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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>05D0718779      | <b>(X3) Date Survey Completed</b><br><br>07/15/2026 |
| <b>Name of Provider or Supplier</b><br><br>Advanced Dermatology Surgery And Medical Group                                  | <b>Street Address, City, State</b><br><br>3650 E South St Ste 306, Lakewood, CA |                                                     |
| 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
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| D3011              | <p>FACILITIES<br/>CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on the surveyor's observations during the laboratory tour, review of the laboratory's policies and procedures, and interviews with the office manager (OM) and laboratory assistant (LA); the laboratory failed to have and follow written and approved laboratory safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. The findings include: 1. The laboratory failed to have a written Safety plan and procedures based on the laboratory's risk assessment to provide protection from physical, chemical, biochemical, and biohazardous materials as needed. 2. Surveyor observed during the laboratory tour that no eye wash station or eye wash portable bottle kit was found in the testing area. The fire extinguisher was located in an area not readily accesible to the laboratory. 3. The laboratory did not have a biological or chemical spill kit in the laboratory area where the Mohs procedure is performed. 4. The OM and LA. affirmed by interview on July 15, 2026, at approximately 1:30 p.m that the laboratory did not have a written and laboratory director approved, signed, and dated Safety Plan based on a risk assessment and lacked an eye washing station and a chemical spill kit in the laboratory area. 5. The safety of laboratory testing personnel could not be assured at this time. 6. The annual testing declaration form submitted at the time of the survey stated 100 samples were processed and reported for Dermatopathology during the time when safety concern for all testing personnel could not be assured.</p> |
| D5217              | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br/>CFR(s): 493.1236(c)(1)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

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 laboratory's proficiency testing (PT) peer review documentation from the year 2023 through 2026, six (6) patients test results, and interviews with the office manager (OM) and laboratory assistant (LA) on July 15, 2026; the laboratory failed to verify the accuracy of tests not included in Subpart I at least twice annually, as required by 42 CFR 493.1236(c). The findings included: 1. The laboratory failed to perform PT (peer review) for both the dermatopathologist performing histopathology slide reading and diagnosis and the Mohs surgeon diagnosis for half of the year 2023, and the years 2024, 2025, and for the past 6 months of the year 2026. 2. The OM and LA confirmed by interview on July 15, 2026, had no accuracy verification (peer review) was performed as stated in statement 1. 3. There was no corrective action documentation available at the time of the survey. 4. According to the laboratory testing declaration (Form LAB-144A) , the laboratory performed approximately 100 tests for Histopathology including Mohs testing and diagnosis annually for which no peer review was performed for the years 2023 to 2026.

**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 the review of the laboratory's policies and procedures, six (6) randomly selected patient test results for Mohs and Histopathology, and interviews with the laboratory's office manager (OM) and laboratory assistant (LA) on July 15, 2026; the laboratory failed to have CLIA compliant written policies and procedures manuals for all tests, assays, and examinations performed by the laboratory available and followed by laboratory personnel. The findings included: 1. The laboratory lacked CLIA compliant written and LD approved, dated, and signed policies and procedures for: Mohs testing including processing and staining, microscope preventive maintenance, document retention, turn-around-time for histopathology reports, Mohs test quality control, storage of slides, and laboratory safety policies. 2. Reliability of the laboratory tests' performance based on complete laboratory procedures to follow by testing personnel to ensure compliance with federal CLIA regulations could not be assured during this survey. 3. The OM and LA affirmed by an interview on July 16, 2026, at approximately 1:00 p.m. that the laboratory failed to provide LD signed, dated, and approved laboratory policies and procedures for all the current tests and examinations performed in the laboratory. 4. According to the testing declaration form (CMS-116) submitted at the time of survey, the laboratory processed, tested, and reported approximately a total of 100 patient tests annually for Mohs and Histopathology, when the laboratory lacked written and approved policies and procedures manuals.

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| <p><b>D5415</b></p> | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br/>CFR(s): 493.1252(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on the surveyor's review of six (6) Mohs patients test results, lack of Mohs procedure reagent list, and interviews with the office manager (OM) and laboratory assistant (LA); the laboratory failed to provide a list of reagents used in the laboratory when processing samples for Mohs to indicate the received date, lot number, expiration date, opening date, and disposal date when such materials are used. The findings include: 1. The laboratory has a contract with Mohs Tek company to process and stain samples for the Mohs test procedure. 2. Based on the surveyor's review of Mohs Tek testing documentation on July 15, 2026, at approximately 1:15 p.m. the OM and LA failed to provide a log of the following reagents used when processing and staining samples for Mohs testing stating: received date, lot number, opening date, expiration date, and initials: Tissue dye markers Hematoxylin/Eosin stains Xylene 100% absolute alcohol Acetone Freezing oil and any other reagents used during the procedure. 3. The laboratory's OM affirmed by interview conducted on July 15, 2026, at approximately 1:15 p.m. that the reagents mentioned in statement #2 were not documented when in use. 4. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 100 for Mohs test procedure using reagents not documented as regulated.</p> |
| <p><b>D5429</b></p> | <p>MAINTENANCE AND FUNCTION CHECKS<br/>CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on the lack of preventive maintenance documentation for the microscope, review of calibration and maintenance records, and interview with the laboratory's office manager (OM); the laboratory failed to perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer for the microscope used for microscopic examination and diagnosis histopathology and Mohs tests. The findings included: 1. The laboratory failed to conduct calibration and preventive maintenance of the Olympus BH2 microscope used for all microscopic examinations. 2. For six (6) out of six (6) randomly selected Mohs and histopathology samples reviewed, ranging from 12/8/2023 to 02/16/2026 samples processed and reported, no records of preventive maintenance of the microscope used to diagnose Mohs and histopathology samples were found for the years 2024 and 2025. 3. The OM confirmed on 07/15/2026 at approximately 2:00 p. m. that the laboratory failed to follow manufacturer's instructions to document the microscope maintenance and calibration for the years 2024 and 2025.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <p><b>D5441</b></p> | <p>CONTROL PROCEDURES</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

This STANDARD is not met as evidenced by:

Based on the surveyor's observation, review of the laboratory quality control (QC) records for Mohs testing, logs of patients' Mohs procedure and results, lack of written and approved Mohs QC policy and procedure, and interview with the office manager (OM) and laboratory assistant (LA); the laboratory failed to provide QC records that monitor the accuracy and precision of the complete analytic process including the number, the type, and the frequency of the QC materials when performing Mohs procedure examinations. 1. On the day of the survey July 15, 2026, at approximately 1:30 p.m. during the Mohs test patient results review, QC documentation and preventive maintenance of the cryostat were missing for the Mohs testing days 2/12/2025 and 7/21/2025. 2. For three (2) out of six (6) random selected patient test results reviewed for Mohs examinations performed, no QC documentation nor cryostat preventive maintenance were available at the time of the survey. 3. The OM and LA confirmed- on July 16, 2026, that the laboratory lacked an established policy and procedure for QC and that no Mohs test procedure QC documentation was available for the dates mentioned in statement 1.

**D5893**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1299(b)(c)

(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality assurance/assessment plan, lack of incident reports documentation, and interview with the laboratory's office manager (OM) and laboratory assistant (LA) on July 15, 2026; the laboratory failed to include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, discussion of postanalytic systems quality assessment reviews, patients tests management, and documentation of systems quality assurance/assessment activities. Findings included: 1. The laboratory had a policy for quality assurance and assessment; however, the laboratory failed to follow the policy for quality assessment and documentation of patient test management, review of accuracy of patient reports for the years 2023, 2024, and 2025. 2. Although the laboratory had a quality assurance plan, no documentation on quality improvement, meetings, or revision of policies and

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|              | <p>procedures to prevent recurrence of problems were found. 3. The OM and LA affirmed by interview on July 15, 2026, at approximately 12:45 p.m. that quality assurance/assessment of all phases of laboratory testing preanalytic, analytic and postanalytic systems were not performed and reviewed nor documented for the years 2023, 2024, and 2025. 4. The laboratory reported performing approximately 100 laboratory tests including Histopathology and Mohs test for which quality assurance /assessment was not performed and incident reports were not documented for the years 2023, 2024, and 2025.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>D6082</b> | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1445(e)(1)</p> <p>(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;</p> <p>This STANDARD is not met as evidenced by:<br/>Based on the lack of peer review records for the years 2023, 2024, and 2025 (D5217) lack of established CLIA compliant policies and procedures (D5401), lack of documentation of the reagents used for the Mohs procedure (D5415), no records of preventive maintenance for the microscope (D5429), and lack of documentation of Quality Assurance (D5893) and quality control (D5441); the laboratory director is cited herein for failure to ensure that testing systems developed and used for each of the Mohs tests and histopathology diagnosis performed in the laboratory, provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.</p> |
| <b>D6084</b> | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1445(e)(2)</p> <p>provide a safe environment in which employees are protected from physical, chemical, and biological hazards;</p> <p>This STANDARD is not met as evidenced by:<br/>Based on the surveyor's findings during the tour and lack of safety policies and procedures, the laboratory director is herein cited for the deficient practice in failure to provide and overall administration of the laboratory to ensure a safe environment in which personnel are protected from physical, chemical, biochemical, electrical hazards, and biohazardous materials. Findings include See D3011.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |