Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1046283	03/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology & Cosmetic Surgery	1503 Buenos Aires Blvd Bldg 100, The Villages, 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
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 staff interview, the laboratory failed to perform and document annual competency assessment on 1 of 1 moderate complexity testing personnel from 3/22/17 to 3/22/19. Findings: Review of the competency records showed that the laboratory failed to have documentation of annual competency assessments for moderate complexity Testing Personnel A who performed Potassium Hydroxide (KOH) and Scabies testing from 3/22/17 to 3/22/19. During an interview on 3/22/19 at 10:55 AM, the Director of Compliance and Risk Management stated they did not perform and document annual competency assessments on the moderate complexity Testing Personnel A who performed KOH and Scabies testing.
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 record review and interview, the laboratory failed to verify the accuracy of the Potassium Hydroxide (KOH) and Scabies testing at least twice a year for 2 out of 2 years (2017-2018). Findings: The laboratory is enrolled in proficiency testing (PT) with American Proficiency Institute (API) for KOH and Scabies testing. API provides

	samples for PT three times a year for KOH and Scabies testing. The laboratory participated in KOH and Scabies testing for the 2nd and 3rd events in 2017, and for the 1st, 2nd, and 3rd events in 2018. No other documentation of the laboratory's attempts to verify the accuracy of KOH and Scabies testing were available. A laboratory must obtain PT score of at least 80% to be successful. Review of the AP results showed the following unsuccessful results: 2017 3rd event 50% 2018 1st event 50% 2018 3rd event 50% During an interview on 3/22/19 at 11:30 AM, the Director of Compliance and Risk Management, acknowledged the unsuccessful API results for KOH and Scabies. The Director of Compliance and Risk Management stated that if the laboratory had verified the accuracy of KOH and Scabies it would have been performed using a split sample and it would have been put in the binder.
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 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 12:04 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.
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 where opened from 3/22/17 to 3 /22/19. During an interview on 3/22/18 at 12:03 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 Pathology Report" for the final patient report for their Mohs procedures. Review of the Mohs map showed that the address of the laboratory was not listed for 5 out of 5 patients (#1, 2, 3, 4, and 5). Patient #1 - 2/5/19 Patient #2 - 11/27/18 Patient #3 - 11/27/18 Patient #4 - 4/4/18 Patient #5 - 11/1/17 During an interview on 3/22/18 at 12:13 PM, the Director of Compliance and Risk Management acknowledged that the address was missing from the Mohs map.