Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2050870	02/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
Comprehensive Dermatology Of Rochester, Pllc	900 Winton Road S, Rochester, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of Standard Operating Procedures (SOPs), competency assessment records, as well as interviews with the Testing Person (TP) and the Laboratory Director (LD), the laboratory failed to perform and document competency assessments. FINDINGS: 1. There was no documentation of competency assessment performance for the LD, Clinical Consultant (CC), Technical Supervisor (TS), and the General Supervisor (GS). 2. This is contrary to instructions included in the current, approved SOPs. 3. The TP and LD confirmed the findings on February 11, 2025, at 3: 15 P.M.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective

	action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the SOPs, lack of thermometer calibration records, as well as interviews with the TP and LD, the laboratory failed to draft and approve procedures for thermometer calibration. FINDINGS: 1. There was no documentation of thermometer calibration certificate for the thermometer utilized for measuring ambient temperature and humidity in the Mohs processing laboratory. 2. The current, approved SOPs did not include instructions for thermometer calibration and certificate retention. 3. The TP and LD confirmed the findings on February 11, 2025, at approximately 3:15 P.M.
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 direct observations, review of SOPs, lack of room temperature records, as well as interviews with the TP and LD, the laboratory failed to monitor and document ambient room temperatures where waived test kits and PPMP reagents were stored and patient specimen testing was performed. FINDINGS: 1. There was no documentation of ambient room temperatures for the area where waived test kits and PPMP reagents were stored and patient specimen testing was performed. 2. No thermometer was present in the area for monitoring ambient temperatures. 3. The current, approved SOPs did not include instructions for performing such activity. 4. The TP and LD confirmed the findings on February 11, 2025, at approximately 3:15 P. M.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on direct observations, review of SOPs, as well as interviews with the TP and LD, the laboratory failed to remove from inventory an expired reagent in the Mohs processing laboratory. FINDINGS: 1. The surveyor's observations in the Mohs processing laboratory confirmed on February 11, 2025, at approximately 12:30 P.M. the following reagent was not removed from inventory: a. Avantik Tissue Marking Dye Blue, lot: 166704, expiration: January 31, 2025, stored on the counter in the Mohs laboratory tissue processing area. 2. The LD informed the surveyor the expired tissue marker dye was utilized for patient specimen processing. Approximately three patient specimens were processed utilizing the respective expired reagent. 3. The current, approved SOPs did not include instructions for performing such activity. 4. The TP and LD confirmed the findings on February 11, 2025, at approximately 2:30 P. M.