

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 08D1077904	(X3) Date Survey Completed 04/30/2025
Name of Provider or Supplier Swier Clinic, Mohs	Street Address, City, State 1400 Savannah Rd, Lewes, DE	
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 was conducted on April 30, 2025 at approximately 2:00 PM. The laboratory was surveyed according to 42 CFR Part 493 Clinical Laboratory Improvement Amendments (CLIA) requirements. Deficiencies were identified as follows:
D5429	<p>MAINTENANCE AND FUNCTION CHECKS 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: Based on interview and facility document and policy review, the laboratory failed to perform required annual preventive maintenance for a Leica CM1510S Cryostat. This was noted for 2 (2023 and 2024) of 2 years reviewed. Findings included: A "Standard Operating Policy and Procedure Manual," adopted 05/01/2014, revealed a section for "Cryostat Safety and Maintenance/Quality Control." The manual specified, "Preventive maintenance and grounding check are done every year or sooner if needed." An undated "Instruction Manual" for the Leica CM1510S Cryostat instrument revealed a requirement to, "Have the instrument inspected by a qualified service engineer authorized by Leica at least once a year." During an interview on 04/30/2025 at 3:15 PM, the Laboratory Director (LD) was asked to provide documentation of annual preventive maintenance of the Cryostat. The LD stated the required maintenance had not been performed.</p>