Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2108687	08/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Hematology Oncology Care Of Northern Virginia, Pc	1900 Opitz Boulevard Suites E & F, Woodbridge, 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 (Woodbridge) on August 22, 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 and include the Condition under 42 CFR part 493 CLIA Regulation: D2000-42 CFR. 493.801 Enrollment and Testing of Samples.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to enroll in a PT program for White Blood Cell Count (WBC), Red Blood Cell Count (RBC), Hemoglobin (HGB), Hematocrit (HCT), Platelet Count (PLT), and Cell Identification (Cell ID) from January 2023 until March 2023. Findings include: 1. A review of the laboratory's PT records revealed a lack of documentation of PT testing enrollment for WBC, RBC, HGB, HCT, PLT, and Cell ID from January 2023 until March 2023. The surveyor requested to review documentation of the laboratory's enrollment in a PT program from January 2023 until March 2023. The laboratory provided proof of PT enrollment dated March 27,

	2023. The laboratory provided no proof of PT enrollment from January 2023 until March 27, 2023 for review. 2. During an interview with the Technical Consultant (TC) on August 22, 2023, at approximately 9:45 AM, the TC stated they realized the lab was not enrolled after their other location received the PT samples and they didn't receive Event 1's samples. Once they realized they were not enrolled, they immediately enrolled in PT but were too late to get samples submitted for Event 1. They have participated in Event 2 and received a score of 100% for WBC, RBC, HGB, HCT, PLT, and Cell ID. 3. In an exit interview with the TC on August 22, 2023, at approximately 12:00 PM, the findings were confirmed.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. 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 22, 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 22, 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. In an interview with the Technical Consultant (TC) on August 22, 2023, at approximately 11:00 AM, the TC stated they realized the October 2022 maintenance log was missing when they were completing their monthly review. They were unable to locate the log. 3. In an exit interview with the TC on August 22, 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 six (6) of nineteen (19) months reviewed (record review timeframe from February 2022 until August 22, 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 22, 2023 revealed a lack of documentation of the performance of the required monthly maintenance outlined above for the following months: October 2022, November 2022, December 2022, February 2023, March 2023 and April 2023. A total of 6 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 22, 2023, at approximately 12:00 PM, the above findings were confirmed. C. Based on a review of the manufacturer's instructions for use, hematology analyzer maintenance records, hematology quality control records, lack of documentation, and an interview, the laboratory failed to document performance of

	the required daily instrument preventative maintenance for eight (8) of 8 days of patient testing in October 2022 (record review timeframe from February 2022 until August 22, 2023). The findings include: 1. Review of the Beckman Coulter DxH 520 Instructions for Use revealed manufacturer's instructions to "Daily-Perform Shutdown, Perform Daily Checks-Verify that all results are within limits, Clean the instrument, Process Controls." 2. Review of the laboratory's DxH 520 hematology analyzer's quality control records and maintenance logs from February 2022 to the date of the inspection on August 22, 2023, revealed a lack of documentation of the performance of the required daily maintenance outlined above for the following patient testing days: 10/4/2022, 10/7/2022, 10/11/2022, 10/14/2022, 10/18/2022, 10/21 /2022, 10/25/2022 and 10/28/2022. A total of 8 days. The inspector requested to review documentation of the daily maintenance for the above listed days. The laboratory provided no documentation to review. In an interview with the Technical Consultant (TC) on August 22, 2023, at approximately 11:00 AM, the TC stated they realized the month of October 2022 maintenance log was missing when they were completing their monthly review. They were unable to locate the log. 3. Review of the laboratory's quality control records for the DxH 520 revealed three levels of QC were performed on 10/4/2022, 10/7/2022. 10/11/2022, 10/14/2022, 10/18/2022, 10/21 /2022, 10/25/2022 and 10/28/2022. 4. In an exit interview with the TC on August 22, 2023, at approximately 12:00 PM, the above findings were confirmed.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, Hematology instrument calibration records, lack of documentation, and an interview, the laboratory failed to perform Complete Blood Count (CBC) calibration procedures for patient testing on the Beckman Coulter DxH 520 Hematology analyzer every six months, according to their procedure, during calendar year 2022. The findings include: 1. Review of the laboratory's procedure manual revealed a Hematology Calibration policy that outlined to calibrate CBC testing at a frequency of every six months. The policy stated: "Calibration of all hematology analytes on the Beckman Coulter DxH 520 Instrument is performed at set up of the instrument, and at a frequency recommended by the manufacturer, which is every six (6) months, for individual testing and analyzer systems using the appropriate number and type of calibrators." 2. Review of the laboratory's 2022 Coulter DxH 520 calibration documentation revealed one calibration record dated 06/02/2022. 3. The inspector requested to review additional calibration records for the DxH 520 analyzer in calendar year 2022. The laboratory provided no additional 2022 calibration documentation for review. The laboratory provided 2023 DxH 520 calibration documentation dated 01/11/2023 and 07/24/2023

	4. In an exit interview with the Technical Consultant (TC) on August 22, 2023, at approximately 12:00 PM, the findings were confirmed.