

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0870688	(X3) Date Survey Completed 12/05/2023
Name of Provider or Supplier Carolina Mountain Dermatology, Pa	Street Address, City, State 78 Long Shoals Road, Arden, 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
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: Based upon review of 2022 and 2023 "Daily H&E (hematoxylin and eosin) Solution Maintenance" logs and interview with TP (testing personnel) #1 on 12/5/23, the laboratory failed to document when weekly and quarterly maintenance was performed on the Linstainer automated stainer. Findings: Review of the 2022 and 2023 "Daily H&E Solution Maintenance" logs revealed a one-page log for each calendar year. Daily, weekly and quarterly maintenance is required for this equipment. The log sheet listed initials by each day the laboratory was operational. This documentation did not specify which specific maintenance task was performed on the date initialed by testing personnel. In interview at approximately 12:15 p.m., TP #1 stated the maintenance requirements are printed at the bottom of the log; however, the laboratory does not document which specific maintenance task is performed on the date initialed by testing personnel. </p>