

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2039532	(X3) Date Survey Completed 02/19/2026
Name of Provider or Supplier Main Line Dermatology	Street Address, City, State 1246 Wrights Lane, West Chester, 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 routine recertification survey was conducted by the Pennsylvania State Agency for Main Line Dermatology on 2/19/2026. The laboratory was found out of compliance with the following condition: 493.1250 Condition: Analytic systems.
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 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 procedure manual and interview with the Clinical Manager (CM), the laboratory failed to meet the analytic system requirements in 493.1251 to ensure that 1 of 1 laboratory procedure manual in use for Dermatopathology (MOHS) was approved, signed and dated by the current Laboratory Director (LD) from 04/23/2024 to 02/19/2026. Refer to D5407.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and interview with the Clinical</p>

Manager (CM), the laboratory failed to ensure 1 of 1 laboratory procedure manual in use for dermatopathology (MOHS) was approved, signed and dated by the current Laboratory Director (LD) from 04/23/2024 to 02/19/2026. Findings include: 1. The laboratory's Quality Assessment procedure stated, "New procedures and all changes to the Manual will be approved, signed and dated by the Laboratory Director before use. The Laboratory Director will also sign, and date the procedure manual ANNUALLY and at other times if required by state law, major changes in procedure, or other circumstances affecting laboratory performance." 2. On the day of survey, 02/19/2026 at 9:30 am, review of 1 of 1 MOHS procedure manual revealed no procedures were approved, signed and dated by the current LD before use from 04/23/2024 to 02/19/2026. 3. The laboratory performed 836 MOHS examinations in 2025. (CMS 116, estimated annual volume, dated 02/23/2026). 4. The CM confirmed the findings above on 02/19/2026 at 10:22 am. *REPEAT DEFICIENCY