

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1067292	(X3) Date Survey Completed 04/30/2024
Name of Provider or Supplier Cosmetic Skin Surgery Center	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5217	<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 4/30/24 at 12:30 pm that the laboratory did not perform BA as mentioned above.</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> <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>

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 4/30/24 at 1:35 pm that the laboratory failed to record Room temperature and humidity and cryostat temperature

D5601

HISTOPATHOLOGY
CFR(s): 493.1273(a)(f)

(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.

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&E) control slide reactions for Histopathology testing for all dates testing was performed in the calendar year 2023. The findings include: 1. The laboratory did not document H&E stain QC reactions on the dates listed below. a. 2/24/23 b. 3/17/23 c. 4/21/23 d. 5/19/23 e. 6/9/23 f. 7/28/23 g. 12/8/23 2. The laboratory read and reported approximately 34 patient. 3. The OM confirmed on 4/30/24 at 1:30 pm that the laboratory did not document H&E QC stain reactions.