Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0725367	07/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
Upstate Dermatology Pc	113 Hudson Avenue, Chatham, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of Standard Operating Procedures (SOPs), lack of manufacturer's instructions, as well as interview with Testing Personnel (TP), the laboratory failed to retain and follow waived test manufacturer's instructions. FINDINGS: 1. There was no documentation of waived test manufacturer instructions for the hCG urine pregnancy test cassettes; Jant Pharmacal Corporation; lot: 2304070; expiration: March 31, 2025. 2. The current SOPs did not include instructions for performing respective waived testing. 3. The TP confirmed the findings on July 30, 2025, at approximately 2: 30 P.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 July 30, 2025, at approximately 11:30 A.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 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 455703, 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 July 30, 2025, at approximately 11:30 A.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. The TP confirmed the findings on July 30, 2025, at approximately 11:30 A.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 review of temperature records, lack of SOPs and manufacturer's instructions, as well as interview with the waived TP, the laboratory failed to monitor and document temperatures in the area where waived test kits were stored and on-site laboratory patient testing was performed. FINDINGS: 1. There was no documentation of ambient room temperature in the area where the waived test kits were stored and on-site laboratory patient testing was performed. 2. The current SOPs did not include instructions for monitoring and documenting temperatures in the laboratory area where waived test kits were stored and on-site laboratory testing was performed. 3. The waived TP confirmed the findings on July 30, 2025, at approximately 2:30 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 July 30, 2025, at approximately 2:30 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 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 July 30, 2025, at approximately 11: 00 A.M. the following reagents and processing materials were not removed from inventory: a. Ultra Freeze Embedding Medium for Frozen Tissue Specimens, Belair Instrument Company, Inc., lot: 3649256, expiration: July 2009, was stored on a shelf above the cryostat in the Mohs processing laboratory. b. 0.9% Sodium Chloride Irrigation USP, Baxter, lot: G108779, expiration: August 2016, was stored on a shelf above the cryostat 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 TP confirmed on July 30, 2025, at approximately 2:30 P.M. that the respective expired reagents and processing materials were not utilized for patient specimen processing. 3. The surveyor's observations in the waived testing area confirmed on July 30, 2025, at approximately 2:30 P.M. the following expired waived test kits were not removed from inventory: a. hCG urine pregnancy test cassettes Jant Pharmacal Corporation Lot: 2304070 expiration: March 31, 2025, was stored in the area where waived testing was performed. b. It was noted that the respective expired test kit was removed from the waived testing area inventory during the survey in partial satisfaction of this requirement. 4. The TP informed the surveyor that the respective expired waived test kit was utilized for patient specimen testing. Due to lack of documentation and records, it could not be determined approximately how many patient specimens were processed utilizing the respective expired test kit. 5. Current SOPs did not include instructions for removal of expired reagents, supplies, and test kits from inventory. 6. The TP confirmed the findings on July 30, 2025, at approximately 2:30 P.M.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of SOPs, equipment maintenance records, as well as interview with the TP, the laboratory failed to document cryostat and fume hood maintenance. FINDINGS: 1. There was no documentation of cryostat lubrication, cleaning, and filter maintenance on the Cryostat & Fume Hood Maintenance Checklist for 2022, 2023, and 2024. 2. There was no documentation of fume hood cleaning on the Cryostat & Fume Hood Maintenance Checklist from January 2025 through July 2025. 3. There was no documentation of Airfiltronix fume preventive maintenance or service records. 4. The current SOPs did not include instructions for performing such activity. 5. The TP confirmed the findings July 30, 2025, at approximately 12:00 P.M.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on review of SOPs, lack of waived testing manufacturer's package insert

	instructions, as well as interview with the waived TP, the laboratory failed to perform and document Quality Control (QC) for waived testing. FINDINGS: 1. There was no documentation of QC performance for the hCG urine pregnancy test cassettes, Jant Pharmacal Corporation, Lot: 2304070, expiration: March 31, 2025. 2. There was no documentation of waived test manufacturer instructions for the respective waived test kits. 3. The current SOPs did not include instructions for performing the respective waived testing or QC performance. 4. The waived TP confirmed the findings on July 30, 2025, at approximately 2:30 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 lack of competency assessment records, SOPs, thermometer calibration documentation, reagent and supply tracking logs, equipment maintenance records, QC documentation, expired reagent and test kit inventory, as well as interviews with the TP, the LD failed to provide overall management and direction of the laboratory services. Refer to D5209, D5403, D5407, D5413, D5415, D5417, D5429, D5449, and D6107.
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, and GS job descriptions. 2. The TP confirmed the findings on July 30, 2025, at approximately 11:30 A.M.