Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2141623	04/04/2018
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology And Skin Cancer Assoc, Pllc	5349 Airline Rd, Arlington, TN	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's wı for testing or examining specimens. This STANDARD is not met as evidenced by: Citation #1 Based on review of the laboratory's procedure manual, the document titled "Quality Contı patient log for MOHS procedure and interview with the laboratory director, the laboratory failed to fc documentation of daily quality control for 14 of 22 days in 2017 and 2018. The findings include: 1. R laboratory's Quality Assurance procedure revealed the following statement: "The first case submitted which consists of NORMAL tissue will be stained for H&E, documented on the control sheet as the C the document titled "Quality Control Staining" revealed Quality Control Staining recorded on dates 9 6-17, 12-4-17, 1-8-18, 2-5-18, 3-5-18 and 4-2-18. 3. Review of the patient log for MOHS procedure r testing on 9-25-17, 10-2-17, 10-16-17, 10-23-17, 10-30-17, 11-6-17, 11-13-17, 11-20-17, 11-27-17, 1 12-18-17, 1-8-18, 1-15-18, 1-22-18, 1-29-18, 2-5-18, 2-12-18, 2-26-18, 3-5-18, 3-19-18, and 4-2-18. the laboratory director via phone on 4-9-18 at 12:15 pm confirmed the laboratory failed to follow poli documentation of daily quality control staining for 14 of 22 days in 2017 and 2018. Citation #2 Based on review of the laboratory's procedure titled "KOH Mount", review of the docume patient test report numbers 1, 2, and 3, and interview with the laboratory director, the laboratory faile procedure for performance of Potassium Hydroxide (KOH) when test was performed and reported by number two, not the laboratory director in 2017. The findings include: 1. Review of the laboratory's p "KOH Mount" revealed the following statement under the section titled Examination: "Slide is then e microscopy by lab director. Lab director then confirms negative/positive results. Results documented patient's electronic medical record." 2. Review of the document titled KOH log revealed the performa

	testing personnel number two (not the laboratory director) for 6 of 8 KOH tests performed in 2017. 3. patient test reports (patients #1, 2, and 3) revealed the electronic signature of testing personnel numbe laboratory director). 4. Interview via phone on 04-09-18 at 12:15 pm with the laboratory director conf laboratory failed to follow policy for KOH when KOH testing was performed by testing personnel nu of the laboratory director in 2017.