Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2136308	08/05/2022
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology And Cosmetic Surgery	6160 N Davis Highway #11, Pensacola, FL	

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
D0000	An initial certification survey was conducted on July 28, 2022 continuing through August 5, 2022 to gather additional information. Advanced Dermatology and Cosmetic Surgery, clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of the laboratory's specimen accession log, patient reports, and interview with the Office Manager, the laboratory failed to ensure the positive identification of a patient's specimen from the time of collection through the completion of testing and reporting of results for 1 of 3 histology reports reviewed. Findings include: Based on review of the accession log, specimen #1 from May 18, 2022, and the patient's final report revealed a discrepancy between the spelling of the patient's last name. During interview on July 28, 2022 at approximately 03:15 p.m., it was confirmed the patient's last name was spelled differently on the accession log and the final report.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager, the laboratory failed to perform personnel competency evaluations on the Clinical Consultant (#A) and for 2 of 2 Testing Personnel (TP) (#B and #C) from November 2021 to July of 2022. Findings include: Record review revealed there were no personnel competency evaluations for laboratory staff #A or TP #B or #C. Based on review of the laboratory's policy, "Competency Assessment for Testing Personnel Procedure", it states "Competency Assessment occurs at hire, at 6 months, and then annually and is performed for each test the testing personnel performs." During interview with the office manager on July 28, 2022, it was confirmed no personnel competencies had been performed on laboratory staff #A, #B, or #C.
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 Policy and Procedures, lack of documentation, and interview with the Office Manager, the laboratory failed to verify the accuracy of frozen section slides twice annually from November of 2021 until July 2022. Findings include: Based on the laboratory's policy "Proficiency Testing Mohs Histopathology", it states, "Proficiency testing will be performed bi-annually. To be sent out and returned by end of June and December." There was no documentation for the months of December 2021 or June of 2022. The Laboratory Director started work in the lab November of 2021. During interview with the Office Manager on July 28, 2022 at approximately 03: 15 p.m., it was confirmed no proficiency testing had been performed to verify the accuracy of frozen section slides since the Laboratory Director started in November of 2021.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager, the laboratory failed to have the current Laboratory Director (LD) approve, sign, and date the Policy and Procedure Manual. Findings include: Based on review of the Policy and Procedure Manual cover sheet, it was revealed that the past LD signed and dated the manual on February 5, 2019. The current LD began work in the laboratory November of 2021. During interview with the Office Manager on July 28, 2022 at approximately 03:15 p. m., it was confirmed the current LD had not approved, signed or dated the Policy and Procedure Manual.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 laboratory tour and interview with the Office Manager, the laboratory failed to dispose of expired reagents from the flammable cabinet. Findings include: During the tour of the laboratory, it was revealed there were expired reagents in the flammable cabinet. The expired reagents were: 1. 4 unopened bottles Xylene Substitute Lot #096229 Expiration 1/15/2022 2. 1 opened bottle 95% Reagent Alcohol Lot #077121 Expiration 2/01/2021 3. 1 opened bottle Eosin-Y Lot #096733 Expiration 3/31/2022 4. 1 unopened bottle 100% Reagent Alcohol Lot #097932 Expiration 4/30/2022 Interview with the Office Manager on July 28, 2022 at approximately 03:15 p.m., confirmed the reagents in the flammable cabinet were expired.
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 record review and interview with the Office Manager, the laboratory failed to perform Quality Assurance (QA) activities. Findings include: Based on record review, it was revealed there was no documentation of QA activities from November of 2021 to July of 2022. Review of the QA policy stated, "the Laboratory Director will discuss with staff, on a quarterly basis, the results of quality assurance reviews and ways in which the laboratory can improve the quality of its work." Interview with the Office Manager on July 28, 2022 at approximately 03:15 p.m., confirmed no QA activity had been performed or documented.