Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1080580	08/23/2023
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, PC on August 23, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 C.F.R. part 493 CLIA Regulations. Specific deficiencies cited are as follows and include the Conditions under 42 CFR part 493 CLIA Regulation: D5400-42 CFR. 493.1250 Condition: Analytic Systems; and D6000-42 CFR. 493.1403 Condition: Moderate Complexity Laboratory Director.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of the laboratory's policies and procedures, 2021 plan of correction (dated October 1, 2021), manufacturer's operators guide, package inserts, instrument calibration verification records, quality control (QC) documents, quality assessment (QA) documents, lack of documentation and interviews, the laboratory failed to: 1. Follow their established policy for the performance of instrument maintenance (see D5429). REPEAT DEFICIENCY. 2. Follow their established policy for performing calibration verification procedures every six months for analytes assayed on the TOSOH A1A 900 and Medica EasyRA (see D5439 A & B). REPEAT DEFICIENCY. 3. Verify new lot numbers of QC material used to monitor the accuracy of analytes on

	the TOSOH A1A 900 and Medica EasyRA (see D5469 A & B). REPEAT DEFICIENCY. 4. Identify and address analytic issues within the specialty of chemistry (see D5791). REPEAT DEFICIENCY.
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: **REPEAT DEFICIENCY** Based on the review of the laboratory's policies and procedures, operator's guides, instrument maintenance logs, 2021 plan of correction (dated October 1, 2021), lack of documentation, and interviews, the laboratory failed to follow their 2021 plan of correction and established policy to perform and document TOSOH A1A-900 quarterly maintenance for three (3) of six (6) quarters from January 2022 until the date of the survey on August 23, 2023. The findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "3. Instrument Maintenance", which stated "a. Equipment maintenance and function checks are performed according to manufacturer's recommendations to ensure optimal instrument performance... (All MUST be documented in the Instrument Maintenance Log with accompanying printouts if necessary)." 2. Review of the TOSOH A1A-900 operator's guide and maintenance schedule revealed the following maintenance procedures to be performed quarterly, "Clean instrument surfaces after any spills, Clean diluent/wash reservoirs with 1:100 dilution of Clorox, Clean diluent/wash tubing with 1:100 dilution of Clorox, Rinse reservoirs with Reagent Grade Type 1 water." 3. Review of the "TOSOH A1A-900 Maintenance Schedule" revealed documentation of the performance of the quarterly maintenance procedures performed on 1/26/2022 (2022 Quarter 1), 7/13/2022 (2022 Quarter 2), and 9/17/2022 (2022 Quarter 3). No further documentation of quarterly maintenance was noted. The surveyor requested to review documentation of the TOSOH quarterly maintenance for 2022 Quarter 4, 2023 Quarter 1 and 2023 Quarter 2. A total of 3 quarters. The laboratory provided no documentation to review. 4. Review of the laboratory's plan of correction (dated October 1, 2021) revealed the following statement, "The newly hired technical consultant will monitor maintenance activities more closely to ensure testing personnel follow through on documenting when they are done...Technical consult will monitor monthly through use of the revised QA TRACKING SHEET: MAINTENANCE ACTIVITIES." 5. In an exit interview with the Technical Consultant and testing personnel on August 23, 2023, at approximately 2:00 PM, the above findings were confirmed.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit

of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
REPEAT DEFICIENCY A. Based on a review of the laboratory's policy and procedure manual, manufacturer's package inserts, TOSOH A1A 900 calibration verification records, 2021 plan of correction (dated October 1, 2021), lack of documentation and interviews, the laboratory failed to follow their 2021 plan of correction and established policy to perform TOSOH A1A-900 calibration verification studies every 6 months from 9/2021 until the date of the survey on August 23, 2023. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a procedure, "Immnochemistry Testing using the TOSOH A1A 900", with the statement "Calibration Verification is required every 6 months for PSA and Ferritin." 2. Review of manufacturer's package inserts for the analytes performed on the TOSOH A1A 900 revealed the following analytes with fewer than 3 calibrators: Carcino-embryonic Antigen (CEA), Prostatic Specific Antigen (PSA), and Ferritin. 3. Review of the laboratory's TOSOH A1A 900 analyzer verification records from September 2021 until the date of the survey on August 23, 2023 revealed the verification studies for CEA, Ferritin and PSA were performed on the following dates: 9/17/2021, 3/16/2022 and 12/14/2023. The surveyor requested to review the documentation of the every 6 month calibration verifications for CEA, PSA and Ferritin from September 2021 until the date of the survey on August 23, 2023. The laboratory provided no further documentation for review. 4. Review of the laboratory's 2021 Plan of Correction on Form CMS-2567 (dated 10/1/202) and supporting documentation revealed the laboratory completed calibration verification of above listed analytes on 9/17/2021 and "Calibration will be performed every 6 months for CEA, PSA and Ferritin...The Technical Consultant will monitor thoroughly newly revised QA TRACKING SHEET: CALIBRATION VERIFICATION REVIEW." 5. In an exit interview with the Technical Consultant and testing personnel on August 23, 2023, at approximately 2:00 PM, the above findings were confirmed. B. Based on a review of the laboratory's policy and procedure manual, manufacturer's package inserts, Medica EasyRA calibration verification records, 2021 plan of correction (dated October 1, 2021), lack of documentation and interviews, the laboratory failed to follow their 2021 plan of correction and established policy to perform Medica EasyRA calibration verification studies every 6 months from September 2021 until the date of the survey on August 23, 2023. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a procedure, "General Chemistry Resting/EasyRA Analyzer", with a statement "Calibration Verification is required every 6 months on all analytes tested on the EasyRA analyzer." 2. Review of the laboratory's EasyRA analyzer calibration verification records from September 2021 until the date of the survey on August 23, 2023 revealed the verification studies were performed as listed below: 09/20/2021-

	BUN, Calcium, Glucose, Magnesium, and Creatinine. 09/27/2021-Sodium, Potassium, Chloride, Iron, Carbon Dioxide, Alkaline Phosphotase, Alanine Transaminase (ALT), Aspartate Aminotransferase (AST), Lactate Dehydrogenase (LDH), Total Protein, Albumin, Total Bilirubin and Total Iron Binding Capacity (TIBC). 03/14/2022-Sodium, Potassium, Chloride, Iron, Carbon Dioxide, Alkaline Phosphotase, Alanine Transaminase (ALT), Aspartate Aminotransferase (AST), Lactate Dehydrogenase (LDH), Total Protein, Albumin, and Total Bilirubin. 03/15 /2022-BUN, Calcium, Glucose, Magnesium, and Creatinine. 03/28/2022-Total Iron Binding Capacity (TIBC). 11/07/2022-Glucose, Magnesium, and Creatinine. 11/14 /2022-Iron, Carbon Dioxide, and Total Bilirubin. 12/14/2022-BUN, Calcium, Sodium, Potassium, Chloride, Total Protein, and Albumin. 05/03/2023-Sodium, Potassium, Chloride, Carbon Dioxide, Total Protein, Albumin, and Total Bilirubin. The surveyor requested to review the documentation of the every 6 month calibration verification for the above listed analytes from 9/2021 until the date of the survey on August 23, 2023. The laboratory provided no additional documentation to review. 3. Review of the laboratory's 2021 Plan of Correction on Form CMS-2567 (dated 10/01/2021) and supporting documentation revealed the laboratory completed calibration of above listed analytes on 09/20/2021 and 09/27/2023 and "Calibration will be performed every 6 months for all analytes on the EasyRA ...The Technical Consultant will monitor thoroughly newly revised QA TRACKING SHEET: CALIBRATION VERIFICATION REVIEW checked every 6 months." 4. In an exit interview with the Technical Consultant and testing personnel on August 23, 2023, at approximately 2: 00 PM, the above findings were confirmed.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (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. (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. (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: **REPEAT DEFICIENCY** A. Based on a review of the laboratory's policies and procedures, quality control (QC) records, 2021 plan of correction (dated October 1, 2021), lack of documentation, and interviews, the laboratory failed to follow their plan of correction and established policy to perform evaluations to verify six (6) of nine (9) new lot numbers of BioRad Lyphochek Immunoassay Plus Control QC materials used for monitoring the accuracy of patient Vitamin D, Carcino Embryonic Antigen (CEA), Ferritin, Prostatic Specific Antigen (PSA) and Thyroid Stimulating Hormone (TSH) testing during the twenty-three (23) months reviewed. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a policy, "Quality Control Policy and Guidelines", which stated "General Guidelines-4. QC ranges provided by the manufacturer of the control materials will be used, but will be

evaluated after multiple runs to determine if the range is appropriate for the mean and SD obtained in this lab...7. All new lot numbers of QC material will be overlapped with existing lot numbers to ensure stated values for the new lot number can be obtained before the existing lot number is discontinued. 8. Unassayed QC material will be overlapped with excising lot numbers until an minimum of 20 data points have been measured, and means and SDs will be calculated based on the 20 (or more) data points." 2. Review of the laboratory's QC records from September 2021 to August 23, 2023 revealed the following 9 BioRad Lyphochek Immunoassay Plus Control lot numbers were utilized to monitor patient Vitamin D, CEA, Ferritin PSA and TSH test results analyzed on the laboratory's TOSOH A1A 900 instrument: 40381, 40382, 40383, 40411, 40412, 40413, 40421, 40422, 40423. The surveyor requested to review documentation that each of the QC lot numbers listed above were confirmed (verified). The laboratory provided verification documentation for lot numbers: 40381, 40382, 40383. The laboratory provided no documentation of the verification of lot numbers: 40411, 40412, 40413, 40421, 40422, 40423 to review. 3. Review of the laboratory's plan of correction on Form CMS-2567 (dated October 1, 2021) revealed the following statement, "The TC (technical consultant) has revised The QA TRACKING SHEET: QC REVIEW to add monitors for lot-to-lot comparison performed." Review of the Quality Assessment Tracking sheets from 9/2021 to 8 /2023 revealed a lack of documentation of the performance of the lot-to-lot comparison of the TOSOH quality control materials listed above. The surveyor requested to review documentation of the lot-to-lot comparison. The laboratory provided no documentation for review. 4. In an exit interview with the Technical Consultant and testing personnel on August 23, 2023, at approximately 2:00 PM, the above findings were confirmed. B. Based on a review of the laboratory's policies and procedures, quality control (QC) records, 2021 plan of correction (dated October 1, 2021), lack of documentation, and interviews, the laboratory failed to follow their plan of correction and establish policy to perform evaluations to verify three (3) of five (5) new lot numbers of Medica EASYQC Chemistry QC materials used for monitoring the accuracy of patient Alanine Transaminase (ALT), Albumin (ALB), Alkaline Phosphotase (ALP), Aspartate Aminotransferase (AST), Total Bilirubin (TBIL), Calcium (Ca), Carbon Dioxide (CO2), Chloride (Cl), Creatinine (Creat), Glucose (Gluc), Iron (Fe), Lactate Dehydrogenase (LDH), Magnesium (Mg), Potassium (K), Sodium (Na), Total Protein (TP), and Blood Urea Nitrogen (BUN) testing during the twenty-three (23) months reviewed. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a policy, "Quality Control Policy and Guidelines", which stated "General Guidelines-4. QC ranges provided by the manufacturer of the control materials will be used, but will be evaluated after multiple runs to determine if the range is appropriate for the mean and SD obtained in this lab...7. All new lot numbers of QC material will be overlapped with existing lot numbers to ensure stated values for the new lot number can be obtained before the existing lot number is discontinued. 8. Unassayed QC material will be overlapped with existing lot numbers until an minimum of 20 data points have been measured, and means and SDs will be calculated based on the 20 (or more) data points." 2. Review of the laboratory's QC records September 2021 to August 2023 revealed the following 5 Medica EASYQC Chemistry QC lot numbers were utilized to monitor patient Alanine Transaminase (ALT), Albumin (ALB), Alkaline Phosphotase (ALP), Aspartate Aminotransferase (AST), Total Bilirubin (TBIL), Calcium (Ca), Chloride (Cl), Creatinine (Creat), Glucose (Gluc), Iron (Fe), Lactate Dehydrogenase (LDH), Magnesium (Mg), Potassium (K), Sodium (Na), Total Protein (TP), and Blood Urea Nitrogen (BUN) test results analyzed on the laboratory's Medica EasyRA instrument: 20266, 202067, 22209, 22210, and 22250. The surveyor requested to review documentation that each of the QC lot numbers outlined above were confirmed

	(verified). The laboratory provided documentation of the verification of lot numbers 20266 and 20267. The laboratory provided no documentation of the verification of lot numbers 22209, 22210, 22250 to review. A total of 3 lot numbers. 3. Review of the laboratory's plan of correction on Form CMS-2567(dated October 1, 2021) revealed the following statement, "The TC (technical consultant) has revised The QA TRACKING SHEET: QC REVIEW to add monitors for lot-to-lot comparison performed." Review of the Quality Assessment Tracking sheets from 9/2021 to 8 /2023 revealed a lack of documentation of the performance of the lot-to-lot comparison of the EasyRA quality control materials listed above. The surveyor requested to review documentation of the lot-to-lot comparison. The laboratory provided no documentation for review. 4. In an exit interview with the Technical Consultant and testing personnel on August 23, 2023, at approximately 2:00 PM, the above findings were confirmed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: **REPEAT DEFICIENCY** Based on the review of the laboratory's "Quality Assessment (QA) Plan", policies and procedures, instrument maintenance records, calibration verification records, quality control (QC) records, 2021 plan of correction (dated October 1, 2021), lack of documentation and interviews, the laboratory failed to follow their established Quality Assessment (QA) plan and identify and address analytic issues within the specialty of chemistry (Cross Reference D 5429, 5439 A & B, and 5469 A & B) from September 2021 until the date of the survey on August 23, 2023. The findings include: 1. Review of the laboratory's "Quality Assessment (QA)", policies and procedures, instrument maintenance, calibration verification and quality control revealed the analytic issues listed below. The laboratory failed to: -follow their established policy and 2021 plan of correction and perform quarterly maintenance on the TOSOH A1A 900 (see D5429) **REPEAT DEFICIENCY**; -follow their established policy and 2021 plan of correction and perform calibration verification for the analytes tested on the TOSOH A1A 900 and Medica EasyRA (D5439 A & B) **REPEAT DEFICIENCY**; -follow their established policy and 2021 plan of correction and perform evaluations to verify or establish control ranges for the QC materials used for monitoring accuracy on the TOSOH A1A 900 and Medica EasyRA (D5469 A & B) **REPEAT DEFICIENCY**. 2. Review of the laboratory's policies and procedures revealed a retired policy, "Quality Assessment", signed by the laboratory director on 06/03/2011 with a revision date of 10/01/2021 and retirement date of October 2022. Review of the policy revealed the following statements, "The major processes or systems to be evaluated are organized by month. The frequency of QA reviews will vary depending on the area of review...Monthly checklists are provided for each of these reviews." 3. Review of the monthly checklists from September 2021 until September 2022 revealed completed QA tracking sheets for twelve (12) of 12 months signed by the laboratory director and former technical consultant. These checklists included the following: a. Maintenance Activities Review-For TOSOH A1A-900(Monitored Activities)-Quarterly cleaning tasks marked as performed with tech initials, indicate date performed. b. Calibration Verification

	Review-For TOSOH A1A (Monitored Activities): Calibration verification(s), performed when due (6 month after previous) Analyte and date last performed. c. QC & Levy Jennings Graph and Review-For MEDICA EasyRA Instrument (Monitored Activities): Was new QC lot number started, if yes, was lot-to-lot comparison done. For TOSOH A1A-900 (Monitored Activities): Was new QC lot number started, if yes, was lot-to-lot comparison done. d. Monthly QA Review/Lab Director Meeting Documentation-Monitored Activity reviewed, Findings/Review of Action Log (if written) and Review of Action Log Corrective Action(s) taken. Each checklist listed sections for "Problem Areas and Corrective Actions Taken." The surveyor noted a lack of documentation of problem area(s) and corrective actions taken for the above listed checklists from September 2021 until September 2022. The surveyor requested to review documentation of any problem areas and corrective actions taken for the lack of TOSOH quarterly maintenance, TOSOH and EasyRA every 6 month calibration verifications, and TOSOH and EasyRA Quality Control lot-to-lot comparisons. The laboratory provided no further documentation to review. 4. In an interview with the Technical Consultant (TC) on August 23, 2023, at approximately 1: 00 PM, the surveyor requested to review the current Quality Assessment (QA) policy. The TC provided a "Quality Assessment Plan". The TC stated the plan was initiated in October 2021. Review of the current QA policy revealed a "Quality Assurance Monitoring Schedule". The TC stated they review Quality Control (QC), maintenance /action logs and calibrations monthly. Other audits are performed quarterly per the current QA policy. 5. Review of the quarterly QA documentation from October 2022 until the date of the survey on August 23, 2023 revealed a lack of documentation of any corrective actions taken for the lack of TOSOH quarterly maintenance, TOSOH and EasyRA every 6 month calibration verifications, and Quality Control lot-to-lot comparisons. The surveyor requested to review documentation of the above listed corrective actions. The laboratory provided no documentation for review. 6. Review of the laboratory's 2021 Plan of Correction on Form CMS-2567 (dated 10/01/2023) revealed the following statement, "The newly hired technical consultant has (1) revised existing or created new QA TRACKING SHEETS...as well as monthly QA TRACKING SHEET: MAINTENANCE ACTIVITIES for sign-offs for the missed maintenance procedures... (3) created new 6 month cal verification procedures on the TOSOH A1A-900 and MEDICA Easy RA...The newly hired technical consultant will monitor monthly as required via the revised or newly created QA TRACKING SHEETS." 7. In an exit interview with the Technical Consultant and Testing Personnel on August 23, 2023, at approximately 2:00 PM, the above findings were confirmed.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the laboratory's policies and procedures, 2021 plan of correction (dated October 1, 2021), manufacturer's operators guide, package inserts, instrument calibration verification records, quality control (QC) documents, quality assessment (QA) documents, lack of documentation and interviews, the laboratory director failed

	to ensure: 1. Quality control policies and procedures were followed (see D6020). 2. The established quality assessment plan identified and addressed analytic issues within the specialty of chemistry (See D6021).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: **REPEAT DEFICIENCY** Based on review of the laboratory's policies and procedures, Quality Control (QC) records, lack of documentation and interviews, the laboratory director failed to ensure the staff followed the 2021 plan of correction (dated October 1, 2021) and established QC policy to perform the verification of new lot numbers of QC materials used to measure the accuracy of analytes on TOSOH A1A 900 and Medica EasyRA (See D5469).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: **REPEAT DEFICIENCY** Based on review of the laboratory's policies and procedures, Quality Control (QC) records, Quality Assessment (QA) records, 2021 plan of correction (dated October 1, 2021), and interviews, the Laboratory Director failed to ensure the 2021 plan of correction and established QA policy was followed and maintained from September 2021 until the date of the survey on August 23, 2023 (See D5791 and D6020).