

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0943829	(X3) Date Survey Completed 06/17/2025
Name of Provider or Supplier Dermatology Center, Pc	Street Address, City, State 3501 Lafayette Boulevard, Fredericksburg, VA	
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
D0000	An announced CLIA recertification survey was conducted at The Dermatology Center on June 17, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The specific deficiencies are as follows:
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 a review of the laboratory's policies and procedures, peer review records, and lack of documentation, the laboratory failed to follow their established policy for semi-annual proficiency testing (PT) peer reviews in calendar year 2024. The findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "Proficiency Testing-Mohs Micrographic Surgery Skin Specimens", with the statement, "Semi-annually, the tech or risk manager will send two cases containing the original slides, label it with the surgical case number, and send it for a microscopic examination by a Board-Certified Dermatopathologist." 2. Review of available PT peer review records for calendar year 2024 revealed PT peer review performed on 08/25/2024. No further documentation of 2024 PT peer review was observed. The surveyor requested to review additional PT peer review documentation for 2024. The laboratory provided no documentation for review. 3. In an exit interview with the Chief Operating Officer on June 17, 2025, at 11:45 AM, the above findings were confirmed. .</p>
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on a laboratory tour, review of the laboratory Quality Assurance (QA) manual, laboratory temperature logs, and an interview, the laboratory failed to follow their established policy to monitor temperatures for eight (8) days out of the seventeen months reviewed. Review timeframe included January 2024 through May 2025. The findings include: 1. During a laboratory tour on June 17, 2025 at 9:10 AM, the surveyor noted one Advantick QS12 in use for Mohs specimen processing. 2. Review of the laboratory's QA manual revealed an established policy for the MOHS tech to monitor and document the laboratory temperature and relative humidity daily. 3. Review of the laboratory's temperature logs for January 2024 through May 2025 revealed a lack of documentation of the laboratory temperature and relative humidity for the following days: 05/15/2024, 05/22/2024, 05/23/2024, 06/20/2024, 07/03/2024, 07/30/2024, 07/31/2024 and 10/09/2024. a total of 8 days. 4. In an exit interview with the Chief Operating Officer on June 17, 2025, at 11:45 AM, the above findings were confirmed.

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.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's policies and procedures, quality control (QC) records, patient logs, and interview, the laboratory failed to follow their established policy to document daily Hematoxylin and Eosin (H&E) stain acceptability for one (1) day with five (5) patient Mohs slides stained/processed/evaluated during the seventeen (17) months reviewed. Review timeframe January 2024 until the date of the survey on June 17, 2025. The findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "Quality Assurance for Routine Stains", with the following statements, "1. A control slide will be run each day the lab operates...The lab director will determine whether the stain is acceptable for the day. Each QC will be logged on the stain QC chart." 2. Review of the QC records from January 2024 through June 17, 2025 revealed a lack of H&E control slide documentation for 12/13 /2024. 3. Review of the laboratory's Mohs patient logs revealed 5 patient Mohs slides stained/ processed/evaluated on 12/13/2024. 4. In an exit interview with the Chief Operating Officer on June 17, 2025, at 11:45 AM, the above findings were confirmed.