Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0688709	08/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Anne Arundel Dermatology, Pa	995 N Prince Frederick Blvd #204, Prince Frederick, 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation and interview with the histotechnician, laboratory staff did not follow established safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. Findings: 1. During a tour of the laboratory at 10:15 AM, it was observed that laboratory staff had placed 5-6 reusable drinking water bottles in various locations in the laboratory including on top of the fume hood, next to the microscope, and on the counter near the cryostat which was in use at the time. 2. The laboratory is required to implement safety policies and procedures to ensure the safety of the testing personnel. The Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA) provide guidelines for laboratory safety. Good laboratory practices state that there should be no eating, drinking, or application of cosmetics in the laboratory. 3. During an interview on 08/12/2022 at 10:15 AM the histotechnician stated that they had told staff to remove the water bottles from the laboratory area upon arrival to the laboratory that morning but that the staff had not complied.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on observation, record review, and interview with the histotechnician, the laboratory did not document performance of routine preventive maintenance on laboratory equipment. Findings: 1. The laboratory uses a "Belair" fume hood over the slide stainer which is used to stain histopathology slides for evaluation during Mohs surgery. 2. During a tour of the laboratory at 10:15 AM on the day of the survey it was observed that the last maintenance recorded on the "Filter Replacement Information" card on the fume hood was "May 18." The "Next replacement due" was documented as "May 20." No other maintenance was documented after May 2018. 3. Record review showed that there was no documentation that fume hood maintenance had been performed since May 2018. 4. During an interview on 08/12/2022 at 10:15 AM the histotechnician stated that the laboratory orders replacement filters and performs the maintenance themselves "every 3 years." They confirmed that preventative maintenance on the fume hood was not documented.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the histology quality control (QC) worksheets, patient logs, and interview with the histotechnician, the laboratory did not document the acceptability of the control slide(s) with each batch of stained slides prepared in the laboratory. Findings: 1. The histology QC worksheets ("Control Slide Logs") and patient logs from January 2021 through July 2022 were reviewed. A notation on the bottom of the worksheet states that "the Mohs surgeon will circle either U for Unsatisfactory or S for Satisfactory" to document the acceptability of the hematoxylin and eosin (H&E) stain in the column labeled "H&E Stain Quality." 2. Patient log review showed that 9 patients were tested on 03/26/2021 and 14 patients were tested on 06/17/2022 but a review of "Control Slide Logs" showed that documentation of the QC of the stains was not recorded on the "Control Slide Logs" worksheet prior to releasing the interpretation and final test result. 3. On 04/29/2022 12 patients were tested. The date and slide number was entered on the QC worksheet but the doctor did not document if the "H&E Stain Quality" was satisfactory or unsatisfactory. 4. During an interview on 08/12/2022 at 11:30 AM the histotechnician confirmed that stain QC was not documented for each day of testing.
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 review and interview with the histotechnician, the laboratory director (LD) did not ensure that all PT reports were reviewed and evaluated to identify any problems that require corrective action. Findings: 1. The laboratory performs histopathology testing for a dermatology office which performs Mohs surgery. Twice a year the laboratory sends one set of patient slides to be reviewed by another dermatologist. The "Slide Quality Review" sheet asks the reviewing doctor to respond "YES" or "NO" to 5 questions about "Slide Quality," including whether the "staining" is "adequate" and if the "margins" are "clear." 2. A review of PT records from 4 events from 2020 through 2022 showed that the reviewing doctor did not answer 5 of 5 questions about the slides' "Stain Quality" on the PT "Slide Quality Review" sheet from 03/05/2021. 3. The PT reports for 4 of 4 events were not signed by the LD, showing that he/she had evaluated the laboratory's performance. 4. During an interview on 08/12/2022 at 11:30 AM the histotechnician confirmed that the LD had not signed PT results, indicating that they had been reviewed to identify any problems that require corrective action.