

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0191111	<b>(X3) Date Survey Completed</b>  02/12/2019
<b>Name of Provider or Supplier</b>  Advanced Dermatology Associates Ltd	<b>Street Address, City, State</b>  1259 South Cedar Crest Blvd Suite 100, Allentown, PA	
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>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory instrument maintenance records, review of the Cleaning, Maintenance and Service of Histology Equipment Policy and interview with the Testing Personnel (TP) #17 and #18, the laboratory failed to follow and document the maintenance of the Leica CV 3000 Coverslipper in 2018 (6 of 12 months). Findings include: 1. On the day of survey, 02/12/2019, review of maintenance records revealed the laboratory failed to document the daily, weekly, and monthly maintenance of the Leica CV 3000 Coverslipper in Februarys, March, June, October, November and December (6 of 12 months) in 2018. 2. In 2018, 39563 histology slides were prepared. 3. TP #17 and 18 confirmed the findings above on 02 /12/2019 around 11:30 am.</p>
<b>D6103</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p>

This STANDARD is not met as evidenced by:  
 Based on review of personnel competency assessment procedure, personnel competency assessment records and interview with the Testing Personnel (TP) #17 and #18, the laboratory Director failed to ensure that policies and procedures were established for monitoring individuals performing delegated regulatory responsibilities for 9 of 10 personnel supervising Mohs, KOH and Scabies testing in 2017 to the date of survey. Findings Include: 1. On the date of survey, 02/12/2019, the lab was unable to provide a complete competency assessment policy that covered monitoring individuals performing delegated regulatory responsibilities for supervising the Mohs, KOH and Scabies testing. a. TP #2 to #9 (8 of 9) are listed on the CMS 209 Form as Clinical Consultants. b. TP #6 and #8 (2 of 2) are listed on the CMS 209 Form as Technical Consultants. c. TP #2 and #3 (2 of 3) are listed on the CMS 209 Form as Technical Supervisors and General Supervisors. \ 2. From 07/11/2017 to 12/31/2017 - 20,12 Mohs, KOH, and Scabies patient tests were performed. 3. From 01/01/2018 to 12/31/2018 - 40,075 Mohs, KOH, and Scabies patient tests were performed. 4. From 01/01/2019 to 02/12/2019 - 463 Mohs, KOH, and Scabies patient tests were performed. 5. TP #17 and #18 confirmed the findings above on 02/12/2019 around 09:30 am \*\*\*\*\* KOH = Sodium Hydroxide

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
 CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
 Based on review of personnel competency assessment records and interview with the Testing Personnel (TP) #17 and #18, the Technical supervisor (laboratory Director) failed to evaluate the competency of 15 of 16 testing personnel who perform, Mohs, KOH, and Scabies testing from 2017 to the date of survey. Findings Include: 1. On the date of survey, 02/12/2019, review of TP annual competency assessments records revealed in 2017 and 2018, 15 of 16 TP (providers) who perform, Mohs, KOH, and Scabies testing were not assessed for competency. 2. From 07/11/2017 to 12/31/2017 - 20,12 Mohs, KOH, and Scabies patient tests were performed. 3. From 01/01/2018 to 12/31/2018 - 40,075 Mohs, KOH, and Scabies patient tests were performed. 4. From 01/01/2019 to 02/12/2019 - 463 Mohs, KOH, and Scabies patient tests were performed. 5. TP #17 and #18 confirmed the findings above on 02/12/2019 around 09:15 am \*\*\*\*\* KOH = Sodium Hydroxide