

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0986772	(X3) Date Survey Completed 06/26/2018
Name of Provider or Supplier Anne Arundel Dermatology Pa	Street Address, City, State 133 Associates Blvd, Alcoa, 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
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: _____ Based on laboratory's maintenance policy for the cryostats and fume hood, lack of maintenance documentation for the cryostats and fume hood and interview with the primary laboratory person, determined the laboratory failed to perform and document maintenance activities for 2016 and 2017. The findings include: 1. The Laboratory's maintenance policy for the cryostats state that PM (preventative maintenance) is to be performed every 6 months. 2. The Laboratory's maintenance policy for the fume hood states that grounding is to be checked every 6 months. 3. Lack of PM documentation in 2017 for the cryostats and lack of grounding checks for the fume hood in 2016 and 2017. 4. Interview with the primary laboratory person at approximately 3:00 p.m. June 26, 2018 confirmed there were no PM's performed on the cryostats in 2017 and no grounding checks performed for the fume hood in 2016 and 2017. _____</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials</p>

for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

_____ Based on review of H&E (Hematoxylin and Eosin) Stain Quality log for patient tracer on April 10, 2018, lack of H&E stain quality since April 5, 2018 and interview with the primary laboratory person, the laboratory failed to document H&E stain quality since April 5, 2018. The findings include: 1. Review of H&E Stain Quality log for patient tracer on April 10, 2018. 2. Lack of H&E Stain Quality documentation since April 5, 2018. 3. Interview with primary laboratory person at approximately 3:00 p.m. June 26, 2018 confirmed there was no H&E stain quality documentation after April 5, 2018 due to implementation of new form which lacked a place for the H&E stain quality.
