Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2043930	10/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Anne Arundel Dermatology	7671 Quarterfield Road Ste 200 A-B, Glen Burnie, 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
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) record review and interview with the laboratory staff, the histopathology laboratory did not document that it checked the Hematoxylin and Eosin (H&E) stain for intended response and predicted characteristics of the stain. Findings: 1. The laboratory performs H&E staining procedures to evaluate histopathology slides made from patient specimens taken during Mohs surgery. Daily stain QC for the H&E stain is recorded on the "Control Slide Log." 2. A review of "Control Slide Logs" from January through October, 2018 showed that the log records the "Date," "Slide Number," "Stain" (marked as "H&E"), and "Reviewed By." There was no documentation of the stain quality of the slides each day of patient testing. 3. During an interview on 10/24/18 at 10:45 AM, the laboratory staff confirmed that daily slide QC was not consistently documented.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

	This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record and procedure manual review and interview with the laboratory staff, the laboratory director (LD) did not ensure that histopathology PT reports were reviewed and evaluated to identify problems that require corrective action. Findings: 1. The procedure, "Quality Control Program," "Physician Proficincey Testing" states that the laboratory sends out "one set of random patient slides" "bi-annually" to be reviewed by another dermatopathologist as part of their PT plan and that "any discrepancies" "will be noted and brought to the providers and Laboratory Directors attention for review." 2. A review of "Slide Quality Review" PT forms from 2017 to 2018 showed that the "Slide Quality Review" form for PT performed on 8/4/17 was incomplete. The doctor performing the second review did not document his/her findings after reviewing the slides. The "Slide Quality Review" form was signed by the LD. 3. During an interview on 10/24/18 at 10:45 AM, laboratory staff confirmed that the LD did not adequately review PT reports to evaluate the proficiency of the testing personnel and to identify problems that require corrective action.