

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2097970	(X3) Date Survey Completed 08/24/2023
Name of Provider or Supplier Hematology Oncology Care Of Northern Virginia	Street Address, City, State 3022 Williams Drive - Suite 100, Fairfax, 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 Hematology Oncology Care of Northern Virginia, PC (Fairfax) on August 24, 2023 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:
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: A. Based on a review of the manufacturer's instructions for use, hematology analyzer maintenance records, lack of documentation, and an interview, the laboratory failed to document performance of the required annual instrument preventative maintenance in calendar year 2022 (record review timeframe from February 2022 until August 24, 2023). The findings include: 1. Review of the Beckman Coulter DxH 520 Instructions for Use revealed manufacturer's instructions to "Yearly-Lubricate the pistons." 2. Review of the laboratory's DxH 520 hematology analyzer's maintenance logs, from February 2022 to the date of the inspection on August 24, 2023, revealed a lack of documentation of the performance of the required annual maintenance outlined above for calendar year 2022. The inspector requested to review documentation of the piston syringe maintenance in calendar year 2022. The laboratory provided no documentation to review. 3. In an exit interview with the TC on August 24, 2023, at approximately 12:00 PM, the above findings were confirmed. B. Based on a review of the manufacturer's instructions for use, hematology analyzer maintenance records, lack of documentation, and an interview, the laboratory failed to document performance of the required monthly instrument preventative maintenance for seven</p>

(7) of nineteen (19) months reviewed (record review timeframe from February 2022 until August 24, 2023). The findings include: 1. Review of the Beckman Coulter DxH 520 Instructions for Use revealed manufacturer's instructions to "Monthly or every 1,000 cycles-Perform Bleach Cycle" and "Monthly-Clean the WBC Bath Filter." 2. Review of the laboratory's DxH 520 hematology analyzer's maintenance logs from February 2022 to the date of the inspection on August 24, 2023 revealed a lack of documentation of the performance of the required monthly maintenance outlined above for the following months: September 2022, October 2022, December 2022, January 2023, February 2023, March 2023 and April 2023. A total of 7 months. The inspector requested to review documentation of the monthly maintenance for the above listed months. The laboratory provided no documentation to review. 3. In an exit interview with the TC on August 24, 2023, at approximately 12:00 PM, the above findings were confirmed.