Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0955128	06/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Annapolis Dermatology Center	71 Old Mill Bottom Rd North Ste 202 And 300, Annapolis, MD	

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
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 standard operating procedure manual and quality assurance (QA) review and interview with the laboratory staff, the laboratory did not ensure that proficiency testing (PT) was performed at least twice annually. Findings: 1. The procedure, "Quality Control Program" states that "The Laboratory Director will randomly select five (5) processed cases every six (6) months each calendar year to forward to a third party laboratory for comparative diagnosis." 2. A review of QA records showed that "Doctor #1" began reading slides at the laboratory in August, 2017. 5 cases from this doctor were sent out and reviewed 6/11/18; and 3. For "Doctor #2," 10 cases from 2017 and 5 cases from 2018 were sent out and reviewed 6/11/18; and 4. During an interview at 1:40 PM, when laboratory staff was asked about the delay in sending out PT, they stated that "We forgot." 3. During an interview on 6/12/18 at 2:15 PM, the LD confirmed that PT slides were not sent out at least twice annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by:

	Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 6/29/2016 for not recording the lot numbers and expiration dates of stains used for staining tissue samples prior to slide preparation. The plan of correction stated that this would be corrected. Based on record review and interview with the laboratory staff, the laboratory failed to ensure that solutions used for staining tissue prior to slide preparation were not used after their expiration date. Findings: 1. The laboratory records for July, 2016 through June, 2018 were reviewed. 2. The records did not include the lot numbers and expiration dates, and the time period for which all the different stains were being used for the year 2017. 3. During an interview on 6/12 /18 at 1:40 PM, the laboratory staff confirmed that no reagents were recorded for 2017.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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 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 quality control (QC) and patient log record review and interview with the testing person, the laboratory did not ensure that daily stain QC was consistently documented, recording the quality of the staining characteristics of the Hematoxylin and Eosin (H&E) stain. Findings: 1. The laboratory performs H&E staining procedures to evaluate histopathology slides in the Mohs laboratory. Daily stain QC for H&E stains are recorded on the "QA Daily" "Frozen Sections" log. 2. A review of daily stain QC logs from January, 2017 through April, 2018 showed that for 23 of 91 days of testing, the results of the stain QC were not documented on the log sheet. 3. During an interview on 6/12/18 at 2:15 PM, the LD confirmed that daily slide QC was not consistently documented.