Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2269243	03/19/2026
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology Of Maryland	1838 Greene Tree Road #340, Pikesville, 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
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: I. Based on procedure manual and proficiency testing (PT) record review and interview with the laboratory director (LD), the laboratory did not ensure that PT was performed at least twice annually for all non-regulated tests performed in the laboratory. Findings: 1. The laboratory performs Hematoxylin and Eosin (H&E) staining procedures to evaluate histopathology slides for Mohs surgery patients. 2. The procedure, "Mohs Quality Assessment Manual" states that a "Mohs proficiency slide review is performed biannually for each Mohs Surgeon by a dermatopathologist." 3. A review of PT records from 2024 to 2026 showed that histopathology PT was performed on 07/01/2024, 01/14/2025, and 01/30/2026. 4. During an interview on 03/19/2026 at 2:00 PM, the LD confirmed that PT slides were not sent out twice annually in 2025. II. Based on procedure manual and proficiency testing (PT) record review and interview with the laboratory director (LD), the laboratory did not ensure that PT was performed at least twice annually for all non-regulated tests performed in the laboratory. Findings: 1. The laboratory performs potassium hydroxide (KOH) slide testing to test for fungal elements and scabies infections on skin scrapings. 2. The procedure, "Verification of PPM Test Results," section "6. Procedure: Parasitology and KOH" states, "Twice a year, the testing personnel will select a patient from whom to collect a specimen for competency and proficiency testing." 3. Record review showed that there was no documentation that PT was performed for KOH testing from 2024 through 2026. 4. During an interview on 03/19/2026 at 10:40 AM, the LD stated that PT for KOH testing was not performed at the laboratory.

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: I. Based on procedure manual and histopathology stain maintenance log record review and interview with the histotechnologist (HT) and the laboratory director (LD), the laboratory failed to follow written procedures for filtering and changing the reagents used for histopathology testing. Findings: 1. The laboratory performs Hematoxylin and Eosin (H&E) staining procedures to evaluate histopathology slides for Mohs surgery patients. The laboratory documents histopathology stain maintenance on the "H & E Automatic Staining Log" (stain log). 2. The procedure, "Policy # CP-L 1017: Quality Control Maintenance" stated, "The stains and reagents must be filtered daily and changed weekly following CP-L 2013 Daily Histology Stain control policy and procedures." The procedure, "Policy # CP-L 2013: Histology Stain Daily Surveillance" stated, "Routine histology stains are changed weekly or after 40-hour use". 3. A review of stain logs from 01/15/2025 through 03/18/2026 showed that the stain log lists each of the 12 reagents used on the left side of the log: Hematoxylin (#1), Water (running) (#2), Water (running) (#3), Acid Alcohol (#4), Water (running) (#5), Bluing (#6), Water (running) (#7), 95% Alcohol (#8), Eosin (#9), Alcohol (#10), Alcohol (#11), and Xylene Substitute (#12). 4. On each day of testing the laboratory writes the date at the top of the next available column, then writes a letter next to each reagent to indicate what maintenance was performed using the key at the bottom of the log. The key indicates that "N=NEW", "C=CHANGE", "F=FILTER", AND "R=ROTATE". On two of five stain logs reviewed, the laboratory had hand-written '" T.O' = Top-off". 5. Stain log review showed that on 01/22/2025, 01/29/2025, and 06 /04/2025 reagents #1 through #7 were marked "NA"; on 03/12/2025, 03/19/2025, 05 /21/2025, and 07/12/2025 reagents #1 through #7 were marked "NA" and reagents #8 through #12 were marked "TO"; and on 02/26/2025 reagents #1 through #12 were marked "NA". 6. During an interview on 03/19/2026 at 11:30 AM, the HT stated that "NA" meant that the reagents were "not touched" and confirmed that "T.O" meant that the lab had added more reagent to the stainer without disposing of the old reagent. 7. During an interview on 03/19/2026 at 2:00 PM, the LD confirmed that the laboratory did not follow the written procedure for performing histopathology stain maintenance. II. Based on surveyor observation, procedure manual and reagent log record review, and interview with the histotechnologist (HT) and the laboratory director (LD), the laboratory failed to ensure that the laboratory followed written procedures for documenting histopathology reagent information and labeling the reagents with the date they were opened. Findings: 1. The procedure, "Policy # CP-L 1017" "6. B. Reagents" states "All reagents used within the laboratory will be documented on LF-0006 Reagent Log". "The reagent name, lot number, date received, expiration date, date opened, disposal date, and initials will be logged when available". "When a reagent bottle or container is opened, the date opened will be written directly on the reagent bottle or container". 2. During a tour of the laboratory on 03/19/2026 at 12:00 PM the surveyor observed that the laboratory stored their histopathology reagents in a flammable cabinet. The flammable cabinet contained the following reagents: two opened bottles of "Gill 3 Hematoxylin" (lot #211102, expiration date 04/30/2026); two bottles (one of two opened) of "Eosin-Y Alcoholic 0.25%" (lot #219662,

	expiration date 01/31/2027); two bottles (one of two opened) of "100% Alcohol" (lot #2600802, expiration date 01/08/2029); two bottles (one of two opened) of "95% Alcohol" (lot #2517003, expiration date 06/19/2028, opened and lot #2603502, expiration date 02/04/2029, unopened); and four bottles (two of four opened) of "XS-3 Xylene Substitute" (lot #231793, expiration date 06/30/2027). 3. None of the opened and in-use histopathology reagents in the laboratory flammable cabinet were labeled with the date that they were opened and put into use. 4. A review of histopathology stain reagent logs from 2025 and 2026 showed that one of the two bottles of "Gill 3 Hematoxylin" (lot #211102, expiration date 04/30/2026) was documented with a "Disposal Date" of 10/02/2025, however the bottle remained in use and was stored in the flammable cabinet. 5. The unopened bottle of "95% Alcohol" (lot #2603502, expiration date 02/04/2029) was not documented on the reagent log. 6. "XS-3 Xylene Substitute" (lot #231793, expiration date 06/30/2027) was logged once on the reagent log, however the laboratory had four bottles of the reagent in the flammable cabinet at the time of the survey. 7. On the 2025 reagent log the laboratory listed four bottles of "Scotts Bluing" with the same lot number and expiration date (lot #134846N, expiration date 09/23/2025), however the "Date Opened" and "Disposal Date" were not documented. "Scotts Bluing" reagent was listed twice on the 2026 reagent log, however there was no lot number or expiration date documented and no reagent present in the flammable cabinet at the time of the survey. 8. During an interview on 03/19/2026 at 12:25 PM the HT stated that the laboratory had just run out of the "Scotts Bluing" reagent and had ordered more. They confirmed that the last bottles used were not documented on the reagent log. 9. During an interview on 03/19/2026 at 2:00 PM, the LD confirmed that the laboratory did not follow the written procedure for documenting histopathology stain reagent information on the reagent log or labeling the reagents with the date they were opened.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on humidity log record review and interview with the laboratory director (LD), the laboratory failed to document corrective action when laboratory room humidity readings were out of range. Findings: 1. The laboratory documents the daily room temperature and humidity of the room where histopathology testing is performed on the "Laboratory Temperature/Humidity Log" (lab temp log). The humidity range printed at the top of the lab temp log was "0%-60%". 2. A review of lab temp logs from 01/15/2025 through 09/24/2025 showed that the humidity was out of the laboratory's acceptable range five out of 35 times documented. 3. There were no corrective actions documented for the out of range humidity readings. 4. During an interview on 03/19/2026 at 2:00 PM, the LD confirmed that there were no corrective actions documented for the days that the laboratory humidity readings were out of range.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems

identified in the analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:
Based on quality control (QC) and quality assurance (QA) record and procedure manual review, surveyor observation, and interview with the histotechnologist (HT) and the laboratory director (LD), the laboratory did not follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. Findings: 1. The procedure, "Mohs Quality Assessment Manual" states, "The Laboratory Director reviews all quality control charts and logs on a routine basis" and "The Laboratory Director will review the corrective action to ensure that appropriate action is taken, and proper procedures were followed". 2. The laboratory documented performance of QA duties on the "High Complexity Laboratory Operations Daily, Weekly, and Monthly Checklist" (quarterly QA log). Page one of the quarterly QA log listed the seven "Tasks" to be performed for "Week 1" through "Week 5": "Accession Log", "Control Slide", "Cryostat Maintenance (Temp, cleaning)", "QC Log (Lab temp, Clean Surface)", "Reagent Log", "Slide Archive", and "Slide Filing". The log had columns for each day of the week and instructed the user to "Initial & Date for Completion". Page two of the quarterly QA log listed weekly tasks: "Changing of H&E Stainer", and "Test Eyewash Station". 3. A review of the quarterly QA log from October 2025 showed that on page one, the laboratory placed check marks next to seven out of seven tasks on "W" (Wednesday) for week 1 through week 4 and on page two, check marks were placed next to two out of two tasks for week 1 through week 4. No initials or dates were documented. The log was signed by the LD on 10/29/2025. 4. The "Mohs Quality Assessment Manual" also states that "applicable laboratory staff hold monthly meetings at each Mohs testing location to ensure quality and overall compliance is maintained within the laboratory. This is documented on LF-0025 Monthly Mohs Meetings". The laboratory documented monthly QA meetings on the "Monthly Meeting Notes" (monthly QA) form. 5. A review of "H & E Automatic Staining Logs" (stain log), "Daily Quality Control Slide" logs (QC log), and patient logs from January 2025 through March 2026 was performed. Patient log review showed that the laboratory tested seven patients on 05/07/2026 (case #25M106 through #25M112), however the QC and stain logs showed that daily slide QC and stain reagent maintenance was documented as being performed on 05/06/2026. 6. During a review of case # 25M106's histopathology slides, the surveyor observed that the slides were labeled with the date 05/07/2025. A review of the same patient's electronic medical record (EMR) confirmed that the Mohs surgery and testing was performed on 05/07/2025. 7. Patient log review also showed that the laboratory tested 10 patients on 05/14/2026 (case #25M113 through #25M122), however there was no stain reagent maintenance documented on the stain log for 05/14/2025. 8. A review of monthly QA forms from January 2025 through March 2026 showed that the errors were not identified or documented on the May 2025 monthly QA form. The "Compliance/Proficiencies/Competencies" section of the form from May 2025 documented that there were "no concerns". The form was signed by the LD on 05/07/2025. The monthly QA form for June 2025 was missing at the time of the survey. 9. Patient log review showed that the laboratory tested one patient on 10/21/2025 (case #RP25233). The QC log and the stain log showed that the laboratory had not performed daily slide QC or stain reagent maintenance on 10/21/2025. 10. During a review of case #RP25233's histopathology slides, the surveyor observed that the slides were labeled with the date 10/15/2025. A review of the same patient's EMR confirmed that the Mohs surgery and testing was performed on 10/15/2025. This error was not identified or documented on the monthly or quarterly QA logs. 11. The

	"Compliance/Proficiencies/Competencies" section of the monthly QA log from July 2025 stated "slides sent for QA" and the "Plan for Correction" was documented as "awaiting results from slide QA." The laboratory did not have documentation that PT slides had been sent out or returned. Cross-refer to D5217, Part I. During an interview on 03/19/2026 at 1:30 PM the HT stated that they thought that slides were sent out for PT but were unsure if they had been returned and did not know where the PT documents were. 12. The laboratory did not ensure that PT was performed at least twice annually for all non-regulated tests performed in the laboratory. Cross-refer to D5217, parts I and II. 13. The laboratory failed to follow written procedures for filtering and changing the reagents used for histopathology testing. Cross-refer to D5401, part I. 14. The laboratory failed to follow written procedures for documenting histopathology reagent information and labeling the reagents with the date they were opened. Cross-refer to D5401, part II. 15. The laboratory failed to document corrective action when laboratory room humidity readings were out of range. Cross-refer to D5785. 16. During an interview on 03/19/2026 at 2:00 PM, the LD confirmed that the laboratory did not follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.