

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2165109	(X3) Date Survey Completed 09/07/2023
Name of Provider or Supplier Midtown Dermatology Services, Pc	Street Address, City, State 317 East 34 Street, 11th Floor, Suite B, New York, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on direct observations, absence of thermometer calibration procedures and records, and interviews with the (Chief Operating Officer) COO and nursing manager, the laboratory failed to retain approved instructions for the calibration of thermometers. FINDINGS: 1. The Thomas Scientific digital thermometer serial: 151852943 utilized for monitoring the temperature of the Mohs processing laboratory calibration was due November 12, 2017. 2. The nursing manager and COO confirmed on September 6, 2023, at approximately 11:00 A.M. that the laboratory did not retain</p>

	<p>thermometer calibration certificates and the manufacturer's instructions for calibration of thermometers. 3. The nursing manger and COO confirmed on September 6, 2023, at approximately 11:00 A.M. that the American College of Mohs Surgery (ACMS) Manual of Frozen Section Processing for Mohs Micrographic Surgery and Maintenance Log did not include written, approved instructions for performing calibrations of thermometers.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the ACMS Manual of Frozen Section Processing for Mohs Micrographic Surgery and interviews with the nursing manager and COO, the laboratory failed to document procedure approval and date of approval by the current laboratory director. FINDINGS: 1. The nursing manger and COO confirmed on September 6, 2023, at approximately 1:00 P.M. that the ACMS Manual of Frozen Section Processing for Mohs Micrographic Surgery did not include documented approval and date of approval by the laboratory director.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on direct observations, review of the Material Safety Data Sheets (MSDS), reagent manufacturer's storage requirements, and interviews with the nursing manager and COO, the laboratory failed to properly store flammable reagents in the Mohs processing laboratory as required by the MSDS and ACMS Manual of Frozen Section Processing for Mohs Micrographic Surgery. FINDINGS: 1. The surveyors' observations in the Mohs processing laboratory confirmed on September 6, 2023, at approximately 2:30 P.M. the Avantik Red, Black, and Green tissue marker dyes were stored in an overhead cabinet located in the Mohs processing laboratory.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:

Based on direct observations, lack of room temperature records, lack of approved standard operating procedures, and an interview with the nursing manager and COO, the laboratory failed to document room temperature in the Mohs processing laboratory. FINDINGS: 1. The nursing manager and COO confirmed on September 6, 2023, at approximately 10:00 A.M. that the Mohs laboratory did not document room temperatures where reagents, stains, and inking materials were stored. 2. The nursing manager and COO confirmed on September 6, 2023, at approximately 11:30 A.M. that the Mohs laboratory standard operating procedures did not include written, approved instructions for monitoring and documenting room temperatures where reagents, stains, and inking materials were stored. a. It was noted that a temperature log sheet and written instructions for monitoring and documenting Mohs laboratory room temperatures were drafted during the survey in partial satisfaction of this requirement.