

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D1067292	<b>(X3) Date Survey Completed</b> 10/25/2023
<b>Name of Provider or Supplier</b> Cosmetic Skin Surgery Center	<b>Street Address, City, State</b> 333 Sylvan Avenue, Englewood Cliffs, 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 Biannual Assessment (BA) records and interview with Office Manager (OM), the laboratory failed to verify the accuracy and reliability of Mohs testing twice annually from 7/30/19 to the date of the survey. The findings include: 1. There was no documented evidence that BA was performed in 2021, 2022 and 2023. 2. The OM confirmed on 10/25/23 at 12:30 pm that the laboratory did not perform BA as mentioned above.</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: Based on surveyor review of the Temperature Log (TL) and interview with the Office Manager (OM), the laboratory failed to record Room temperature and humidity and cryostat temperature where Histopathology tests are performed on the date of the</p>

	<p>survey. The finding includes. 1. The TL did not have room temperature and humidity listed on the form. 2. The TL recorded Cryostat temperature twice in the calendar year 2023 2. The OM confirmed on 10/25/23 at 1:35 pm that the laboratory failed to record Room temperature and humidity and cryostat temperature</p>
<p><b>D5415</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of the Staining Station and interview with the Office Manager (OM) the laboratory failed to label the identity of all staining jars used for Histopathology testing from 10/04/19 to the date of the survey. The OM confirmed on 10/25/23 at 12:35 pm that all staining jars were not labeled.</p>
<p><b>D5601</b></p>	<p><b>HISTOPATHOLOGY</b> CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of Quality Control (QC) records and interview with the Office Manager (OM), the laboratory failed to document Hematoxylin and Eosin (H&amp;E) control slide reactions for Histopathology testing on the date of survey. The findings include: 1. The laboratory did not document H&amp;E stain QC reactions. 2. The laboratory read and reported approximately 60 patients annually,. 3. The OM confirmed on 10/25/23 at 1:30 pm that the laboratory did not document H&amp;E QC stain reactions.</p>