Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1080580	07/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Northern Virginia Hematology Oncology Associates	2079 Daniel Stuart Square, 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 Northern Virginia Hematology Oncology Associates on July 16-17, 2025 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:
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 review of the laboratory's policies and procedures, Quality Assurance records, lack of documentation and interview, the laboratory failed to follow their established policy to perform "safety audits" annually in calendar year 2024 and 2025. Review timeframe August 2023 until July 2025. The findings include: 1. Review of the laboratory's Quality Assurance (QA) Policy revealed a "Quality Assurance Monitoring Schedule" with the statement "January QC and maintenance/action logs review. Calibration review if needed. Transcription audits. Safety/Infection Control QA Audit. Proficiency Testing Audit." 2. Review of the laboratory's QA records revealed a lack of documentation of the Safety/Infection Control QA Audit for calendar year 2024 and 2025. The surveyor requested to review documentation of the annual audits. The laboratory provided no documentation for review. 3. In an exit interview with the Technical Consultant, primary testing personnel and Office Manager on July 17, 2025 at 11:45 AM, the findings were confirmed.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)

	(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on a review of daily Hematology quality control (QC) records, patient test records, lack of documentation, policies, manufacturer's user guide, and interview, the laboratory failed to perform daily Hematology QC procedures per their policy on one (1) day of seventeen (17) days in March 2024 and 1 of eighteen (18) days in April 2024 while reporting forty (40) Complete Blood Count (CBC) results. The findings include: 1. Review of the daily Sysmex XN 430 hematology QC records and patient CBC test logs from August 2023 to the date of the inspection, July 17, 2025, revealed the following two dates lacked documentation of QC procedures: 03/12/2024 - 20 patients reported; 04/09/2024 - 20 patients reported; A total of 40 patient CBC results were reported without QC verification. The surveyor requested to review QC results for the dates listed above. The laboratory provided no documentation for review. 2. Review of the laboratory's policies revealed a "Quality Control Policy and Guidelines" policy with the statement, "General Guidelines: 1. A minimum of 2 levels of QC will be run each day of testing for every non-waived procedure in the laboratory." 3. Review of the online Sysmex XN 430 User Guide revealed instructions in Section 2, "Quality control is performed in order to monitor an instrument's performance over time. XN-L Check tri level is the quality control material used to monitor the performance of the XN analyzer each day of operation. Quality control should be run according to licensing agency regulations." 4. In an exit interview with the Technical Consultant, primary testing personnel and Office Manager on July 17, 2025 at 11:45 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 policies and procedures, quality control (QC) records, and interviews, the laboratory failed to follow their established policy to review Chemistry, Endocrinology and Hematology quality control statistics monthly during the twenty-three (23) months reviewed. Review timeframe: August 2023 through June 2025. The findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "Quality Control Policy and Guidelines", with the statement "All QC results will be reviewed by the Technical Consultant or Laboratory Director on a monthly basis. This review will be documented by the completions of the QA Tracking sheet for Quality Control." 2. Review of the QA tracking sheet revealed documentation of QC review by the Technical Consultant (TC) quarterly for October 2023, January 2024, April 2024, July 2024, October 2024, January 2025,

	April 2025 and July 2025. 3. In an interview on July 16, 2025 at 11:00 AM, the TC stated they review QC results and reports quarterly. 4. In an exit interview with the Technical Consultant, primary testing personnel and Office Manager on July 17, 2025 at 11:45 AM, the findings were confirmed.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: A. Based on a review of daily Hematology quality control (QC) records, patient test records, lack of documentation, policies, manufacturer's user guide, and interview, the laboratory director (LD) failed to ensure the policy for the performance of daily Hematology QC procedures was followed. Cross Reference D5447. B. Based on a review of the laboratory's policies and procedures, monthly quality control (QC) records, lack of documentation and interviews, the laboratory director (LD) failed to ensure the established quality assessment (QA) policy for monthly review of Chemistry, Endocrinology and Hematology QC and Levey Jennings (LJ) charts was followed. Cross Reference D5469. C. Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form, laboratory personnel files, laboratory's policies and procedures, lack of documentation, and an interview, the LD failed to ensure the laboratory followed their established policy to document hematology semi-annual competency assessments for new testing personnel. Cross Reference D6053.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory policies and procedures, personnel records, lack of documentation, and interview, the technical consultant (TC) failed to follow the laboratory's established policy to perform semi-annual competency assessments for one (1) of two (2) new laboratory testing personnel (TP). The findings include: 1. Review of the CMS 209 form revealed that the laboratory director (LD) identified four TP responsible for hematology testing. 2. A review of personnel records revealed TP# 1 and #2 were identified as new TP since the previous inspection in August 2023 (See Personnel Code Sheet). Further review revealed the 2 new TP's initial hematology training and semi-annual competency as: TP #1 - training February 2024, semi-annual competency documentation dated 7/2024; TP #2 - training May 2023, no semi-annual competency documentation. The surveyor requested to view semi-annual competency assessment records for TP #2 documented in calendar year 2023. The laboratory provided no documentation for review. 3. Review of the laboratory's policies and procedures revealed a policy, "Section 2-Staff

	Training & Competency Testing, II. Competency Testing a. Will be performed by the technical consultant for each newly hired testing individual after successful completion of initial training for each test/instrument/test system, at 6 months of independent work and annually thereafter." 4. In an exit interview with the TC, primary testing personnel and Office Manager on July 17, 2025 at 11:45 AM, the findings were confirmed.