Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2133900	10/02/2024
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology Of Maryland	200 Harry S Truman Parkway Ste 400, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the office manager (OM), the laboratory did not ensure that all the testing personnel (TP) who tested patient samples performed the PT. Findings: 1. The laboratory currently has two TP listed on the "Laboratory Personnel Report" (CMS-209) who perform histopathology testing. 2. During an interview on 09/20/2024 at 10:50 AM, the OM stated that TP #2 began testing on 09/29/2023. 3. PT record review showed that TP #2 did not participate in the PT program in 2023. 4. During an interview on 09/20/2024 at 1:48 PM, the OM confirmed that PT samples were not tested each year by all the staff who perform patient testing to ensure accurate and reliable patient test results.
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance. This STANDARD is not met as evidenced by: Based on procedure manual review and interview with the office manager (OM), the laboratory did not retire histopathology procedures that were no longer in use.

	Findings: 1. A review of the approved procedure manual showed that it included the procedures, "Automatic Staining Procedure - Toluidine Blue" and "Manual Staining Procedure - Toluidine Blue". 2. During an interview on 09/20/2024 at 11:30 AM, the OM stated that the laboratory staff told them that the laboratory did not perform staining of histopathology slides with the Toluidine Blue stain. The OM confirmed that the procedures were not removed from the procedure manual nor were they labeled with the date of discontinuance.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: I. Based on record review and interview with the office manager (OM), the laboratory did not ensure that a copy of all quality system assessment (QA) records were maintained by the laboratory for a minimum of two years. Findings: 1. Monthly QA records were reviewed from March 2023 through August 2024. 2. The laboratory stores the following monthly logs in a QA binder: "Laboratory Temperature/Humidity Log"; "Monthly Meeting Notes"; "H E Staining Log"; "Cryostat Temperature Log"; "Cryostat(s) Cleaning and Maintenance Log"; and "Microscope Cleaning and Maintenance Log". 3. QA record review showed that there were no "Laboratory Temperature/Humidity Logs" present for March through December 2023; there were no "Monthly Meeting Notes" present for March through December 2023 and April through July 2024; and the "H E Staining Log" for June 2024 was present, however the log was blank. 4. None of the six QA logs listed above were present for March, May, June, or August 2023. 5. During an interview on 09/20/2024 at 1:48 PM, the OM confirmed that the laboratory failed to maintain a copy of all QA records for at least two years. II. Based on patient record review and interview with the office manager (OM), the laboratory did not retain a copy of all patient test records for a minimum of two years. Findings: 1. Random review of patient records showed that for one of two patients reviewed, (case # DS23-123, performed on 10/14/2023) the Mohs map which is used to document the surgical process was missing from the electronic medical record. 2. During an interview on 09/20/2024 at 1:48 PM, the OM confirmed that they were unable to find a copy of the Mohs map for case # DS23-123.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on procedure manual and proficiency testing (PT) record review and interview with the office manager (OM), the laboratory did not follow the written procedure for performing PT. Findings: 1. The procedure, "Attachment B: Proficiency Testing Mohs Histopathology Procedure Reference Guide" states that the laboratory should perform

	PT "Bi-annually" and that "Between Jan. 1 - June 30th - first set of 5 slides should be sent" and "Between July 1st - December 30th - second set of 5 slides should be sent." 2. The laboratory currently has two TP listed on the "Laboratory Personnel Report" (CMS-209) who perform histopathology testing. 3. A review of PT records from 2023 and 2024 showed that the laboratory sent out its first set of PT slides for TP #1 on 09 /10/2024, and the PT slides for TP #2 on 01/26/2024 and 04/19/2024. 4. PT slides were not sent out for TP #2 in 2023. Cross-refer to D2007. 5. During an interview on 09/20/2024 at 1:48 PM, the OM confirmed that the laboratory did not follow its procedure for performing PT.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on procedure manual review and interview with the office manager (OM), the laboratory failed to ensure that the laboratory's procedure manual was approved by the current laboratory director (LD) before use. Findings: 1. During an interview on 09/20 /2024 at 9:30 AM, the OM stated that the current LD took over as LD on 08/30/2023. 2. Procedure manual review showed that the laboratory's procedure manual was signed and approved on 02/25/2023 by the previous LD. The laboratory's written procedure manual was not approved by the current LD. 3. This was confirmed by the OM during the exit interview on 09/20/2024 at 1:48 PM.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on laboratory procedure manual and temperature log record review and interview with the office manager (OM), the laboratory failed to document corrective actions when cryostat temperatures were out of range. Findings: 1. The procedure, "Quality Control Maintenance," "6.B. Cryostat Temperature" states that "If the temperature is found to be out of range, i.e., -27 C [Celsius] to -18 C, corrective action must take place to return the temperature to its acceptable range." 2. A review of "Cryostat Temperature Logs" from October 2023 through July 2024 showed that the cryostat temperature was out of range three out of four days of testing in October 2023; two out of two days of testing in November 2023; and one out of three days of testing in July 2024. There were no corrective actions documented for the out of range temperatures. 3. During an interview on 09/20/2024 at 1:48 PM, the OM confirmed

	that corrective actions were not documented for the out of range cryostat temperatures.
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 and quality assurance (QA) record review and interview with the office manager (OM), the laboratory director (LD) failed to follow the established QA program to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings: 1. The "Mohs Quality Assessment Manual" procedure, section "IV. Post-Analytical" states that "On a quarterly basis, applicable laboratory personnel e.g., Histotechnican, Mohs Surgeon, Laboratory Director will review ten (10) percent of cases done during the previous quarter." QA record review showed that a quarterly QA review of previous histopathology cases had not been conducted since 06/06/2020. 2. Section "XIII. Quality Assessment Review with Staff" states that the LD "will discuss with the staff, on a quarterly basis, the results of quality assurance reviews and ways in which the laboratory can improve the quality of its work." QA record review showed that there was no documentation of quarterly QA reviews with the laboratory staff performed in 2023. Cross-refer to D3031, part I. 3. The laboratory did not ensure that all the testing personnel who tested patient samples performed the proficiency testing (PT). Cross-refer to D2007. 4. The laboratory did not retire histopathology procedures that were no longer in use. Cross-refer to D3029. 5. The laboratory did not ensure that a copy of all QA records and logs was maintained by the laboratory for a minimum of two years. Cross-refer to D3031, part I. 6. The laboratory did not retain a copy of all patient test records for a minimum of two years. Cross-refer to D3031, part II. 7. The laboratory did not follow the written procedure for performing PT. Cross-refer to D5401. 8. The LD failed to approve the laboratory's procedure manual before use. Cross-refer to D5407. 9. The laboratory failed to document corrective actions when cryostat temperatures were out of range. Cross-refer to D5781. 10. During an interview on 09/20/2024 at 1:48 PM, the OM confirmed that the LD failed to monitor the overall QA in the laboratory to identify failures in quality when they occurred.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on procedure manual review and interview with the office manager (OM), the

	laboratory director (LD) did not ensure that the duties and responsibilities were specified in writing for each person performing pre-analytic, analytic, and post-analytic phases of testing. Findings: 1. The procedure, "Job Duties of Laboratories Performing Tests of High to Moderate Complexity" included a list of duties and responsibilities for the LD, clinical consultant, technical consultant, general supervisor, and testing person. It did not include the duties and responsibilities for the position of technical specialist (TS), which is required for laboratories performing high complexity testing. 2. During an interview on 09/20/2024 at 1:48 PM, the OM confirmed that the laboratory's approved procedure manual did not include a written list of duties and responsibilities for the TS.