

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D1023017	<b>(X3) Date Survey Completed</b> 03/03/2022
<b>Name of Provider or Supplier</b> Skin & Laser Surgery Center Pc	<b>Street Address, City, State</b> 2200 Opitz Boulevard, Suite 100, Woodbridge, VA	
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>D0000</b>	An announced virtual CLIA recertification survey was conducted for Skin & Laser Surgery Center on March 3, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on January 31, 2022 and virtual record review conducted on March 1, 2022. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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 a review the laboratory's policies and procedures, peer review documentation, lack of documentation, and interviews, the laboratory failed to perform two (2) of four (4) annual Histopathology peer review from January 2020 until December 2021 (24 months). Findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "Test Comparison/Peer Review" which stated "Peer reviews are done yearly (at least two) to review slide interpretation with an independent laboratory. Document agreement or disagreement and corrective actions." 2. Review of the laboratory's verification of accuracy records from January 2020 to December 2021 revealed a lack of documentation of histopathology two times accuracy verification performance and evaluation for calendar year 2020. The inspector requested documentation of the two times annual verification of accuracy for histopathology for 2020. The laboratory provided no additional documentation for review. 3. In an exit interview with the Mohs Technician on March 3, 2022 at approximately 11:50 AM, the above findings were confirmed.</p>
<b>D5417</b>	<b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b>

CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's "Cryostat temperature and Staining Chemical log", "Log Sheet for Mohs Surgery" accession log and interview, the laboratory failed to ensure the Hematoxylin stain used for staining Mohs specimens was within manufacturer's expiration date while staining sixty-four (64) Mohs patient specimens from January 24, 2022 until March 1, 2022. Findings include: 1. A review of the laboratory's "Cryostat temperature and Staining Chemical Log" revealed a gallon of Mercedes hematoxylin stain (lot number 2001725 exp 01/21/2022) was in use from January 24, 2022 until date of the survey, March 3, 2022. There were no other lots of hematoxylin stain listed on the laboratory's "Cryostat temperature and Staining Chemical log" for January 2022, February 2022 and March 2022. 2. A review of the laboratory's "Log Sheet for Mohs Surgery" revealed 64 Mohs patient specimens were stained from January 24, 2022 until March 1, 2022 while utilizing the expired hematoxylin stain (lot number 20001725 exp date 01/21/2022). 3. In an exit interview with the Mohs Technician on March 3, 2022 at approximately 11:50 AM, the findings were confirmed.