

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2247721	(X3) Date Survey Completed 02/19/2026
Name of Provider or Supplier Dermatology Partners	Street Address, City, State 3760 Brookside Road, Macungie, PA	
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
D0000	A recertification survey conducted by the Pennsylvania State Agency on 02/19/2026 found the Dermatology Partners Macungie laboratory to be out of compliance with the following condition: 493.1230 Condition: General laboratory systems.
D5200	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's peer review records, and interview with the Senior Director of Clinical Development (SDCD), the laboratory failed to ensure that general laboratory systems requirements were met under 493.1236 for the verification of accuracy for MOHS microscopic slide examinations performed for 1 of 1 year in 2025. (Refer to 5217)</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE 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 the laboratory's peer review records, and interview with the Senior</p>

Director of Clinical Development (SDCD), the laboratory failed to ensure that the verification of accuracy for MOHS microscopic slide examinations was performed at least twice annually, as required for tests not included in subpart I for 1 of 1 year in 2025. Findings Include: 1. On the day of the survey, 02/19/2026 at 09:47 am, the laboratory failed to provide documentation for the verification of accuracy of MOHS microscopic slide examinations stained using hematoxylin and eosin (H&E) performed at least twice annually in 2025. 2. The laboratory performed 1,400 microscopic slide examinations(histopathology) in 2025 (CMS-116, estimated annual volume, dated 2/18/2026). 3. The SDCCD confirmed the findings above on 02/19/2026 at 10:30 am. ** Repeat Deficiency**