

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0995999	(X3) Date Survey Completed 04/10/2025
Name of Provider or Supplier Apex Pediatrics	Street Address, City, State 1021 W Williams Street Suite 105, Apex, 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
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) 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 do the following:</p> <p>This STANDARD is not met as evidenced by: Based on review of operator's manual, review of 2023, 2024 and 2025 maintenance logs, and interview with testing personnel (TP) #5, 04/10/25, the laboratory failed to perform semi-annual maintenance on the Cell-Dyn Emerald hematology analyzer since time of last survey, 02/23/23, a period of approximately 25 months. Findings: Review of operator's manual for the Cell-Dyn Emerald hematology analyzer revealed under Section 9 "Semi-Annual Maintenance...Lubricating the Pistons....For optimal operation, the Syringe Pistons should be lubricated every six months as described below.". Review of 2023, 2024, and 2025 maintenance logs for the Cell-Dyn Emerald hematology analyzer revealed no documentation of the performance of the semi-annual maintenance. Interview with TP #5 at approximately 11:00 a.m. confirmed the laboratory had not performed the semi-annual maintenance. TP #5 stated the service representative told them it was not required.</p>