies for monthly quality assurance when it did not conduct and document monthly quality assurance lab reviews (22 of 26 months reviewed) or monthly meetings with staff (26 of 26 months reviewed) in 2022, 2023, and 2024. The findings include: 1. A review of the laboratory's QA Program revealed the following statement: "The Laboratory Director must hold monthly staff meetings. Minutes should be taken and retained as documentation." 2. A review of the policy titled "Quality Assurance" revealed the following statements: -"Monthly the nurse or tech will check off the Monthly Quality Assurance Checklist. This will cover the quality assessment program for procedures used in this office. This checklist is used to evaluate General Laboratory Systems, Pre-analytic Systems, Analytic Systems, and Post-analytic Systems." -"The lab director will also review and sign off the checklist monthly." 3. A review of the laboratory's QA records revealed the following: -There were no documented monthly staff meetings from January 2022 to February 2024 (26 of 26 months reviewed). -In 2022, the lab director did not complete or sign off on any documented monthly quality assurance checklists (12 of 12 months reviewed). -In 2023, the lab director did not complete or sign off on 8 of 12 monthly quality assurance checklists (January to April and September to December). -In 2024, the lab director did not complete or sign off on any documented monthly quality assurance checklists (2 of 2 months reviewed). 4. An interview with the MOHS Surgical Coordinator on 03/13/2024 at 11:00 a.m. confirmed the findings.
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 instructions for use, 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 03/13/2024 at 8:00 a.m. revealed a Leica CM 1520 (ID: 1103) cryostat instrument used for processing patient tissue samples removed during MOHS procedures. 2. A review of the Leica CM 1520 cryostat instructions for use 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 1520 cryostat in 2022, 2023, or 2024. 4. An interview with the MOHS Coordinator on 03/13 /2024 at 11:00 a.m. confirmed the laboratory did not monitor laboratory humidity.