

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2023312	(X3) Date Survey Completed 08/06/2025
Name of Provider or Supplier Silicon Valley Dermatology	Street Address, City, State 2050 Clarmar Way, San Jose, 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
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's quality assessment records, randomly chosen patient records for Mohs procedure and an interview with the laboratory director (LD), it was determined the laboratory failed to provide the quality control slide to assess the quality of staining materials on each day of Mohs. The findings include: 1. Based on the surveyor's review of 2022-2025 Mohs patient records, it was determined that one out of seven records was missing a quality control (QC) slide on October 14, 2022. 2. The LD affirmed by interview on August 6, 2025, at approximately 3:00 p.m., that the quality control slide for Mohs on October 14, 2022 was not found. No corrective action was available at the time of survey. 3. Based on the testing declaration form submitted on August 6, 2025, the laboratory performed and reported approximately 90 Mohs cases including the time when the QC slide was missing. Thus, the quality of staining and the reliability of the Mohs records could not be assured.</p>
D5821	<p>TEST REPORT CFR(s): 493.1291(k)</p> <p>(k)When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the</p>

original report, as well as the corrected report.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory's quality assessment (QA) policy /procedure, randomly chosen patient test records, and an interview with the laboratory director (LD), it was determined that the laboratory failed to correctly document patient information upon its occurrence. The findings include: 1. The surveyor reviewed six provider performed microscopy (PPM) patient test records from July 11, 2022 to April 22, 2025. One out of six records contained discrepancies, specifically: a. Patient KIMBY370, examined on December 16, 2024 was recorded as positive for KOH in the QA log sheet but was reported negative in the final report. 2. Another set of patient records were reviewed by the surveyor for Mohs test and two out of seven records revealed discrepancies for the following: a. Patient 22-041, examined on October 14, 2022, had missing entries for the cryostat temperature and cryostat preventive maintenance (PM). b. Patient 25-010, examined on February 28, 2025, had missing entries for the cryostat PM log and the slides were found broken at the time of the survey. No corrective action report available for review. 3. In addition, Mohs records reviewed from October 14, 2022 until July 18, 2025 showed that no records for stain PM were performed. Last recorded PM entry was on July 30, 2021. 4. The LD affirmed by interview on August 6, 2025, at approximately 3:00 p.m., that the discrepancies occurred, mentioned in statements #1, #2, and #3 were missed during the quality assessment check. The accuracy and reliability of patient tests reported cannot be assured. 5. According to the laboratory's testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 10 PPM tests and 90 Dermatopathology tests, including the time when the discrepancies in the records occurred.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(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 surveyor's review of the laboratory's policy/procedure, selected patient test records for PPM and Dermatopathology, and an interview with the laboratory director on August 6, 2025; this deficiency is herein cited due to failure to ensure that quality control and quality assessment programs established were followed to assure the quality of services offered and identify problems as it occur. The findings include: 1. Missing quality control slide. See D5473. 2. Errors in test reports. See D5821.