Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0558065	11/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Skin And Beauty Center	9535 Reseda Blvd Ste 304, Northridge, 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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on the surveyor's review of six (6) randomly selected Mohs patient testing records, Mohs log sheet, final reports, and an interview with the Mohs tech (MT) on November 13, 2025; the laboratory failed to follow established policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. The findings include: 1. Review of Mohs patient log for one (1) out of six (6) records reviewed revealed a discrepancy on the number of slides documented: the Mohs log documentation indicated for patient RM sample processed on 08/27/2024 consisted of four (4) sample slides processed and stained. The MT and laboratory staff located only three (3) slides processed and stained for Mohs during sample review. 2. No corrective action was documented for the discrepancy on the number of slides recorded and stored. 3. The MT confirmed by interview on the day of the survey November 13, 2025, at approximately 12:15 p.m. a discrepancy on the number of sample slides documented in the Mohs log and the slides found for review. 4. The laboratory's testing volume declaration submitted at the time of survey stated that 800 Mohs tests were performed and reported annually including the time when the discrepancies occurred.
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 CLIA compliant written procedures, and interview with the Mohs tech (MO); 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. In addition, the existing procedures for KOH and Sarcoptes scabiei var, hominis (Scabies) slide preparation and interpretation were not CLIA compliant either. 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 specimens, and criteria for specimen acceptability and rejection. 2. The laboratory failed to have written procedures for managing laboratory records, including receipt and retention of Histopathology reports and records relating to Mohs procedures. 3. The laboratory failed to have written policy and procedure for at least twice annually 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 CLIA compliant KOH and Scabies protocols for examining, determining, and reporting results. 6. The laboratory failed to have any other written policies and procedures pertinent to a Dermatopathology laboratory such as a comprehensive Laboratory Safey Plan. 7. The MT affirmed by interview at the time of the survey the lack of CLIA compliant procedures.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic,

	and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on the lack of corrective action reports for the errors found during patient review, lack of CLIA compliant protocols, and interviews with the Mohs tech and laboratory staff, the laboratory director is herein cited for failure to provide quality laboratory services in the preanalytic, analytic and postanalytic phases of laboratory testing. See D5203 and D5403.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedures, survey findings, and interviews with the Mohs tech on November 13,, 2025; the laboratory director is herein cited for failure to ensure that a CLIA compliant, approved, signed, and dated, procedure manual and laboratory policies that accurately reflects current laboratory practices is available for all personnel. See D5403.