Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0685650	09/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
Anza Dermatology Laboratory	901 S State St, Ste #100, Hemet, 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
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 the Dermatology Histology Laboratory procedure titled, "Mohs Procedure", the lack of records for Stain Quality, and interview with laboratory personnel, it was determined that the written procedure failed to include instructions for a Control slide to assess and document the Quality of Staining reagents each day of use. Findings included: a. The laboratory Mohs Procedure provided instructions for transferring a tissue section to a labeled glass slide and stain using Progressive Hematoxylin and Eosin or Toluidine Blue. After coverslipping, the slide is interpreted

	by the Doctor. b. The Mohs Procedure omitted assessing the quality of the stains, making adjustments as needed, and documenting if the staining was satisfactory or unsatisfactory for interpreting the slides. c. Laboratory Assistant-3 affirmed (8/26/25 at 2:00PM) the aforementioned written procedure and lack of instructions for a Control Slide or documenting Stain Quality each day of staining Mohs slides. .
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the Dermatology Histology Laboratory procedure titled, "Mohs Procedure", the lack of temperature records, and interview with Laboratory Assistant - 2, it was determined the laboratory failed to monitor and record the temperature of the Cryostat for the timeframe March 2023 - February 2024. Findings included:. a. The Mohs Procedure instructed: "Cryostat temperature is taken and maintenance done and recorded on days of activity in Mohs Laboratory". b. Cases randomly selected for this Survey from the Mohs Logs documented dates Mohs Procedures were performed, as follows: Date of Service Mohs Case # ---------- 5/24/23 23 - 208 10/25/23 23 - 425 1/31/24 24 - 43 c. The laboratory failed to have records for Cryostat temperatures for the timeframe March 2023 - February 2024. d. Laboratory Assistant - 2 affirmed (8/26/25 at 3:00 PM) the aforementioned findings. e. The reliability and quality of the Cryostat to function properly during the twelve months of March 2023 to February 2024 could not be assured during this Survey. .
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on review of laboratory records for Mohs procedures, the lack of records, and interview with laboratory personnel, it was determined the laboratory failed to assure and document the quality of H & E and Toluidine Blue staining reagents met the criteria for acceptability each day of use. Findings included: a. Mohs Logs documented the performance of Mohs procedures during the timeframe of 2022 - 2025. Cases were randomly selected for this Survey, as follows: Date Mohs Case # ---------- 4/20/22 22 - 163 6/29/22 22 - 276 11/30/22 22 - 509 2 /16/23 23 - 70 5/24/23 23 - 208 10/25/23 23 - 425 1/31/24 24 - 43 7/11/24 24 - 353 12 /12/24 24 - 615 (continued) 2/20/25 25 - 106 5/14/25 25 - 288 8/21/25 25 - 502 b. The laboratory was unable to provide records documenting the quality of the stains each date Mohs procedures were performed. c. Laboratory Assistant -3 affirmed (8/26/25 at 2:00 PM) the aforementioned findings; and thus, the laboratory failed to ensure the

	quality of the stains were satisfactory each day of use. d. The reliability and quality of the stains used each date of Mohs procedures was not assured during this Survey. The laboratory performed 507 Mohs procedures annually (LAB144A Laboratory Testing Declaration, 5/25/25). .
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: . Based on the findings and deficiencies cited, the Laboratory Director is herein cited for deficient practice in ensuring that quality control procedures were established and Cryostat monitoring and maintenance were maintained to assure the quality of Mohs procedures performed. Findings included:. a. D5403; the Laboratory Director approved the written Mohs Procedure although it lacked instructions for assuring and documenting Stain Quality. b. D5435; under the Laboratory Director's administration, the laboratory failed to monitor and maintain the Cryostat temperature. b. D5481; the Laboratory Director performed Mohs procedures without documenting Stain Quality each date of service.