Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1072918	06/23/2025
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology Of Maryland	10153 York Rd Suite 104, Cockeysville, 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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of the "Mohs Quality Assessment Manual" (QA manual) and patient specimen logs and interview with the laboratory director (LD) and histotechnician (HT), the laboratory failed to follow written policies for assigning unique case numbers to patient specimens. Findings: 1. The QA manual stated that the "Specimen is logged on the LF-0010 Mohs Accession Log and given the next case number" and that the "Mohs Op-report/flowsheet will contain the unique case number." 2. The QA manual also stated that "The case number will consist of the following: 1. Mohs Surgeon's first initial of their last name," "2. First initial of the office location," "3. Last number of the year," and "4. A hyphen and then starting with the number one and continuing in numerical order." 3. The laboratory had two separate patient logs for 2024, one contained in a binder labeled "Advanced Dermatology Hunt Valley Laboratory Log Book" (binder 1) and the other contained in a binder labeled "2024 Mohs Log Dr. Cooper" (binder 2). 4. Both patient logs included case numbers 24M001-24M131 that were assigned to different patients. For example, binder 1 assigned case number 24M001 to patient A and binder 2 assigned case number 24M001 to patient B. 5. The assigned case numbers did not follow the nomenclature defined in the QA manual (#2 above). 6. During the exit interview on 06/23/2025 at 1: 45 PM, the LD and HT confirmed that the assigned case numbers did not adhere to the nomenclature defined in the QA manual and that in 2024 the same case numbers were assigned to different patients.

D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 manual and "Daily Quality Control Slide" logs (QC logs) and interview with the laboratory director (LD) and histotechnician (HT), the laboratory failed to ensure that the patient accession number used for daily slide preparation and staining QC was documented on the QC logs for 47 of 160 entries reviewed. Findings: 1. The "Mohs Laboratory Quality Assessment" procedure stated that "A daily quality control slide is prepared by using the first case of the day; the doctor will look for the normal reaction of the stain on the tissue and indicate it on the LF-0010 Daily QC Slide Log." 2. The QC logs included a column titled "Accession# of Control" to record the accession number of the patient specimen that was used for daily slide preparation and stain QC. 3. The QC logs were reviewed from 10/30/2023-06/23/2025 which included a total of 160 daily QC entries. 4. The patient accession number was not recorded for 47 entries from 01/13/2025-06/23/2025. 5. During the exit interview on 06/23/2025 at 1:45 PM, the LD and HT confirmed that the patient accession number used for daily slide preparation and stain QC was not recorded on the QC log for 47 of 160 entries.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with the histotechnician (HT), the laboratory failed to label the containers on the automatic stainer with the identity of the staining reagents contained within. Findings: 1. The laboratory used an automatic stainer to stain the patient slides from Mohs micrographic surgery. 2. The staining reagent containers observed on the automatic stainer were not labeled with the identity of the contents contained within. 3. During the survey on 06/23/2025 at 9:45 AM, the HT confirmed that the staining reagent containers found on the automatic stainer were not labeled with identity of the reagents contained within.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on review of potassium hydroxide (KOH) testing records and interview with the laboratory director (LD) and histotechnician (HT), the laboratory failed to document the lot number and expiration date of the KOH reagents used for testing to ensure the reagents were not used beyond their expiration date. Findings: 1. The laboratory performed KOH testing to identify potential fungal infections. 2. The lot number and expiration date of the KOH used for testing was not documented on any of the patient testing or reagent logs. 3. During the exit interview on 06/23/2025 at 1: 45 PM, the LD and HT confirmed that the lot number and expiration date for the KOH reagent used for patient testing was not documented anywhere.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 review of the procedure manual and cryostat maintenance logs and interview with the laboratory director (LD) and histotechnician (HT), the laboratory failed to document monthly cryostat maintenance activities for 15 of 21 months reviewed. Findings: 1. The "Cryostat Maintenance Record" section of the "Quality Control Maintenance" procedure stated the following: a. "Cleaning and Monthly Maintenance must be recorded on LF-0009 Cryostat Cleaning and Temperature Maintenance Log." b. "The cryostat must be oiled and greased on a monthly basis and the initial of the histologist/pathologist and date are recorded." 2. The "A. Cryostat" section of the "Equipment Management Laboratory" procedure provided instructions for performing monthly fumigation of the instrument and stated to "Document monthly on LF-0009 Cryostat Cleaning and Temperature Maintenance Log" 3. The Cryostat Cleaning and Temperature Maintenance Log included a section to document the "Monthly Oiling & Fumigation/Decon Cryostat #1 and #2." 4. Cryostat maintenance logs for 10/2023-06/2025 were reviewed for a total of 21 months. 5. Monthly maintenance activities were not documented from 10/2023 through 12/2024 (15 months). 6. During the exit interview on 06/23/2025 at 1:45 PM, the LD and HT confirmed that monthly maintenance activities for the cryostat were not documented as performed from 10/2023 through 12/2024.
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 manual and temperature logs and interview with the laboratory director (LD) and histotechnician (HT), the laboratory failed to document corrective actions when humidity fell outside the acceptable ranges. Findings: 1. The "E. Laboratory Temperature" section of the "Quality Control Maintenance" procedure stated the following: a. "Room temperature and humidity are logged daily on LF-0016 Laboratory Temp/Humidity Log." b. "Laboratory room humidity must remain in the range of 0% - 60% humidity." c. "If the temperature or humidity is found out of range, the corrective action is logged on LF-0016 Temp/Humidity Log." 2. Temperature records for 01/2024-06/2025 were reviewed and humidity was outside the acceptable range (OOR) on the following dates: a. 05/2024 (OOR 1 of 11 dates recorded): 62% on 05/09/2024 b. 08/2024 (OOR 1 of 7 dates recorded): 62% on 08/09/2024 c. 09 /2024 (OOR 7 of 11 dates recorded): i. 66% on 09/05/2024: The log noted "Need humidifier" ii. 61% on 09/12/2024 iii. 61% on 09/16/2024 iv. 63% on 09/17/2024 v. 68% on 09/23/2024: The log noted "asked manager for dehumidifier" vi. 70% on 09 /26/2024 vii. 63% on 09/30/2024 d. 10/2024 (OOR 1 of 9 dates recorded): 64% on 10 /01/2024 e. 11/2024 (OOR 1 of 11 dates recorded): 64% on 11/07/2024 f. Except where noted (09/05/2025 and 09/23/2025), no corrective actions or potential risk to patient specimens were documented on the temperature logs. 3. During the exit interview on 06/23/2025 at 1:45 PM, the LD and HT confirmed that corrective actions were not documented when humidity fell outside the acceptable ranges.