Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2077647	08/06/2025
Name of Provider or Supplier	**Street Address, City, State**	
Upstate Dermatology Pc	1770 Route 9, Suite 202, Clifton Park, 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
D3001	FACILITIES CFR(s): 493.1101(a)(1) (a) The laboratory must be constructed, arranged, and maintained to ensure the following: (a)(1) The space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on direct observations, review of Safety Data Sheets (SDS), lack of Standard Operating Procedures (SOPs), as well as interview with the Testing Person (TP), the laboratory failed to ensure proper ventilation for conducing all phases of the testing process. FINDINGS: 1. There was no ventilation system in the Mohs processing laboratory where manual hematoxylin and eosin (H & E) staining of patient specimens were performed. 2. It was noted that, although no fume hood or biosafety cabinet was present in the Mohs processing laboratory, the Cryostat and Fume Hood Maintenance Checklist documented fume hood cleaning and filter maintenance. 3. Avantik Cover Mount 2, Toluene Based, lot: 160971, expiration: November 30, 2024, and Avantik Tissue Marking Dye Green, lot: 27320, expiration: January 2016 were stored in a cabinet above the sink in the Mohs processing laboratory. 4. No reagents, stains, or solutions were stored in the flammable Jamco Products Safety Storage cabinet located the Mohs processing laboratory. 5. The current SOPs did not include instructions for safe handling and storage of hazardous and flammable materials including reagents, solutions and stains used in the Mohs processing laboratory for patient testing. 6. The TP confirmed the findings on August 6, 2025, at approximately 10:30 A.M.
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 SOPs, personnel competency assessment records, as well as interview with the TP, the laboratory failed to perform and document competency assessments. FINDINGS: 1. There was no documentation of competency assessment performance for the Clinical Consultant (CC), Technical Supervisor (TS), and General Supervisor (GS). 2. The current SOPs did not include instructions for performing CC, TS, and GS competency assessments. 3. It was noted that Histotechnician TP competency assessment was performed and documented. 4. The TP confirmed the findings August 6, 2025, at approximately 1:00 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 SOPs, lack of thermometer calibration records, as well as interview with the TP, the laboratory failed to draft and approve procedures for thermometer calibration. FINDINGS: 1. There was no calibration documentation or certificate of analysis available for the EXTECH Instruments, Model 445703, digital thermometer/humidstat used in the Mohs processing laboratory to measure room temperature and humidity. 2. The current SOPs did not include instructions for thermometer calibration and certificate retention. 3. The TP confirmed the findings on August 6, 2025, at approximately 1:00 P.M.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

	This STANDARD is not met as evidenced by: Based on review of SOPs and interview with the TP, the laboratory failed to document approval and date of approval of the procedures by the current Laboratory Director (LD) before use. FINDINGS: 1. There was no documentation of LD review, approval, and date of approval for any of the current laboratory procedures in use. 2. It was noted that LD signature was documented for "Mohs Tissue Procedure" however no date of approval was indicated. 3. The TP confirmed the findings on August 6, 2025, at approximately 1:00 P.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 review of SOPs, lack of records, as well as interview with the TP, the laboratory failed to track reagents, solutions, supplies received and utilized in the Mohs processing laboratory for patient testing. FINDINGS: 1. There was no tracking documentation of lot number, expiration date, date received, and date in use for reagents, solutions and supplies utilized in the Mohs laboratory. 2. The current SOPs did not include instructions for documenting lot number, expiration date, date received, and date in use for reagents, solutions and supplies utilized in the Mohs processing laboratory. 3. The TP confirmed the findings on August 6, 2025, at approximately 10:30 A.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 interview with the TP, the laboratory failed to remove from inventory expired reagents, solutions, and testing supplies utilized for patient specimen processing. FINDINGS: 1. The surveyor's observations in the Mohs laboratory confirmed on August 6, 2025, at approximately 10:30 A.M., the following reagents and processing materials were not removed from inventory: a. Avantik Cover Mount 2, Toluene Based, lot: 160971, expiration: November 30, 2024, was stored in a cabinet above the sink in the Mohs processing laboratory. b. Avantik Tissue Marking Dye Green, lot: 27320, expiration: January 2016, was stored in a cabinet above the sink in the Mohs processing laboratory. c. It was noted that the respective expired reagents were removed from the Mohs processing laboratory inventory during the survey in partial satisfaction of this requirement. 2. The current SOPs did not include instructions for removal of expired reagents, supplies, and test kits from inventory. 3. The TP informed the surveyor that

	the respective expired reagents were not utilized for patient specimen processing. 4. The TP confirmed the findings on August 6, 2025, at approximately 1:00 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 lack of competency assessment records, SOPs, thermometer calibration documentation, reagent and supply tracking logs, expired reagent inventory, as well as interview with the TP, the LD failed to provide overall management and direction of the laboratory services. Refer to D5209, D5403, D5407, D5415, D5417, and D6107.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) (e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and This STANDARD is not met as evidenced by: Based on direct observations, review of SDS, as well as interview with the TP, the LD failed to ensure that the environmental conditions of the laboratory were appropriate for the testing performed. Refer to D3001.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) provide a safe environment in which employees are protected from physical, chemical, and biological hazards; This STANDARD is not met as evidenced by: Based on direct observations, review of SDS, as well as interview with the TP, the LD failed to provide a safe environment in which employees were protected from chemical hazards. FINDINGS: 1. No reagents, stains, or solutions were stored in the flammable Jamco Products Safety Storage cabinet located the Mohs processing laboratory. 2. The TP stated the Mohs histotechnician transported all reagents, stains, and solutions in their personal vehicle from other site locations. 3. The current SOPs did not include instructions for safe handling and transporting of hazardous materials, such as, reagents, solutions and stains used in the Mohs processing laboratory for patient testing. 4. The TP confirmed the findings on August 6, 2025, at approximately 10:30 A.M.
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 lack of SOPs, competency assessment records, as well as interview with TP, the LD failed to ensure that policies and procedures were established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain 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. Refer to D5209.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on review of SOPs and interview with the TP, the LD failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. Refer to D5407.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) (e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of SOPs, lack of job descriptions and competency assessments, as well as interview with the TP, the LD failed to specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. FINDINGS: 1. There was no documentation of LD, CC, TS, GS, and TP job descriptions. 2. The TP confirmed the findings on August 6, 2025, at approximately 1:00 P.M.