Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2001126	08/03/2023
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology And Cosmetic Surgery	1918 Se 17th St Ste 300, Ocala, 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	At the time of the announced, onsite initial certification survey, Advanced Dermatology and Cosmetic Surgery was found to NOT be in compliance with the CLIA laboratory requirements of 42 CFR 493.
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 record review and staff interview, the facility failed to document room temperature and humidity for 1 of 14 testing days reviewed in 2023. Findings included: Review of the document titled "Laboratory temp/humidity log" showed no documentation of the laboratory room temperature or humidity for July 18, 2023. The record review of the Mohs patient testing log showed 9 patients tested. Interview with the Clinic Manager on 8/3/23 at 10:30AM confirmed that no temperatures were documented for that day.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a

	maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document all maintenance activities for 1 of 2 Mohs testing days in July 2023. The findings included: 1. Review of the laboratory Mohs log showed 9 patients were tested on 7/18 /23. The laboratory document titled "H E Stain Log" did not have any documentation showing the Hematoxylin and Eosin stain used on 7/18/23 was changed or filtered. The facility policy titled "Quality Control Maintenance" states "The stains and reagents must be filtered daily and changed weekly." 2. The laboratory document titled "Cryostat Cleaning and Maintenance Log" dated July 2023 did not show documentation that the cryostat was cleaned after use. The facility policy titled "Quality Control Maintenance" states "The cryostat must be cleaned after each use and the initials of the histologist record on the appropriate date." On 8/3/23 at 10: 30am, the Clinic Manager acknowledged there was missing information on the logs.
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 record review and staff interview, the facility failed to maintain daily quality control (QC) slide documentation for Mohs testing for 7 out of 14 testing days reviewed in 2023. The findings include: The review of QC documentation showed no record for the quality of the Hematoxylin and Eosin stains used during Mohs testing on 2/21/23, 3/28/23, 4/25/23, 5/23/23, 6/27/23, 7/13/23, and 7/18/23. The interview with the Clinic Manager on 8/3/23 at 10:30am confirmed the QC documentation was missing.