Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2236107	03/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Anne Arundel Dermatology	6701 Fairfax Rd, Chevy Chase, 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) and patient record review and interview with the testing person (TP), 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 opened in December, 2021. The TP reads and interprets dermatology histopathology slides two days a week at this laboratory, and also performs histopathology testing two days a week onsite at the outside laboratory where the slides are prepared and stained. 2. The laboratory had three examples of patient records onsite at the time of the survey. Patient record review showed that there was no documentation of the TP's evaluation of the H&E stain QC for three of three patients reviewed. 3. During an interview on 03/06/2023 at 10:15 AM the TP confirmed that they do not record the daily stain QC for H&E stains interpreted at this laboratory.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on procedure manual review and interview with the testing person (TP) and electronic correspondence with an offsite laboratory, the laboratory director (LD) failed to establish a quality assurance (QA) program to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings: 1. The laboratory opened in December, 2021. The TP reads and interprets dermatology histopathology slides two days a week at this laboratory, and also performs histopathology testing two days a week onsite at the outside laboratory where the slides are prepared and stained. 2. Procedure manual review showed that the laboratory did not have a QA policy and a review of laboratory records showed that there were no QA reviews available at the time of the survey. 3. During an interview on 03/06/2023 at 10:15 AM, the TP stated that they did not know what the laboratory did as part of their QA program and confirmed that there was no QA procedure present at the time of the survey. 4. After the survey on 3/6/2023 the histotechnician from the outside laboratory emailed a copy of a procedure titled, "Quality Assurance /Management Plan," stating that the TP had called them after the survey and said that I "needed to view (their) QA." 5. Review of this QA procedure showed that it belonged to the outside laboratory where the slides are made, and was not the QA procedure for the laboratory being surveyed. This was confirmed by the offsite histotechnician in an email on 03/08/2023.