

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D1057816	<b>(X3) Date Survey Completed</b>  06/28/2024
<b>Name of Provider or Supplier</b>  Advanced Dermasurgery Associates	<b>Street Address, City, State</b>  12222 Coit Road, Suite 101, Dallas, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory policies, CMS 209 form, laboratory twice annual accuracy records, and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated histopathology (MOHs) procedures at least twice annually for 2 of 2 testing events in 2023. Findings included: 1. Review of the CMS-116 form submitted at survey by the laboratory revealed the laboratory performed histopathology (MOHs) procedures. 2. Review of the laboratory's "Quality Assurance Program" policy stated: "Quality Assurance Indicators ... - Comparison of Test Results Twice annually, slides from randomly chosen Mohs and in-house biopsy specimens will be sent to a dermatopathologist for evaluation of slide adequacy and second opinion of results from the Mohs surgery procedure. A request will be made for consulting slides to be returned to [XX], M.D., and accompanying reports will be filed in the Mohs laboratory as part of the quality assurance record. 3. Review of CMS-209 form submitted by the laboratory revealed Testing Person-1 (TP-1) and Testing Person-2 (TP-2) performed MOHs procedures. 4. Review of the laboratory's twice annual accuracy records revealed there were no twice annual accuracy assessment records for TP-1 for 2 of 2 events 2023. 5. During an interview on 06/28/2022 at 9:42 am, the Director of Regulatory Compliance confirmed there were no twice annual accuracy assessments for TP-1 in 2023.</p>