

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  09D2136624	<b>(X3) Date Survey Completed</b>  06/16/2022
<b>Name of Provider or Supplier</b>  Integrated Dermatology Of 19th Street Llc	<b>Street Address, City, State</b>  1145 19th Street Nw Suite 301, Washington, DC	
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>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 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 record review and interview, the MOHS surgery maps and written procedure did not include a key that matched the ink colors to the markings made on the MOHS map. Markings on the MOHS maps were made to show ink placement on the tissue removed from the patient and examined microscopically. Findings: 1. The laboratory places ink on the tissue removed during the MOHS surgery to orient the tissue, the placement of the ink and ink color is shown by markings (e.g. dashes or dots) depending on ink color; 2. The written procedure did not include a key matching the markings to ink color and three of three MOHS maps reviewed did not include a</p>

key; and 3. The laboratory did show the surveyor an unused MOHS map that included a key, but during interview with the histotechnician on the afternoon of the survey, the laboratory did not ensure that the MOHS map with the key was the map in general use.

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:  
Based on observation of the laboratory microscope and interview with the testing person (TP), the lab failed to perform maintenance and function checks on the microscope used for reviewing patient slides. Findings: 1. Observation of the microscope on the day of survey at 12:30 PM showed the last time preventative maintenance (PM) procedures were performed was on March 2019 and due in March 2022. 2. The microscope did not have the PM procedures performed during the month of March 2022. 3. The TP confirmed on the day of the survey at 12:30 PM that the microscope did not have the PM procedures performed during the month of March 2022.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the 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 record review and interview, the laboratory director did not ensure that the quality assurance procedure identified errors in testing records. Findings: 1. Patient A had a biopsy prior to MOHS surgery, both biopsy and MOHS surgery were performed on August 11, 2021; 2. The test report for the biopsy identified the biopsy date as July 7, 2021 and not the actual date of biopsy which was August 11, 2021; and 3. This was confirmed with the histotechnician during interview, the afternoon of the day of survey.