

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2323893	(X3) Date Survey Completed 05/28/2026
Name of Provider or Supplier Latham Dermatology Pllc	Street Address, City, State 711 Troy Schenectady Suite 208, Latham, 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 lack of training and competency assessment records, review of Standard Operating Procedures (SOPs), as well as interview with the Regional Practice Manager (RPM), the laboratory failed to follow written policies and procedures to assess employee competency. FINDINGS: 1. There was no documentation of training and competency assessment for the Mohs processing technicians. 2. This was contrary to instructions indicated in the Latham Dermatology Laboratory Management Quality Assurance (QA) manual training policies which specified documentation of staff training and competency assessments. 3. The RPM confirmed the findings on May 28, 2026, at approximately 3:30 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 RPM, 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 the Latham Dermatology Laboratory Management

	QA binder laboratory's policies and procedures. 2. The RPM confirmed the findings on May 28, 2026, at approximately 3:30 P.M.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(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. (b)(2)(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 lack of thermometer calibration records and SOPs, as well as interview with the RPM, the laboratory failed to define a function check protocol that ensures instrument performance that is necessary for accurate and reliable test results and result reporting. FINDINGS: 1. There was no documentation of calibration for the Antonki digital thermometer hygrometer utilized for monitoring ambient room temperature and humidity in the Mohs processing laboratory. No serial or model number was available for the thermometer hygrometer. 2. The Latham Dermatology, PLLC SOPs did not include instructions for thermometer calibration and certificate retention. 3. The RPM confirmed the findings on May 28, 2026, at approximately 3:30 P.M.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of temperature and humidity records, lack of corrective action documentation and SOPs, as well as interview with the RPM, the laboratory failed to perform and document all corrective actions taken, including actions taken when test systems did not meet the laboratory's established performance specifications. FINDINGS: 1. There was no documentation of corrective action performance for the Hematoxylin and Eosin Staining Maintenance Log Mohs processing laboratory room temperatures that deviated from the acceptable range of 68F to 78F for the following days: August 22, 2025, 78.4F; December 12, 2025, 81F; January 16, 2026, 79.9F; and March 6, 2026, 78.8F. 2. There was no documentation of corrective action performance for the Hematoxylin and Eosin Staining Maintenance Log cryostat temperatures that deviated from the acceptable range of -24C to -30C for the following days: September 12, 2025, -21C and March 6, 2026, +8C. 3. Approximately

	fifty-three Mohs patient specimens were processed during the respective dates. 4. The Latham Dermatology, PLLC "Thermometer/Temperature Controls" SOP did not include instructions for documenting corrective action for out-of-range temperatures. 5. The RPM confirmed the findings on May 28, 2026, at approximately 3:30 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 review of QA documents, temperature and humidity records, SOPs, lack of training, competency assessment, corrective action records, and job descriptions, as well as interview with the RPM, the LD failed to provide overall management and direction of the laboratory services. Refer to D6093, D6096, D6102, D6106, and D6107.
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 lack of personnel training, competency assessment records, review of QA documentation, as well as interview with the RPM, the LD failed to ensure that quality control and assessment programs were maintained to assure the quality of laboratory services provided and to identify failures in quality as they occurred. FINDINGS: 1. There was no documentation of training and competency assessment for the Mohs processing technicians. 2. This was contrary to the Latham Dermatology, PLLC Laboratory Management QA manual "Quarterly QA Checklist" General Laboratory Systems QA records dated December 18, 2025, and April 18, 2026, which were signed by the RPM, confirming all lab personnel had been trained to perform the tests they were authorized to perform, evaluated as often as stated in the laboratory policies, and all personnel evaluations were documented, retained in the appropriate personnel files. 3. The RPM confirmed the findings on May 28, 2026, at approximately 3:30 P.M.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance characteristics are identified, and This STANDARD is not met as evidenced by: Based on lack of corrective action documentation, review of QA documentation, as

	well as interview with the RPM, the LD failed to ensure that all necessary remedial actions were taken and documented whenever significant deviations from the laboratories established performance characteristics were identified. FINDINGS: 1. There was no documentation of corrective action performance for the Hematoxylin and Eosin Staining Maintenance Log Mohs processing laboratory room temperatures that deviated from the acceptable range of 68F to 78F for the following days: August 22, 2025, 78.4F; December 12, 2025, 81F; January 16, 2026, 79.9F; and March 6, 2026, 78.8F. 2. There was no documentation of corrective action performance for the Hematoxylin and Eosin Staining Maintenance Log cryostat temperatures that deviated from the acceptable range of -24C to -30C for the following days: September 12, 2025, -21C and March 6, 2026, +8C. 3. This was contrary to information indicated in the Latham Dermatology, PLLC Laboratory Management QA manual "Quarterly QA Checklist" Analytic Systems QA records dated December 18, 2025, and April 18, 2026, which were signed by the RPM confirming corrective action performance was performed and documented for out of acceptable range humidity or temperature. 4. The RPM confirmed the findings on May 28, 2026, at approximately 3:30 P.M.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on lack of training and competency assessment records as well as interview with the RPM, the LD failed to ensure prior to testing patients' specimens, all personnel had received appropriate training for the type and complexity of services offered, and demonstrated that they could perform testing operations reliably to provide and report accurate results. FINDINGS: 1. There was no documentation of training and competency assessment for the Mohs processing technicians. 2. The RPM confirmed the findings on May 28, 2026, at approximately 3:30 P.M.
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, as well as interview with the RPM, the LD failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. FINDINGS: 1. There was no documentation of LD review, approval, and date of approval for the in-use Latham Dermatology, PLLC laboratory's policies and procedures located in the Latham Dermatology Laboratory Management QA binder. 2. The RPM confirmed the findings on May 28, 2026, at approximately 3:30 P.M.
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 RPM, 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 Clinical Consultant (CC), Technical Supervisor (TS) and General Supervisor (GS) job descriptions. 2. It was noted LD and TP job descriptions were available for review. 3. The RPM confirmed the findings on May 28, 2026, at approximately 3:30 P.M.