Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2175030	02/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology Of Maryland	101 Centennial Street #H, La Plata, 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
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on review of the patient logs, observation of the slides, and interview with the senior location manager (SLM), the laboratory failed to document when slides were sent offsite for outside proficiency testing (PT) review. Findings: 1. Physical slides prepared on 03/16/2023 were reviewed for comparison to the patient logs. 2. Slides for case M23-038 were missing from the storage box. 3. Slides had recently been sent to another location for PT review, but the list of slide numbers included in the PT shipment were not available at the time of the survey. 4. In an email received on 02/14 /2024 at 1:10 PM, the SLM confirmed that they were "not able to find the list of what was sent out" to be able to verify if the missing slides for case M23-038 could be accounted for.
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 review of the proficiency testing (PT) policy and interview with the senior location manager (SLM), the laboratory failed to document biannual peer review PT for the Mohs surgeons for 2022 and 2023 as stated in the policy. Findings: 1. The "Mohs Histopathology & Proficiency Testing Policy" stated "Peer review proficiency testing for all Mohs surgeons and histopathologists will be performed bi-annually. Proficiency testing is to be sent out and returned by June 30th and December 31st each year" and "Results of the peer review proficiency testing will be recorded on the Mohs Proficiency Form (LF-0024) and maintained in the CLIA manual." 2. Patient testing began on 05/20/2022. There were no completed Mohs Proficiency Forms. 3. During the survey on 02/08/2024 at 12:55 PM, the SLM confirmed that there were no records that biannual peer review PT for the Mohs surgeons was performed for 2022 and 2023.
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 review of the procedure, patient logs, and slides and interview with the senior location manager (SLM), the laboratory failed to assign patient case numbers as defined in the procedure. Findings: 1. The "Mohs Quality Assurance Manual" stated that "The case number will consist of the Mohs surgeon's first initial of their last name, the first initial of the office location, the last number of the year, a hyphen and then starting with the number one continue in numerical order." 2. Patient testing began on 05/20/2022. 3. The Mohs surgeon from 05/20/2022-07/23/2023 had the initials AF, the Mohs surgeon from 09/12/2023 to the present had the initials SD, and the practice location was La Plata, MD. 4. From 05/20/2022 to the end of 2023, the case numbers were assigned as "M" followed by the last two digits of the year, followed by a hyphen, followed by a sequential numerical designation (e.g., M23-001, M23-002 ...). 5. Starting in 2024, the case numbers were assigned as "SD" (the initials of the present Mohs surgeon), followed by "24", followed by a hyphen, followed by a sequential numerical designation (e.g., SD24-001, SD24-002 ...). 6. During the survey on 02/08/2024 at 12:55 PM, the SLM confirmed that the patient case numbers were not assigned as defined in the quality assurance manual.
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 review of the procedure and cryostat temperature log and interview with the senior location manager (SLM), the laboratory failed to document corrective actions when the cryostat temperature was out of acceptable range on 8 of 8 days recorded from May to October 2023. Findings: 1. The "Cryostat Temperature" section of the "Quality Control Maintenance" policy stated "If the temperature is found to be out of range, i.e., -27 C to -18 C., corrective action must take place to return the temperature to its acceptable range." 2. The "Cryostat Temperature Log" stated "Note: Action should be taken and documented if temperature is outside required range: Normal Range is -18 C to -27 C." 3. The temperature logs recorded out-of-range cryostat temperatures one of one day in May (-30 C), one of one day in June (-35 C), one of one day in July (-33 C), three of three days in September (-35, -35, and -33 C), and two of two days in October (-35 C both days) 2023. 4. During the survey on 02/08 /2024 at 12:55 PM, the SLM confirmed that the cryostat temperature was out of acceptable range for 8 of 8 days from May to October 2023 with no documented corrective actions.
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 review of the quality assurance (QA) procedure and interview with the senior location manager (SLM), the laboratory director failed to ensure that the quarterly QA case review was performed as stated in the procedure. Findings: 1. The "Mohs Quality Assurance Manual" stated that "It is the responsibility of the Laboratory Director to assure compliance with regard to all policies and procedures of the laboratory" and "On a quarterly basis, the Histotechnician or Director of Laboratory Operations will review ten (10) percent of cases done during the previous quarter. This process will include pulling the patient charts, the Mohs log, and slides. They will be checked to make sure that the op-report, map, Mohs log and slides are accurate. If there are any discrepancies, it will be noted on the Quarterly QA form and corrective action will be taken to prevent this from happening again." 2. Patient testing began on 05/20/2022. There were no records available for quarterly QA case reviews performed for 2022 or 2023. 3. During the survey on 02/08/2024 at 12:55 PM, the SLM confirmed that there were no records of quarterly QA case reviews performed for 2022 or 2023.