Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2041801	12/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Choice Dermatology Llc	12 Ridge Street, Basking Ridge, 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 Olympus BX50 Microscope Instruction Manual (IM) and interview with the office manager (OM), the laboratory failed to document the room termperature and humidity on each day of testing per the IM requirements in the microscope room from 10/12/23 to 12/17/24. The findings include: 1. The surveyor observed requirements for the microscope room as room temperature, 0-40C and humidity, 30-90%, in the IM, but room temperature and humidity were not documented on each day of testing. 2. The OM confirmed on 12/17/24 at 1:30 pm that room temperature and humidity were not documented on each day of testing in the microscope room.
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 Therm-Pro thermohygromoter in the Cryostat room and interview with the Office Manager (OM), the laboratory failed to provide a written procedure for and documentation of calibration for all thermohygrometers used in the Cryostat Room and microscope room and documentation of calibration from 10/13/23 to 12/17/24. The findings include: 1. The laboratory could not provide a written procedure for the calibration or replacement of all thermohygrometers in use or to be used in the microscope room, including the Therm-Pro thermohygrometer used in the Cryostat room. 2. The laboratory could not provide documentation of calibration for the Therm-Pro thermohygrometer, used for room temperature and humidity in the Cryostat room. 3. The OM confirmed on 12/17/24 at 1:45 pm that they could not provide a written procedure for performing calibration or replacement of the thermohygrometers nor provide documention of calibration for the Therm-Pro Thermohygrometer.