

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D1078031	<b>(X3) Date Survey Completed</b>  03/22/2019
<b>Name of Provider or Supplier</b>  Advanced Dermatology & Cosmetic Surgery	<b>Street Address, City, State</b>  1816 Salk Ave, Tavares, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5403</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory's procedure manual failed to include complete step by step instructions for performing proficiency testing. Findings: Review of the procedure titled "Proficiency Testing Mohs Histopathology" showed that the procedure failed to include what corrective action would be take if the second pathologist did not agree with the Mohs Surgeon. During an interview on 3/22 /198 at 3:37 PM, the Director of Compliance and Risk Management acknowledged that the procedure did not include what corrective action would be taken if the second pathologist did not agree with the Mohs Surgeon.</p>

**D5609**

**HISTOPATHOLOGY**

CFR(s): 493.1273(e)(f)

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to document and maintain a record of the open dates for reagents used in their Hematoxylin & Eosin (H&E) stains. Findings: Record review of the laboratory's log titled "Reagent Log" showed that the laboratory failed to record when the reagents were opened from 3/22/17 to 3/22/19. During an interview on 3/22/18 at 2:31 PM, the Director of Compliance and Risk Management confirmed they didn't record the open date for their reagents on the log.

**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's final reports did not include all of the required information. Findings: The laboratory uses their Mohs map titled "Mohs Micrographic Surgery" for the final patient report for their Mohs procedures. Review of the Mohs map showed that the address of the laboratory listed on the Mohs map was the wrong address for 5 out of 5 patients (#1, 2, 3, 4, and 5). Patient #1 - 1/28/19 Patient #2 - 12/3/18 Patient #3 - 12/3/18 Patient #4 - 3/29/18 Patient #5 - 5/11/17 During an interview on 3/22/18 at 3:37 PM, the Director of Compliance and Risk Management acknowledged that the address was wrong on the Mohs map.