

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0959143	(X3) Date Survey Completed 12/03/2024
Name of Provider or Supplier Peninsula Dermatology Skin Cancer Surgery Center	Street Address, City, State 1601 Commonwealth Ave, Williamsburg, 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 Peninsula Dermatology Skin Cancer Surgery Center (Williamsburg) on December 3, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
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 a lab tour, review of the laboratory Quality Assurance (QA) manual, laboratory temperature logs, and an interview, it was determined that the laboratory failed to monitor temperatures for seven (7) days out of the twenty three months reviewed. Review timeframe included January 2023 through November 2024. Findings include: 1. During a laboratory tour on 12/3/24 at approximately 1:15 pm, the inspector noted two Avantik-QS11 Cryostats (Serial numbers 56219 and 60277) and a slide warmer in-use. 2. Review of the laboratory's QA manual revealed an established policy for the MOHS tech to monitor and document laboratory temperatures daily. 3. Review of the temperature logs for January 2023 through November 2024 revealed no documentation that temperatures were recorded on the</p>

following days: 9/20/23, 9/22/23, 9/28/23, 11/3/23, 11/17/23, 6/21/24, 8/30/24, a total of 7 days. 4. An interview with the Lab Director and Clinical Assistant director on 12/3/24 at approximately 5 PM confirmed the above findings.

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 a review of procedures, quality control (QC) records, patient logs, and interview, the laboratory failed to document daily Hematoxylin and Eosin (H&E) stain acceptability for five (5) days with thirty six (36) patient Mohs slides stained/ processed during the twenty three months reviewed. Review timeframe January 2023 - November 2024. Findings include: 1. Review of the laboratory's Quality Control procedure revealed that a control slide is made and evaluated each day a frozen section is prepared. 2. Review of the QC records from January 2023 through November 2024 revealed no control slide documented for the following five dates: 2/8/23, 5/26/23, 10/27/24, 8/30/24, and 11/22/24. 3. Review of the patient logs revealed the following number of patient Mohs slides stained/ processed/evaluated on the five days with no QC documentation: 2/8/23 - 10 patients, 5/26/23 - 8 patients, 10/27/23 - 4 patients, 8/30/24 - 7 patients, and 11/22/24 - 7 patients. A total of 36 patients slides. 4. An interview with the Lab Director and Clinical Assistant director on 12/3/24 at approximately 5 PM confirmed the above findings.