

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0928815	(X3) Date Survey Completed 07/30/2026
Name of Provider or Supplier Michael K Burns Md	Street Address, City, State 450 Sutter St Ste 1412, 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
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on a review of the laboratory's stained slides , including a random selection of twenty- seven (27) stained slides from 04/04/2024 to 07/02/2026, and interview with laboratory assistants on July 30, 2026, it was found that 6 out of 27 slides were stuck to adjacent slides. This indicates that the laboratory failed to maintain or store stained slides according to the required conditions for proper preservation. The findings included: 1. The laboratory performed Mohs Micrographic Surgery onsite. 2. During the survey, the surveyor examined 27 slides collected over 6 days and discovered that 6 of them were stuck to the adjacent slides o Patient #1 (04/04/2024): 2 slides adhered together. o Patient #2 (09/18/2025): 2 slides adhered together. o Patient #3 (07/02 /2026): 2 slides adhered together. 3. On July 30, 2026, at approximately 11:00 a.m., laboratory assistant #1 and laboratory assistant #2 confirmed that the slides had adhered to each other. 4. The laboratory's testing declaration form, signed by the laboratory director on July 27, 2026, stated that the laboratory performed approximately 700 histopathology tests annually.
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 with laboratory assistant on July 30, 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 30, 2026, at approximately 11:00 a.m., the laboratory assistant 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 27, 2026, stated that the laboratory performed approximately 720 tests annually.
D5315	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(c) (c) The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS. This STANDARD is not met as evidenced by: Based on a review of specimen grossing records, interviews with laboratory personnel, and a review of eight (8) randomly selected patient test results on July 30, 2026, the laboratory failed to refer high-complexity specimen grossing tests to a CLIA-certified laboratory in 2023, 2024, 2025, and 2026. The findings were as follows: 1. The laboratory conducted high-complexity dermatopathology testing, and specimens were sent to an external reference laboratory (LAB#2) for specimen grossing. Gross examination consisted of tasks such as weighing, measuring, describing color, ensuring proper orientation for diagnostic purposes, and assessing other tissue characteristics, as well as performing mechanical procedures like inking and marking. All of these are considered high-complexity tests. 2. On July 30, 2026, at approximately 10:30 a.m., laboratory personnel confirmed that the laboratory did not maintain any record indicating that LAB#2 is CLIA certified. A follow-up email on August 4, 2026, at 12:00 p.m., confirmed that LAB#2 did not have a CLIA certificate. 4. The laboratory's testing declaration form, signed by the laboratory director on July 27, 2026, stated that the laboratory performed approximately 700 histopathology tests including dermatopathology annually.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory policies and procedures, specimen referral, stored slides and an interview with the laboratory assistant on July 30, 2026, it was determined that the Laboratory Director (LD) of high complexity testing failed to provide comprehensive management and direction as required under 493.1445 of this subpart in 2023, 2024, 2025 and 2026. The findings included: 1. The laboratory director failed to ensure that stained slides were stored under the necessary conditions for proper preservation. See D3013 2. The laboratory director failed to ensure that the reference laboratory for specimen grossing maintains a current CLIA certificate. See 5315 3. The laboratory director failed to ensure that the laboratory verified the accuracy of high-complexity histopathology and moderate-complexity mycology tests at least twice annually. See D5217