Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0570880	08/06/2025
Name of Provider or Supplier	**Street Address, City, State**	
Skin Surgery Medical Group Inc	5222 Balboa Ave Fl 6, San Diego, CA	

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 review of laboratory records selected at random for this Survey, the lack of laboratory records, and interview with laboratory personnel, it was determined that the laboratory failed to at least twice annually in 2022, 2023, and 2024 verify the accuracy of pathology reported for biopsy specimen and the accuracy of clearing tumor in Mohs procedures. Findings included: 1. Pathology of biopsy specimen were reported by the Testing Person/Laboratory Director, as follows Mohs Date Case # Biopsy Pathology ---------- 2/09/22 T22-129 1/26/22 12/07/22 T22-784 12/05/22 3/22/23 T23-184 2/27/23 6/14/23 T23-356 6/07/23 4/16/24 T24-136 3/18/24 2. Other Mohs procedures were performed by the Testing Person/Laboratory Director, as follows: Mohs Date Mohs Case # ---------- 7/27/22 T22-466 11/28/23 T23-689 10/01/24 T24-268 12/10/24 T24-320 3. The laboratory failed to have records verifying the accuracy of biopsy Pathology reports and the accuracy of Mohs procedures at least twice each year for 2022, 2023, and 2024. 4. The Laboratory Director and laboratory administrator affirmed (8/06/25 at 3:30 PM) the aforementioned findings; and thus, the failure to verify the accuracy of Pathology reports and the accuracy of Mohs procedures at least twice each year for 2022 - 2024. .
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 laboratory records and interview with the Laboratory Director, it was determined that the laboratory failed to have a laboratory manual of written policies and procedures approved by the Laboratory Director for personnel to use as their reference. Findings included: 1. The record titled, CMS116 CLIA Application (8 /06/25), documented laboratory testing in Histopathology, specifically Mohs procedures to clear tumor. 2. The laboratory failed to provide it's Laboratory Manual for this Survey. 3. The Laboratory Director affirmed (8/06/25 at 3:30 PM) the lack of a Laboratory Manual; and thus, the failure to have written policies and procedures for the staff to follow to ensure compliance. 4. Laboratory records documented the staff assisted with the collection and handling of biopsy specimen and Mohs specimen and managing laboratory records as the Laboratory Director/Testing Person reported Biopsy Pathology reports and performed Mohs procedures since 2022. .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on review of laboratory records, the lack of laboratory written procedures, and interview with the Laboratory Director it was determined that the laboratory failed to have written requirements for specimen management, written procedures for managing laboratory records with regularly scheduled self audits for quality assessment, and a process for documenting failures and noncompliance, appropriate corrective actions, and monitoring for recurrence. Findings included: 1. The laboratory failed to have written requirements for positive patient identification, patient preparation, specimen collection and labeling, storage, preservation, transportation and referral of Biopsy specimen, and criteria for specimen acceptability and rejection. 2. The laboratory failed to have written procedures for managing laboratory records, including receipt and retention of Pathology reports and records

	relating to Mohs procedures. 3. The laboratory failed to have written policy and procedure for at least twice annually (January - December) verifying the accuracy of tests performed onsite, including but not limited to Mohs to clear tumor and as applicable, Frozen Biopsy sections to identify pathology during Mohs procedures. 4. The laboratory failed to have a written policy and procedure for regularly scheduled self audits of laboratory records to assess the quality of preanalytic, analytic, and postanalytic processes, apply remedial corrections as appropriate, and monitor for quality assurance and compliance. 5. The laboratory failed to have any other written policies and procedures pertinant to a Dermatopathology laboratory. .