Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2108687	03/24/2026
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 on March 24, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on a tour of the laboratory, review of the laboratory's policy and procedure manual, lack of documentation and interview, the laboratory failed to establish a policy for the monitoring of the laboratory's eyewash station from April 2024 until the date of the survey on March 24, 2026. The findings include: 1. During a tour of the laboratory with the Technical Consultant (TC) on February 24, 2026, at 10:00 AM, the surveyor noted an eye wash station containing a bottle of "Honeywell eyesaline" eyewash solution (lot number F23012-21) with an expiration date of 12/2025. The TC stated, "We will order a new bottle." 2. Review of the laboratory's policy and procedure manual revealed a lack of a policy that defined the criteria for the monitoring of the "Honeywell eyesaline" eyewash solution. The surveyor requested to review a policy for the monitoring of the eyewash solution. The TC stated they did not have a policy for monitoring the eyewash solution. 3. In an exit interview with the Technical Consultant on March 24, 2026, at 11:30 AM, the findings were confirmed.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)

	(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, proficiency testing records, lack of documentation and an interview, the laboratory failed to follow their established policy and retain instrument printouts for proficiency testing (PT) samples for two (2) of five (5) samples analyzed for American Proficiency Institute (API) Hematology/Coagulation 2024 Event 1. The findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT evaluation records revealed the laboratory submitted results for 2024 Hematology/Coagulation Event samples DxH-01, 02, 03, 04 and 05. Further review of the PT records for API 2024 Hematology/Coagulation Event 1 revealed instrument printouts for samples DxH-01, DxH-03 and DxH-5. The surveyor requested the instrument printouts for the proficiency testing samples DxH-02 and DxH-04. The laboratory provided no documentation for review. 2. Review of the laboratory's policy and procedure manual revealed a policy, "Section 7-Proficiency Testing Policy and Procedures", with the following statements, "Record Retention...2. Also keep a copy of all printouts from instruments with all your survey answers." 3. In an exit interview with the Technical Consultant on March 24, 2026 at 11:30 AM, the findings were confirmed.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, lack of documentation, and an interview, the laboratory failed to monitor daily room temperature (RT), relative humidity percent (RH%), and refrigerator temperatures to ensure manufacturer's requirements were followed for the DxH 520 hematology analyzer and quality control (QC) materials utilized for Complete Blood Count (CBC) testing for five (5) of eight (8) patient testing days in January 2026. Record review was from March 2024 until the date of the survey on March 24, 2026. The findings include: 1. Review of the laboratory's policies an procedures revealed a policy that outlined daily monitoring of environmental conditions that included laboratory room temperature/ humidity ranges to be within the following guidelines: Room Temperature: 64-90 F (18-32 C). Humidity: Maximum 80%, 2. Review of the Beckman Coulter DxH 500 Series Procedure revealed the following statement, "Beckman Coulter controls are to be stored refrigerated at 2-8 degrees Celcius." 3. Review of the available laboratory records from March 2024 to March 24, 2026, revealed no record of laboratory room temperature/humidity or refrigerator temperature monitoring for the following 5 patient testing days in January 2026: 01/06

	/2026, 01/20/2026, 01/23/2026, 01/27/2026 and 01/30/2026. The surveyor requested to review documentation of the monitoring of the RT, RH% and refrigerator temperature. The laboratory provided no documentation for review. 4. In an exit interview with the Technical Consultant on March 24, 2026, at 11:30 AM, the findings were confirmed.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on a laboratory tour, a review of the laboratory's policy and procedure manual, Beckman Coulter DXH 500 Series Control Package Insert, and interview, the laboratory failed to follow their established policy and label three (3) of three (3) DxH 500 hematology control (QC) vials with the open dates and new expiration dates. The findings include: 1. During a laboratory tour at approximately 10:10 AM on March 24, 2026, the surveyor noted three (3) of three (3) vials of Beckman Coulter DxH QC in a tray labled, "Change controls every 2 weeks." stored in the laboratory's refrigerator. The open vials were: Abnormal Low (lot number 362618111 expiration date 04/26/2026); Normal (lot number 362618112 expiration date 04/26/2026); Abnormal High (lot number 362618111 expiration date 04/26/2026). The surveyor inquired if the vials were in use for the DxH 520 Hematology analyzer. The technical consultant confirmed the vials were in use for the DxH 520. The surveyor noted the 3 vials did not have the open date or new expiration date on the vials. The surveyor asked when the testing personnel opened the control vials. The technical consultant stated, "I am not sure. They have been told to label the vials." 2. Review of the Beckman Coulter Package Insert revealed stability and storage instructions, "16* Open Vial days, *Assumes that the Instructions for Use section of the Consumable IFU/Setting Sheet is performed a maximum of 16 times within 16 days." 3. Review of the laboratory's policy and procedure manual revealed a policy/procedure, "Part 1: Quality Control Policy and Procedures", with the following statements, "QC Material Expiration...2. Once opened, QC material is stable for 14 calendar days. Testing personnel will write the open date (OD) and new expiration date (ED) on the vial when opened and their initials to indicate they are observing the recalculation of the expiration date of the opened QC material...4. Testing personnel MUST write this information on each vial of QC material when it is first opened from the box." 4. In an exit interview with the Technical Consultant on March 24, 2026, at 11:30 AM, the findings were confirmed.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by:

	Based on a review of the laboratory's policy and procedure manual, maintenance checklists, and interview, the laboratory failed to perform/document daily maintenance protocols for the Beckman Coulter DxH 520 Hematology analyzer for nineteen (19) of twenty-four (24) patient testing days from January 2026 until the date of the survey on March 24, 2026. Review timeframe March 2024 until the date of the survey on March 24, 2026. The findings include: 1. Review of the laboratory's policy and procedure manual revealed a policy, "3. Instrument Maintenance", with the following statements, "a. Equipment maintenance and function checks are performed according to manufacturer's recommendations to ensure optimal instrument performance. b. Maintenance may be required as follows (All MUST be documented on the Instrument Maintenance Log sheet with accompanying printouts, if necessary) ..." 2. Review of the DxH 520 Maintenance checklist revealed the listing of daily maintenance tasks, "Perform Shutdown, Perform Daily Checks-Verify that all results are within limits, Clean the Instrument, Process Controls." 3. Review of the DxH 520 Maintenance checklist from March 2024 through the date of the survey on March 24, 2026 revealed a lack of daily maintenance documented on: January 2026: 01/16/2026, 01/20/2026, 01/23/2026, 01/27/2026, 01/30/2026 February 2026: 02/03/2026, 02/06 /2026, 02/10/2026, 02/13/2026, 02/17/2026, 02/20/2026, 02/24/2026, 02/27/2026 March 2026: 03/03/2026, 03/06/2026, 03/10/2026, 03/13/2026, 03/17/2026, 03/20 /2026. A total of 19 days. 4. In an exit interview with the Technical Consultant on March 24, 2026, at 11:30 AM, the findings were confirmed.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, quality control (QC) records, lack of documentation and interview, the laboratory failed to follow their established policy to confirm recovered values are within the table of expected results or establish new laboratory means before the current QC lot is discontinued for twenty-four (24) of 24 months. Record review was from March 2024 until March 2026. The findings include: 1. Review of the laboratory's policy and procedure manual revealed a policy, "Quality Control Policy and Procedures", with the statement, "All new QC lot numbers of materials will be overlapped at least one time with the previous (old) lot number to ensure the stated values for the new lot number can be obtained before the existing lot number is discontinued." 2. Review of the manufacturer's instructions for the DxH 500 Series control revealed the following instructions, "Assay values on a new lot of control should be confirmed before the new lot is put into routine use." 3. Review of quality control records for the Coulter DxH 520 Hematology analyzer from March 2024 until March 2026 revealed a lack of documentation of new lot numbers of DxH 500 series QC being confirmed prior to current lot numbers of quality control being discontinued. 4. In an exit interview with

	the Technical Consultant on March 24, 2026, at 11:30 AM, the findings were confirmed.