

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0593365	(X3) Date Survey Completed 07/31/2026
Name of Provider or Supplier Dermatology Medical Group	Street Address, City, State 490 Post St Ste 700, San Francisco, 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 fourteen (14) patient reports, and interviews on July 31, 2026, it was determined that the laboratory did not verify the accuracy of high complexity Histopathology and moderate complexity Mycology tests at least twice annually for the years 2023, 2024, and 2025. The findings included: 1. The laboratory conducted Histopathology testing for Mohs Micrographic Surgery and Mycology using Potassium Hydroxide (KOH) testing, which are 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 July 31, 2026, at approximately 11:00 a.m., the laboratory testing personnel confirmed that 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 22, 2026, stated that the laboratory performed approximately 1140 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 and an interview with laboratory testing personnel (TP) on July 31, 2026, the laboratory did not maintain a written procedure manual that included all necessary criteria relevant to laboratory operations for 3 of 3 years from 2023 through the date of the survey. The findings included: 1. The laboratory performed Histopathology testing and Mycology using Potassium Hydroxide (KOH) testing. The laboratory processed slides in-house. 2. On July 31, 2026, at approximately 11:00a.m. laboratory testing personnel confirmed that the laboratory maintained only the policies and procedures related to slide processing. The laboratory failed to provide policy and procedure manuals outlining all essential criteria for laboratory operations, including preanalytic, analytic, and postanalytic testing for Mohs, Dermatopathology, and KOH prep procedures performed on site. 3. The laboratory's testing declaration form, signed by the laboratory director on July 22, 2026, stated that the laboratory performed approximately 1140 tests annually.

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 a review of laboratory policies and procedures, and interviews with testing personnel conducted on July 31, 2026, at approximately 11:00 a.m., it was determined that the Laboratory Director (LD) of high complexity testing failed to ensure that an approved procedure manual was accessible to all individuals involved in any part of the testing process. The findings included: The laboratory director failed to ensure that the procedure manual is available to all personnel responsible for any aspect of the testing process. See D5217, D 5403