Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0870907	01/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Catskill Dermatology Pc	110 Bridgeville Road, Monticello, 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 interview with the Office Manager (OM), the laboratory failed to perform and document personnel training and competency assessments. FINDINGS: 1. There was no documentation of training and competency assessment for testing personnel (TP), JS. 2. The current, approved SOPs did not include instructions for performing clinical consultant (CC), technical supervisor (TS), and general supervisor (GS) competency assessments. 3. The OM confirmed the findings on January 16, 2025, at approximately 4:30 P.M.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory systems quality assessment (QA) procedures, QA records, as well as interview with the OM, the laboratory failed to perform and document QA. FINDINGS: 1. There was no documentation of QA records for years

	2022, 2023, and 2024. 2. This is contrary to instructions indicated in the current, approved Quality Systems Assessment Plan. 3. The OM confirmed the findings on January 16, 2025, at approximately 4:30 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 interview with the OM, the laboratory failed to draft and approve procedures for thermometer calibration. FINDINGS: 1. There was no documentation of analog thermometer calibration certificate for the thermometer utilized for measuring office room refrigerator temperatures where patient specimen testing reagents were stored. 2. The current, approved SOPs did not include instructions for thermometer calibration and certificate retention. 3. The OM confirmed the findings on January 16, 2025, at approximately 4:30 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 Laboratory Director (LD) and OM, the laboratory failed to

	monitor and document ambient room temperatures in the areas where patient specimen testing was performed and reagents, processing materials were stored. FINDINGS: 1. There was no documentation of ambient room temperatures for the lab processing and office room where patient specimen testing was performed and reagent, processing materials were stored. 2. No thermometers were present in the office and lab processing room to monitor ambient temperatures. 3. The current, approved SOPs did not include instructions for performing such activity. 4. The LD and OM confirmed the findings on January 16, 2025, at approximately 3:00 P.M. and 4:30 P.M. respectively.
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, lack of SOPs, as well as interview with the OM, the laboratory failed to remove from inventory expired reagents located in the lab processing room and office room utilized for patient specimen processing. FINDINGS: 1. The surveyor's observations in the lab processing room confirmed on January 16, 2025, at approximately 11:30 A.M. the following reagents were not removed from inventory: a. CDI Tissue Marking Dye Lot: 9344 Exp.: December 31, 2021, was stored under the fumehood in the lab processing room. b. Epredia Eosin-Y with Phloxine Lot: 124807 Exp.: May 2024, was stored in the Justrite flammable storage cabinet in the lab processing room. c. SelecTech Eosin Phloxine 515 Lot: 072209 Exp.: July 2, 2021, was stored in the Justrite flammable storage cabinet in the lab processing room. d. EKI Hematoxylin Stain Solution, Mayer Modified Lot: 1519413 Exp.: July 16, 2017, was stored in the Justrite flammable storage cabinet in the lab processing room. e. Epredia Periodic Acid Solution (0.5%) Lot: 134949N Exp.: October 8, 2024, was stored in the Justrite flammable storage cabinet in the lab processing room. 2. The surveyor's observations in the office room confirmed on January 16, 2025, at approximately 4:30 P.M. the following reagent was not removed from inventory: a. Schiff's Reagent Exp. December 2024, was stored in the refrigerator in the office room. 3. The current, approved SOPs did not include instructions for removal of expired reagents from inventory. 4. The OM informed the surveyor that the respective expired reagents were utilized for patient specimen processing. Due to lack of records, it could not be determined approximately how many patient specimens were processed utilizing the respective expired reagents. 5. OM confirmed the findings on January 16, 2025, at approximately 4:30 P.M.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on inventory and use of expired reagents, lack of SOPs, competency

	assessment and training records, QA records, temperature logs, thermometer calibration certificates, as well as interview with the OM, the LD failed to provide overall management and direction of the laboratory services. Refer to D5209, D5291, D5403, D5413, and D5417.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of the General Laboratory Systems QA procedures, QA records, as well as interview with the OM, the LD failed to comply with current, approved policies to assure the laboratory followed and maintained the QA Plan. Refer to D5291.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of SOPs, competency assessment records, as well as interview with the OM, the LD failed to perform and document personnel competency assessment performance as well as draft, approve SOPs for performing such activity. Refer to D5209.