

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D2245294	<b>(X3) Date Survey Completed</b>  04/22/2024
<b>Name of Provider or Supplier</b>  Warrenton Dermatology Skin Surgery Center	<b>Street Address, City, State</b>  28 Blackwell Park Lane Suite 102, Warrenton, 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 CLIA Recertification survey was conducted at the Warrenton Dermatology Skin Surgery Center on 04/22/24 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
<b>D3011</b>	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on an observation of the laboratory, review of manufacturer's Safety Data Sheet (SDS), and interview, the laboratory failed to follow manufacturer's instructions for disposing the UltraClear Xylene Substitute reagent used to fix Mohs histological samples to examination glass slides at the date of survey on 04/22/2024. Findings include: 1. During an interview with testing personnel (TP) #1 and observation of the laboratory testing area on 04/22/2024 at approximately 12:15 PM, it was revealed that the laboratory utilizes the UltraClear Xylene Substitute reagent to fix Mohs histological samples to examination glass slides for microscopic review. In the same interview, the inspector asked TP #1 how they dispose of the xylene substitute reagent. They stated, "we pour the reagent down the sink." 2. Review of the SDS for the Xylene substitute reagent revealed the following instructions, "Section 6 Environmental Precautions- Prevent entry to sewers and public waters, Avoid release to the environment. Collect spillage." "Section 13: Disposal Considerations, Waste Disposal Recommendations- Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations. Ecological-</p>

Waste Materials- Avoid release to the environment. This material is hazardous to the aquatic environment. Keep out of sewers and waterways." 3. An exit interview with the laboratory director and TP #1 on 04/22/2024 at 13:00 confirmed the findings.

**D5217**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:

Based on the review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), lack of documentation and an interview, the laboratory failed to verify the accuracy of the potassium hydroxide (KOH) microscopic examinations twice annually in the calendar year 2023. Findings include: 1. Review of the CMS 116 application and interview with testing personnel #1 on 04/22/24 at 11:30 AM revealed the laboratory performs KOH microscopic examinations. 2. The inspector requested to review documentation of the verification of accuracy twice annually for the KOH microscopic examinations in the calendar year 2023. The documentation was not available for review. 3. An exit interview with the laboratory director and TP #1 on 04/22/2024 at 13:00 confirmed the findings.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on the review five randomly selected patient histology slides and Mohs surgical maps, lack of documentation and an interview, the laboratory failed to ensure the laboratory's name and address was included on three of the five selected Mohs surgical maps at the date of the survey on 04/22/24. Findings include: 1. The surveyor randomly selected five patients for documentation comparison of the histology slides to the Mohs surgical maps that are used as part of the patient final test record and treatment. An interview with testing personnel #1 on 04/22/24 at 12:00 revealed the laboratory provides the Mohs surgical maps as part of the a patient's final test report. 2. The surveyor observed that three of the five Mohs surgical maps lacked documentation of the laboratory's name and address (case numbers M-23-131, M-23-288 and M-24-030). 3. An exit interview with the laboratory director and TP #1 on 04/22/2024 at 13:00 confirmed the findings.