

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D0964009	<b>(X3) Date Survey Completed</b> 03/26/2019
<b>Name of Provider or Supplier</b> Skin Laser & Surgery Specialists Of	<b>Street Address, City, State</b> 20 Prospect Avenue Suite 702, Hackensack, NJ	
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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Biannual Assessment (BA) records and interview with the Clinical Coordinator (CC), the laboratory failed to verify the accuracy and reliability of Histopathology testing twice a year in the calendar years 2017 and 2018. The findings include: 1. The form used for BA was entitled Quality Assurance Peer Review Requisitions. 2. The slide was sent to reviewing Pathologist with the diagnosis. 3. The CC confirmed on 3/26/19 at 10:30 am that BA was not performed.</p>
<b>D5413</b>	<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> <p>This STANDARD is not met as evidenced by: a. Based on surveyor review of the Temperature Logs (TL) and interview with the Clinical Coordinator (CC), the laboratory failed to monitor and document Room Temperature (RT) and Humidity where Histopathology tests were performed from 4</p>

/11/17 to the date of survey. The CC confirmed on 3/26/19 at 10:30 am that the laboratory did not document RT and Humidity. b. Based on surveyor review of the TL and interview with the CC, the laboratory failed to define an acceptable temperature range for the Leica Cryostat used in Histopathology tests from 4/11/17 to the date of the survey. The CC confirmed on 3/26/19 at 10:40 am that the an acceptable range was not defined.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 surveyor review of the Maintenance Record (MR) and interview with the Clinical Coordinator (CC), the laboratory failed to perform and document monthly maintenance as specified by the manufacturer on the Leica Cryostat used for Histopathology tests in the calendar year 2018. The finding includes: 1. MR records revealed the monthly defrost on the LC was not documented from January to September, November and December 2018. 2. The CC confirmed on 3/26/19 at 11:00 am that maintenance as specified by the manufacturer was not performed.

**D6102**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(12)

The laboratory director must 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 surveyor review of Personnel Records (PR) and interview with the Clinical Coordinator (CC), the Laboratory Director failed to ensure that education records for one of two Testing Personnel (TP) were available from 4/11/17 to the date of a the survey. The CC confirmed on 3/26/19 at 10:00 am that education records were not available for all TP.