Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2136485	04/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology Of Ohio	4834 Socialville Foster Road, Ste 20, Mason, OH	

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
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 an interview with the Location Manager (LM), the laboratory failed to define criteria consistent with the manufacturer's instructions for reagent storage conditions for reliable tissue biopsy procedures and test result reporting. This deficient practice has the potential to affect all patient specimens from December 1 2018 through April 24 2019. Findings Include: 1. Review of the laboratory's policy and procedure manuals titled "ADCS Clinics, LLC d/b/a Advanced Dermatology, Advanced Cosmetic Surgery", provided on the date of the inspection, approved via signature and date by the Laboratory Director on 04/22/2019, did not find any instructions to monitor and document temperature conditions consistent with manufacturer's operating specifications. 2. Review of the "Advanced Dermatology Laboratory Temp/Humidity Log" revealed the following: "Range 36-105 degrees" 3. Review of the StatLab Bluing Reagent" safety data sheet revealed the following: Section 7.2 "Store at 15-30C" C; degrees Celsius 3. The Surveyor requested the laboratory's policy and procedure for the storage temperature ranges consistent with the manufacturer's instructions from the LM. The LM confirmed the laboratory did not establish a policy and procedure for the reagent storage criteria consistent with the manufacturer's instructions, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 10/24/2019 at 10:21 AM.

D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation, and an interview with the Location Manager (LM), the laboratory failed to label all histopathology stains located in the stainline with their IDs, current lot numbers, and expiration dates. This deficient practice has the potential to affect all patient specimens from December 1 2018 through April 24 2019. Findings Include: 1. Direct observation of the Histopathology MOHs tissue grossing and processing area, on 04/24/2019 at 11:03 AM, found 11of 11 unlabeled containers containing reagents, solutions, and stains utilized for MOHs tissue biopsy hematoxylin and eosin (H&E) staining. 2. The Surveyor requested the LM explain the laboratory's labeling protocol. The LM was unaware of any labeling protocol. The interview occurred on 04/24/2019 at 11:15 AM
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and an interview with the Location Manager (LM), the Laboratory Director failed to ensure prior to testing patients' specimens, Testing Personnel (TP) #1 and TP#2 had received the appropriate training and had demonstrated they could perform all testing operations reliably to provide and report accurate results for the high complexity tissue biopsy grossing and slide interpretation procedures performed. This deficient practice has the potential to affect all patients between December 1, 2018 through April 24 2019. Findings Include: 1. Review of the laboratory's policy and procedure titled "ADCS Clinics, LLC d/b/a Advanced Dermatology, Advanced Cosmetic Surgery, Competency Assessment for Testing Personnel", provided on the date of the inspection, approved via signature and date by the Laboratory Director on 04/16/2019, did not find any mention of an initial training and competency assessment policy and procedure for TP. 2. The Surveyor requested the laboratory's TP initial training and competency assessment documentation prior to testing patient tissue biopsies for TP#1 and TP#2 from the LM. The LM provided training documents and a competency assessment from another location. The LM confirmed the laboratory did not establish and follow an initial training and competency assessment policy and procedure for TP per location, did not train and assess the competency of TP#1 and TP#2 prior to the high complexity tissue biopsy

	grossing and slide interpretation procedures performed and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 04 /24/2019 at 10:22 AM.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on review of CMS form 209, the laboratory failed to have one or more General Supervisors who were qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. All patients from December 01, 2018 to April 24, 2019 have the potential to be affected by this deficient practice. Findings Include: 1. Review of CMS form 209 showed no General Supervisor listed.