

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0906539	(X3) Date Survey Completed 07/19/2023
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 observation of Mohs slides prepared onsite, review of 2021-2023 laboratory cryostat temperature records, and interview with laboratory administrative personnel, the laboratory failed to monitor and document the temperature of the cryostat in 2021. Findings included: 1. Mohs slides from 2021 - 2023 were randomly selected for this survey. 2. Laboratory records were reviewed for monitoring and documenting the cryostat temperature each date that Mohs slides were prepared. 3. For 8 out of 8 dates in 2021, the laboratory failed to have cryostat temperature records as follows: 3/19/21 4/13/21 5/06/21 7/21/21 8/11/21 9/07/21 11/24/21 12/21/21 4. Laboratory administrative personnel affirmed (7/19/23 at 4:00pm and 7/27/23 at 6:45 am) the laboratory failed to have cryostat temperature records for the dates in 2021. .</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p>

This STANDARD is not met as evidenced by:

Based on the lack of cryostat temperature records for 2021, the laboratory failed to establish a written policy and procedure of ongoing quality assessment to monitor, identify, and correct problems in the laboratory. See D5413.