

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0912897	(X3) Date Survey Completed 09/04/2025
Name of Provider or Supplier Golden State Dermatology	Street Address, City, State 6769 N Fresno St, Ste 101, Fresno, 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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's observations during the laboratory tour, and interviews with the office manager (OM); the laboratory failed to follow safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. The findings include: 1. The laboratory failed to follow their safety policy and procedure to provide protection from physical, chemical, biochemical, and biohazardous materials as needed based on the laboratory's risk assessment. 2. Surveyor observed during the laboratory tour that no eye wash station or eye wash portable bottle kit was found in the testing area. 3. the laboratory had a biological spill kit, however; no chemical spill kit was available. 4. The OM by interview on September 4, 2025, at approximately 4:00 p.m. affirmed that the laboratory lacked an eye washing station and a chemical spill kit 5. The safety of laboratory testing personnel could not be assured at this time. 6. The annual testing declaration form submitted at the time of the survey stated 550 samples were processed and reported for Dermatopathology during the time when safety concern for all testing personnel could not be assured.</p>
D3043	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7)</p> <p>(a)(7) Slide, block, and tissue retention-- (a)(7)(i) Slides. (a)(7)(i)(A) Retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). (a)(7)(i)(B) Retain histopathology slides for at least 10 years from the date of examination. (a)(7)(ii) Blocks. Retain pathology specimen</p>

blocks for at least 2 years from the date of examination. (a)(7)(iii) Tissue. Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.

This STANDARD is not met as evidenced by:

Based on the lack of updated policies and procedures reflecting the current practice, review of randomly selected patient test records, and interview with the office manager (OM); the laboratory failed to provide an approved and signed policy and procedure for retention of documents and storage requirements. Findings include: 1. In reference to the retention requirements in 42 CFR Part 493.1105 (Standard Retention Requirements), the laboratory is herein cited for the deficient practice of lacking an approved and signed retention and storage requirements policy and procedure. 2. The OM stated during an interview on 9/4/2025 at approximately 3:00 p. m., that the laboratory does not have a policy and procedure for record retention and storage for: test results, test procedures, quality system assessment record, and Histopathology slides. 3. Based on the laboratory's testing declaration submitted at the time of the survey, the laboratory performed an estimated 550 patient samples during the time that no retention and storage policy and procedure was implemented.

D5203

SPECIMEN IDENTIFICATION AND INTEGRITY
CFR(s): 493.1232

The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

This STANDARD is not met as evidenced by:

Based on review of patient testing records, patient final testing reports, and interviews with the office manager (OM) on September 4, 2025, at approximately 3:00p.m.; it was determined that for one (1) out of five (5) randomly selected patient Mohs testing records reviewed, the laboratory failed to follow written policies and procedures for specimen analytical phase testing, through completion of testing and reporting results. The findings included: 1. Review of Mohs documentation and patient's final test report found the following discrepancy: Patient 1: Date of Mohs 7/20/2023, location stated in the Mohs log as Right Inferior Helix. Location stated in the final report; Right Lateral Forehead. 2. The OM affirmed that records were discrepant for one (1) out of five (5) Mohs patients' records reviewed as stated in #1 above. 3. No corrective action was recorded. 4. Based on the laboratory's annual test volume declaration signed by the LD on 9/04/2025 the laboratory performed and reported 500 Mohs procedures for which its accuracy cannot be confirmed.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on the surveyor's observation during the laboratory's tour and interviews with the office manager (OM), the laboratory failed to label reagents used in the laboratory to indicate the received date, opening, preparation, and expiration dates when such materials are used. The findings include: 1. Based on the surveyor's observation during the laboratory's tour on September 4, 2025, at approximately 3:15 p.m. no received date, opening date, and preparation labels were used or documented for reagents: " Tissue dye markers " Hematoxylin " Xylene " 100% absolute alcohol " Acetone " Freezing oil 2. There was not a reagent log available for the date received, lot number, expiration date and, and opening date. 3. The laboratory's OM affirmed by interview conducted on September 4, 2025, at approximately 3:15 p.m. that the reagents mentioned in statement #1 were not labeled with the received date, opening, preparation, and/or expiration date or a reagent log. 4. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 500 samples for Mohs test procedure using reagents not labeled as regulated.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(1)

(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the laboratory's policies and procedures, randomly selected patient test records, preventive maintenance documentation, and interview with the office manager on September 4, 2025, the laboratory director is herein cited due to failure to ensure that several aspects of the preanalytical, analytic, and postanalytic phases of the laboratory testing were monitored. The findings include See D3011, D3043,D5203, and D5415.