

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2150801	(X3) Date Survey Completed 08/11/2026
Name of Provider or Supplier La Jolla Dermatology & Laser Surgery Center	Street Address, City, State 7301 Girard Ave Ste 202, La Jolla, 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 the surveyor's review of Proficiency Testing (PT) records, random selection of seven (7) patient reports, and interviews on August 11, 2026, it was determined that the laboratory did not verify the accuracy of high complexity Histopathology test at least twice annually for the years 2023, 2024, and 2025. The findings included: 1. The laboratory conducted Histopathology testing for Mohs Micrographic Surgery, which is not listed in subpart I of the 42 CFR part 493. For test procedures not listed in subpart I, the laboratory must verify the accuracy of the test procedures at least twice annually. 2. On August 11, 2026, at approximately 1:00 p.m., the laboratory director confirmed that all peer review cases for the years 2023, 2024, 2025, and 2026 were collectively submitted for peer review on July 30, 2026. The laboratory did not maintain records for accuracy verification of tests at least twice annually during 2023, 2024, and 2025. 3. The laboratory's testing declaration form, signed by the laboratory director on July 30, 2026, stated that the laboratory performed approximately 500 tests annually.
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 the surveyor's review of the laboratory's procedures and policies, random selection of seven (7) patient reports, and interviews on August 11, 2026, the laboratory did not maintain a written procedure manual that included all necessary criteria relevant to laboratory operations. The findings included: 1. The laboratory performed Histopathology testing. The tests in histopathology include both gross examination (macroscopic), and microscopic examination of the slide(s) with evaluation and diagnostic interpretation. 2. On the day of survey, the laboratory maintained the policies and procedures for slide processing. On August 11, 2026, at approximately 1:30 p.m. laboratory testing personnel confirmed the laboratory failed to maintain policy and procedure manuals outlining all essential criteria for laboratory operations. The missing components included quality control procedures, verification of test accuracy, and step-by-step protocols for microscopic examination of slides. See D5217 3. The laboratory's testing declaration form, signed by the laboratory director on July 30, 2026, stated that the laboratory performed approximately 500 tests annually.