Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2096188	10/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology And Cosmetic Surgery	484 Us Hwy 1 Ste C, Sebastian, 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 October 21, 2021. Advanced Dermatology and Cosmetic Surgery clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain Quality Control (QC) records documenting the Hematoxylin and Eosin (H&E) stain quality for 2 (2019, 2020) of 3 (2019, 2020, 2021) years reviewed. Findings: Review of the laboratory's QC records showed the log titled, "Daily Quality Control Slide" for recording the H&E stain quality was not available for review for 2019 and 2020. The Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 10/21/2021, noted the laboratory had an estimated annual test volume of 168 histopathology tests per year. On 10/21/2021 at 10:26 AM, the Manager stated she did not know were the logs were located.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step

	performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory's procedure manual failed to include instructions for labeling the Mohs surgical specimen from 03/16/2020 to 10/21/2021. Findings: Review of the "Revision History" for the laboratory procedures showed the last "Content Revision/Annual Review" was on 03/16/2020 and the last "Annual Review" was on 2/2/2021. Review of the procedure titled, "Mohs Quality Assurance Manual" noted the "Specimen is placed in a petri dish." The procedure did not include instructions for labeling the specimen placed in the petri dish. On 10/21/2021 at 12:43 PM, the manager stated they put a computer generated label with the patients name, date of birth and medical record number on the petri dish and that information was not in the procedure.
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 record review and interview, the laboratory failed to provide all required information for the Mohs surgical reports for 5 of 5 sampled patients, (#1, #2, #3, #4, #5). Findings: The laboratory provided a copy of the patients' visit notes for the Mohs surgical procedures to patients if requested. Review of the visit notes showed the name of the laboratory was missing from the report. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the Laboratory Director on 10/21/2021, the laboratory's annual estimated histopathology test volume was 168 tests. On 10/21/2021 at 12:37 PM, the Manager stated the laboratory's name was not on the reports.