Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0937983	02/26/2024
Name of Provider or Supplier	**Street Address, City, State**	
Schweiger Dermatology, Pc - Princeton	800 Bunn Drive Suite 201, Princeton, NJ	

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) 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: (1) Water quality. (2) Temperature. (3) Humidity. (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 surveyor review of the staining dyes and "Room Temperature and Humidity Log" (LOG) and interview with the Histotechnicians (HT), the laboratory failed to provide an accurate room temperature acceptable range per the staining dyes labels on the LOG from 6/13/23 to the date of the survey. The findings include: 1. The surveyor observed the strictest requirement for the room temperature, 68-86F, based on the staining dyes labels, but the acceptable range was 40-95F on the LOG. 2. The HT's confirmed on 2/26/24 at 2:30 pm that the acceptable range for room temperature on the LOG was not accurate.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or

	baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and Antonki thermohygromoter and interview with the Histotechnicians (HT) at the time of the survey, the laboratory failed to provide a written procedure for and documentation of calibration for all thermometers used in the laboratory from 6/13/23 to the date of the survey. The findings include: 1. The laboratory could not provide a written procedure for the calibration or replacement of all thermometers used, including the Antonki thermohygrometer, in the laboratory. 2. The laboratory could not provide documentation of current calibration for the Antonki thermohygrometer, used for room temperature and humidity, which expired on 12/14/2023. 3. The HT's confirmed on 2/26/24 at 2:45 pm that they could not provide a written procedure for performing calibration or replacement of the thermometers nor provide documention of current calibration for the Antonki thermohygrometer.