Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1070461	08/16/2023
Name of Provider or Supplier	**Street Address, City, State**	
Golden State Dermatology Associates	2490 Hospital Dr, Ste 201, Mountain View, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records and written procedure, the lack of records, and interview with laboratory administrative personnel, the laboratory failed to verify the accuracy of histopathology testing. Findings included: 1. To satisfy this requirement to verify the accuracy of testing at least twice annually, the laboratory procedure titled, "Pathology Peer Review", instructed the Back Office personnel: "Two slides per pathologist will be sent out for consult/second opinion each year", to include Mohs cases, pathology slides, or any combination and to place the consult reports in the CLIA binder. 2. Form CMS209, Laboratory Personnel Report (CLIA), dated 8/14 /23, named four persons testing in Histopathology. Laboratory records documented testing performed, as follows: Testing Type of testing Year Person ---------- 1 Mohs, Biopsies 2021, 2022, 2023 2 Biopsies 2021, 2022, 2023 3 Biopsies 2021, 2022, 2023 4 Biopsies ---- , 2022, 2023 3. The laboratory failed to provide for review records of second opinion/peer review for Testing person-3 in 2021 and 2022, and Testing person-4 in 2022. 4. The administrative personnel affirmed (8/16/23 at 4:00pm) the aforementioned written procedure and lack of peer review records for Testing person-3 and Testing person-4. 5. And thus, the reliability and quality of dermatopathology results reported by Testing person-3 in 2021-2022, and Testing person-4 in 2022, could not be assured in the absence of peer reviews. .
D5805	TEST REPORT CFR(s): 493.1291(c)

	The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of laboratory reports for the timeframe 2021 - 2023, the test reports failed to clearly state where testing was performed. Findings included: 1. Six of 6 laboratory reports reviewed stated two addresses, as follows: a. 370 N. Wiget Lane Walnut Creek, CA 94598 b. 2490 Hospital Drive suit 201 Mountain View, CA 94040 2. Each laboratory report included Gross Description, a high complexity test; and failed to clearly state the address where it was performed. 3. The laboratory issued 3,000 reports annually, including Grossing (form CMS116, CLIA Application, 8/14 /23). .
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on the lack of laboratory records for 2021-2022, the laboratory is herein cited for failing to establish quality assessment activities to monitor, assess, identify problems, and provide corrective actions to ensure compliance after testing. Findings included: 1. The laboratory failed to identify there were no peer review records in 2021-2022 for two out of four Testing persons. .