

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0933383	(X3) Date Survey Completed 11/20/2024
Name of Provider or Supplier Golden State Dermatology - Merced	Street Address, City, State 388 E Yosemite Ave Ste 100, Merced, 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 observation during the laboratory tour, review of policies and procedures, preventive maintenance (PM) records, and interview with the office manager (OM), it was determined that the laboratory failed to follow and document the established safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. The findings include: 1. Based on the surveyor's observations during the laboratory tour on November 20, 2024, no eye wash station or portable eye wash bottles were found. 2. Based on the review of the PM records, no documentation could be retrieved for the eye wash bottle at the time of the survey. 3. The OM affirmed by interview on November 20, 2024, at approximately 12:50 p.m. that the laboratory lacked an eye wash log for the years 2022, 2023, and 2024 and failed to find the physical bottle near the processing and testing areas. 4. Based on the laboratory's annual testing volume declaration submitted at the time of the survey, the laboratory processed and reported approximately 3,202 patient test samples for Dermatopathology.</p>
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system</p>

performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policies and procedures, equipment function check documentation, preventive maintenance (PM) log sheets, five (5) randomly selected Mohs patient test records, and an interview with the office manager (OM), it was determined that the laboratory failed to ensure function checks and PM performed were documented. The findings include: 1. Based on the survey on November 20, 2024, at approximately 12:00 p.m., no documentation could be retrieved for the stain preventive maintenance (PM) for four (4) out of 5 Mohs patient test records reviewed for the years 2022 and 2023. 2. Based on the review of PM records, no documentation could be retrieved to support the OM ' s claim that the eye wash bottle was checked for the years 2022, 2023, and 2024. 3. The OM stated in an interview at approximately 12:00 p.m. on November 20, 2024, that the laboratory had separate binders for Mohs on each year but could not locate it at the time of the survey as mentioned in statement #1. Also, the OM affirmed in the same interview that the laboratory lacked an eye wash PM record to document every check as cited in statement #2. 4. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory performed and reported approximately 3,202 patient tests for Dermatopathology.

D6084

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(2)

The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards.

This STANDARD is not met as evidenced by:

Based on the surveyor's findings, the laboratory director is herein cited for the deficient practice in failure to provide and overall administration of the laboratory to ensure a safe environment in which personnel are protected from physical, chemical, biochemical, and biohazardous materials. Findings include: See D3011 and D5435.