

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D0693098	<b>(X3) Date Survey Completed</b>  05/23/2023
<b>Name of Provider or Supplier</b>  Upstate Dermatology Pc	<b>Street Address, City, State</b>  461 Clinton Street Ext, Suite 1, Schenectady, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3013</b>	<p>FACILITIES CFR(s): 493.1101(e)</p> <p>Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.</p> <p>This STANDARD is not met as evidenced by: Based on direct observations of the Mohs slides and an interview with the general supervisor, the laboratory failed to properly store Mohs slides to ensure preservation. FINDINGS: 1. The general supervisor confirmed on May 23, 2023, at approximately 10:15 A.M. the surveyor's findings that the laboratory stored Mohs slides beneath the sink in the Mohs processing laboratory.</p>
<b>D5403</b>	<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</p>

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.

This STANDARD is not met as evidenced by:  
Based on direct observations of the Springfield medication refrigerator/freezer thermometer, lack of thermometer calibration procedures and records, and an interview with the general supervisor, the laboratory failed to retain approved instructions for the calibration of thermometers. FINDINGS: 1. The general supervisor confirmed on May 23, 2023, at approximately 10:00 A.M. that the "Mohs Tissue Procedure" manual did not include written, approved instructions for performing calibrations of thermometers. 2. The general supervisor confirmed on May 23, 2023, at approximately 10:00 A.M. that the laboratory did not retain thermometer calibration certificates and the manufacturer's instructions for calibration of thermometers.

**D5411**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(a)

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.

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 an interview with the general supervisor, the laboratory failed to properly store flammable reagents in the Mohs processing laboratory as required by the MSDS. FINDINGS: 1. The surveyors' observations in the Mohs processing laboratory confirmed on May 23, 2023, at approximately 10:15 A.M. the following reagents and processing materials were not properly stored in the flammable materials storage cabinet as required by the MSDS and the manufacturer's storage requirements: a. Avantik Acetone lot: 2235002 and lot: 2220720 were stored beneath the sink in the Mohs processing laboratory. b. National Diagnostics Histo-Clear lot: 09-22-26 was stored in a canvas bag on the floor located front of the flammable materials storage cabinet. c. Avantik Gill3 Hematoxylin stain lot: 16391A was stored in a cardboard box located on a plastic shelf in the Mohs processing laboratory. d. Several units of Avantik 100% Alcohol lot: 2300610 were stored on a plastic shelf in the Mohs processing laboratory.

**D5413**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(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: (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.

This STANDARD is not met as evidenced by:

Based on direct observations, room temperature records, and an interview with the general supervisor, the laboratory failed to install a room temperature thermometer for the measurement of the temperatures in the Mohs processing laboratory. FINDINGS:

1. The general supervisor confirmed on May 23, 2023, at approximately 10:00 A.M. that the Mohs laboratory did not include a thermometer for monitoring room temperatures where reagents, stains, and inking materials were stored. a. It was noted that the Springfield thermometer utilized for monitoring the temperatures of the Danby medication refrigerator/freezer was temporarily transferred to the Mohs laboratory on days when patient specimen processing occurred.