Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0946554	07/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
Golden State Dermatology	400 Taylor Blvd Suite 301, Pleasant Hill, 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 the review of the laboratory's proficiency testing (PT) documentation from 2023 through 2026, and interviews with the practice manager and regional director on July 9, 2026, it was determined that the laboratory failed to verify the accuracy of tests not included in Subpart I at least twice annually, as required by 42 CFR 493.1236 (c). The findings include: 1. The surveyor reviewed the laboratory's proficiency testing documentation from 2023 through 2026, and found that specifically for potassium hydroxide (KOH) and scabies testing, there was no documentation available for review at the time of the survey. 2. During an interview on July 9, 2026, the practice manager and regional director confirmed that the testing personnel had no accuracy verification (alternative assessment) documentation for KOH preparations and scabies microscopic examinations for the years 2023, 2024, 2025, and 2026. 3. According to the testing declaration (Lab-144) form submitted at the time of survey, the laboratory performed and resulted approximately 10 tests for KOH and scabies tests annually including the time when at least twice annually, there was a lack of accuracy verification. . .
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory's tour, review of nine patient test records from October 11, 2023 to June 30, 2026, and interviews with the practice manager and regional director on July 9, 2026, it was determined that the laboratory failed in using reagent materials beyond its expiration date for patient testing. The findings include: 1. The laboratory performed potassium hydroxide (KOH) and scabies testing. Observations during the tour revealed that reagents used for these tests were beyond their expiration dates. a. KOH 10% in DMSO, Lot number 010126, expired January 23, 2026. b. Chlorazol Black E with lot number 2285, expired October 12, 2024. 2. The surveyor reviewed nine patient test records for KOH and scabies tests and found that five were performed using reagents beyond their expiration dates: a. Patient 1617927, examined November 14, 2025 (scabies) b. Patient 1240297, examined February 23, 2026 (KOH) c. Patient 1857071, examined June 8, 2026 (KOH) d. Patient 807168, examined June 15, 2026 (KOH) e. Patient 807635, examined June 30, 2026 (scabies) 3. During an interview on July 9, 2026, at approximately 12:10 p.m., the practice manager and regional director confirmed that the bottles used for KOH and scabies testing were used beyond its expiration date and no newer bottles were availble at the laboratory. 4. According to the laboratory's annual testing declaration submitted at the time of the survey, the laboratory performed and reported approximately 10 KOH and scabies tests annually including the time when the reagents used for patient testing were used beyond its expiration date. .
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(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 the surveyor's review of the laboratory's policy and procedure, nine patient records, lack of preventive maintenance (PM) documentation, and interviews with the practice manager and regional director on July 9, 2026, it was determined that the laboratory failed to ensure performed tests and function checks were documented or maintained for the microscope prior to patient testing. The findings include: 1. The laboratory used two different microscopes. a. The Leica DM570 with serial number: 614780 was used for pathology. b.The Nikon Alphaphot-2 with serial number 1110223 was used for the KOH and scabies testing. 2. The laboratory's policy stated that the preventive maintenance (PM) for the microscopes were to be performed annually. However, specifically for Nikon, the record for 2024 was not found. The PM documentation available for review included PM performed on July 27, 2023, July 10, 2025, and July 7, 2026. 3. Two out of nine records that were selected for review by the surveyor were performed when there was no documentation to verify that the microscope was serviced. a. Patient 1518771, examined in August 30, 2024 b. Patient 1498405, examined on January 22, 2025 4. During an interview on July 9, 2026, at approximately 9:45 a.m., the practice manager and regional director confirmed that PM documentation for the Nikon microscope was not available at the

	time of the survey. 5. According to the testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 10 KOH and scabies tests annually, including during the period when PM for the microscope in 2024 could not be verified.
D5821	TEST REPORT CFR(s): 493.1291(k) (k)When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on the surveyor's review of nine patient test reports from October 11, 2023 to June 30, 2026, the patient log sheet, and interviews with the practice manager and regional director on July 9, 2026, it was determined that the laboratory failed to address errors in patient records prior to finalizing reports. The findings include: 1. The surveyor reviewed nine patient records and identified one record with a discrepancy in site documentation between the log sheet and final report. a. For patient 1857071, examined on June 8, 2026, the KOH log sheet recorded the specimen site as right side abdomen, while final report recorded the site as epigastric skin. b. No amendment report or corrective action documentation was available at the time of the survey. 2. Both the practice manager and regional director confirmed in an interview on July 9, 2026, at approximately 12:10 p.m. that the laboratory failed to address errors in patient records prior to finalizing reports. 3. According to the laboratory's testing declaration form (Lab-144) submitted at the time of survey, the laboratory performed and reported approximately 10 tests for KOH and scabies annually including the time when the discrepancies occurred.
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 policy and procedure, patient test records, preventive maintenance documentation, lack of proficiency testing records, and interviews with the practice manager and regional director on July 9, 2026, the laboratory director is herein cited for failure to provide quality laboratory services for all aspects of testing, especially in the preanalytic, analytic and postanalytic phase of testing. The findings include: 1. The laboratory failed to verify accuracy of at least twice annually for the KOH and scabies testing for the years 2023, 2024, 2025, and 2026. See D5217. 2. The laboratory used reagents beyond its expiration date for

	patient testing. See D5417. 3. The laboratory failed to maintain preventive maintenance records for the microscope in 2024. See D5435. 4. The laboratory failed to address errors in information prior to finalizing reports. See D5821.