

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0906539	(X3) Date Survey Completed 12/03/2020
Name of Provider or Supplier Golden State Dermatology Associates	Street Address, City, State 355 Lennon Ln Ste 255, Walnut Creek, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records for instrument maintenance and an interview with laboratory personnel (LP) on 12/3/2020 between 2:00 p.m. and 3:30 p.m, it was determined that the temperature log for the cryostat had gaps in daily temperature monitoring Findings include: 1. On 12/3/2020, an inspection was conducted between 2:00 p.m. and 3:30 p.m. 2. During a review of the laboratory documentation for equipment maintenance and monitoring , it was noted at approximately 2:45 p.m. that there were gaps in the cryostat temperature log sheet. The laboratory performs MOHS testing Monday-Friday each week. The LP recognized these atypical findings. 3. The Cryostat temperature log had no entries between 9/28/2020 and 11/23/2020, indicating a lack of monitoring and documentation. 4. MOHS services are contracted to MobileMOHS.</p>