

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2109355	(X3) Date Survey Completed 01/29/2024
Name of Provider or Supplier Hendersonville Dermatology, PLLC	Street Address, City, State 15 Market Center Drive, Suite A, Flat Rock, NC	
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 upon review of the laboratory's policies and review of 2022 and 2023 records of accuracy, the laboratory failed to verify the accuracy of dermatopathology slides read in the laboratory, at least twice annually, in 2023. Findings: Review of the laboratory's "Proficiency Testing" policy revealed "Semi-annually, the tech or Risk Manager will send two cases containing the original slides, label it with only the surgical case number, and send it out for a microscopic examination by a Board Certified Dermatopathologist." Review of 2022 and 2023 records to verify the accuracy of dermatopathology slides read in the laboratory revealed the performance of these activities in the following months: June 2022 September 2022 August 2023</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by:</p>

Based upon review of the laboratory's policies and review of 2022 and 2023 maintenance logs, the laboratory failed to perform and document maintenance activities established in its own maintenance protocol. Findings: Review of the laboratory's "Quality Control Policies and Documentation" policy revealed the following in section "Cryostat:"... "7. Air filter is cleaned as part of the maintenance every 6 months".... "9. The fly wheel and moving components on the cryostat are oiled, as recommended by the manufacturer, daily or when in use"... Review of the laboratory's "Stain Maintenance Auto-Stainer" policy revealed ..."7. The hematoxylin and eosin are changed as needed during the week, but fresh is always set up at the new workweek." Review of 2022 and 2023 maintenance logs revealed the following:

1. There was no documentation of the cryostat air filter being cleaned every 6 months.
2. There was no documentation of the moving components on the cryostat being oiled.
3. Review of the laboratory's Stain Maintenance logs revealed fresh hematoxylin and eosin stain reagents are not set up each new workweek.