Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0933384	07/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Redding Dermatology	2135 Airpark Dr, Ste B, Redding, 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 patients Mohs records for 2022-2024, the lack of records for the timeframe 2022-2023, and interview with the laboratory administrative person, it was determined that the laboratory failed to verify the accuracy of Mohs procedures to clear tumors. Findings included: a. The Mohs Log Books and patients Mohs records revealed procedures had been performed in 2022- 2024. b. The laboratory failed to provide for this survey: records of ("peer") review of Mohs slides verifying final stage and clearing of tumor. c. The laboratory administrative person affirmed (7/25/24 at 2: 00 PM) the aforementioned findings and that no Mohs slides had been reviewed in 2022 and 2023. d. The reliability of the Mohs procedures to clear tumors in 2022-2023 could not be assured. Annual Mohs volumes are as follows: 2022 = 71 2023 = 47 .
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based on review of records for Mohs procedures, missing information, and interview with the laboratory administrative person, it was determined the laboratory failed to test and assess the quality of staining materials each day of Mohs. Findings included: a. Review of 2022-2024 Mohs records revealed 8 out of 8 dates failed to document the quality of staining with the Mohs surgeon/Testing person's approval, as follows: Date ---------- 1/31/22 5/12/22 10/13/22 1/10/23 6/01/23 11/02/23 2/13/24 7/09/24 b. The laboratory administrative person affirmed (7/25/24 at 12:00 PM) that the aforementioned records were missing Stain Quality assessment and acceptability by the Mohs surgeon/Testing person on each date of Mohs. c. And thus, the quality of staining and the reliability of the Mohs records could not be assured. The laboratory performed 71 Mohs procedures in 2022 and 47 in 2023. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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. This STANDARD is not met as evidenced by: Based on the deficiencies cited at D5217 and D5473, it was determined that the laboratory failed to establish and follow written policy and procedure for an ongoing process to regularly monitor laboratory records and correct problems as they are identified. Findings included: a. The laboratory had no process for self monitoring and thus failed to identify in 2022 and 2023 that no Mohs slides had been selected for review. b. The laboratory had no process to assure records were complete and thus failed to identify that the quality of staining materials had not been assessed and approved by the Testing person/Mohs surgeon. .
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the findings and deficiencies cited, the Laboratory Director is herein cited for deficient administration and overall operation of the laboratory. Findings included: a. The Laboratory Director had not established a process of monitoring Mohs records to ensure that the quality of staining materials were assessed, approved and documented by the Testing person/Mohs surgeon. b. The Laboratory Director had not established a process of monitoring for Mohs review records to ensure slides were selected and reviewed each year.