Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0573825	02/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology & Laser Center Of Redlands	255 Terracina Blvd Ste 206, Redlands, 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 lack of the laboratory's Evaluation of proficiency testing performance for its histopathology, and interview with the office manager, it was determined that the laboratory, at least twice annually, failed to verify the accuracy of histopathology testing it performed for the years of 2019 and 2020. The findings included: a. The laboratory performed Mohs surgery onsite including the examination of the skin tissue slides, a histopathology testing which is not included in subpart I of 42 CFR part 493. b. The laboratory failed to verify is the accuracy of histopathology testing performance at least twice annually for the years of 2019 and 2020. c. The office manager affirmed (2/17/21 @ 10:50 am) that there were no evaluation of histopathology proficiency testing performance or peer review documents available at the time of survey.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of lack of the laboratory's Evaluation of proficiency testing performance for its histopathology, and interview with the office manager, it was determined that the laboratory, at least twice annually, failed to document all histopathology proficiency testing evaluation and verification activities for the years

	of 2019 and 2020. The findings included: a. The laboratory performed Mohs surgery onsite including the examination of the skin tissue slides, a histopathology testing which is not included in subpart I of 42 CFR part 493. b. The laboratory failed to document the evaluation of histopathology testing performance at least twice annually for the years of 2019 and 2020. c. The office manager affirmed (2/17/21 @ 10:50 am) that there were no documents for the evaluation of histopathology proficiency testing performance or peer review documents for the years of 2019 and 2020 available at the time of survey.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures (P&P) for Mohs surgery including the acceptable temperature condition of the Cryostat, observation of the histology staining facility in house, notice of the staining reagent supplies, and interview with the laboratory personnel, it was determined that the laboratory failed to perform and to follow its written P&P in a manner that provides test results within the laboratory's stated performance specifications. The findings included: a. The laboratory performs Mohs surgery procedures and process tissue slide cutting and staining onsite. b. The laboratory had established an acceptable temperature for a Cryostat temperature between -20 to -30 oC in its P&P. c. The Cryostat temperature records of 2020 from 1/9/2020 to 12/21/20, showed and indicated that acceptable temperature range between -15 to -29 oC which is inconsistent with its written P&P. d. The laboratory personnel affirmed (2/17/2021 @ 10:45 am) that the acceptable temperature range of -15 to -29 oC was on the chart which is different from the written P7P of -20 to -30 oC.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's Cryostat temperature records, and interview with the laboratory personnel and the office manager, it was determined that the laboratory failed to monitor and document the Cryostat temperature and to ensure accurate and reliable test system operation, and test result reporting, and to assure the consistency with the written policies and procedure (P&P) of Mohs surgery procedures. The findings included: a. The laboratory performed Mohs surgery and process skin tissue

	slide cutting and staining onsite. b. The laboratory failed to monitor and document the Cryostat temperature between 5/21/2020 and 12/21/2020 (total of 21). c. The laboratory personnel affirmed (2/7/2020 @ 10:45 am) that lack of Cryostat temperature documentations between 5/21/2020 and 12/21/2020.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the histology staining facility in house, notice of the staining reagent supplies, and interview with the laboratory personnel, it was determined that the laboratory failed to labeled the reagent supplies properly when it was once opened to ensure the stability of the reagents, storage requirement, and expiration date. The findings included: a. The laboratory performs Mohs surgery procedures and process tissue cutting and staining onsite. b. The laboratory stored Gill 3 Hematoxylin and Eosin Working Solution. c. The Eosin bottle was labeled as 6/2020 opened, and Gill 3 was labeled as open date of 12-2020. d. The laboratory personnel affirmed the labeled information were "dated" rather than the month and the year. e. The laboratory failed to "date" the open date properly.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the lack of the evaluation of histopathology proficiency testing performance, observation of the histology staining facility in house, notice of the staining reagent supplies, and interview with the laboratory personnel and the office manager, it was determined that the laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included: a. The laboratory failed to verify and to document, at least twice annually, the accuracy of the histopathology examination for the years of 2019 and 2020, see D-5217 and D-5221 b. The laboratory failed to monitor and document the Cryostat temperature properly, see D-5411 and D-5413 c. The laboratory failed to label a date, when the reagents once they were opened to ensure the quality of the reagents, see D-5415