Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2216846	04/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Schweiger Dermatology Pllc	4535 Southwestern Blvd Suite 202, Hamburg, NY	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of waived testing manufacturer's package insert instructions, lack of Standard Operating Procedures (SOPs) and temperature records, as well as interview with the General Manager (GM), the laboratory failed to monitor and document temperatures in the area where waived test kits were stored and on-site laboratory patient testing was performed. FINDINGS: 1. There was no documentation of ambient room temperature in the area where waived test kits were stored and on-site laboratory patient testing was performed. 2. The Clarity HCG (urine Cassette), Lot 2310039, Expiration: September 30, 2025; manufacturer's package insert included instructions for storage temperature range of 35F - 86F. 3. The current, approved SOPs did not include instructions for monitoring and documenting temperatures in the laboratory area where waived test kits were stored and on-site laboratory testing was performed. 4. The GM confirmed the findings on April 9, 2025, at approximately 10: 00 A.M.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)

	(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. This STANDARD is not met as evidenced by: Based on direct observation, review of SOPs, as well as interview with the GM, the laboratory failed to properly identify Mohs laboratory automated stainer reagent, concentration, lot number, expiration date, and storage requirements. FINDINGS: 1. The surveyor's observations in the Mohs processing laboratory on April 9, 2025, at approximately 10:00 A.M. confirmed the Thermo Scientific Linistat automated stainer, SN: LS1113A0809 reagents were not labeled with identification, concentration, lot number, expiration date, and storage requirements. 2. The current, approved SOPs did not include instructions for performing such activity. 3. The GM confirmed the findings on April 9, 2025, at approximately 12:30 P.M.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on review of waived testing manufacturer's package insert instructions, the laboratory's Quality Assessment Plan (QAP), as well as interview with the GM, the laboratory failed to perform and document Quality Control (QC) for waived testing. FINDINGS: 1. There was no documentation of QC performance for the Clarity HCG (urine Cassette), Lot 2310039, Expiration: September 30, 2025. 2. This is contrary to instructions indicated in the laboratory's QAP and manufacturer's package insert instructions. 3. The GM confirmed the findings on April 9, 2025, at approximately 10: 00 A.M.