Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1080580	02/27/2019
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 February 27, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
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: ***REPEAT DEFICIENCY*** Based on a review of the policy and procedure manual, calibration verification records and interviews, the laboratory failed to perform calibration verifications for the Medica Easy RA and TOSOH A1A 900 twice annually for calendar year 2018 (Cross Reference D5439).
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 policy and procedure manual, Medica Easy RA calibration verification records, analyzer's online test data, patient test logs, and interviews, the laboratory failed to perform twice annual calibration verification studies for the Medica Easy RA in calendar year 2018. Findings include: 1. Review of the laboratory's procedure manual revealed a Quality Assurance (QA) policy which states "Quantitative test systems require calibration verification be performed every 6 months..." 2. Review of the laboratory's 2017 and 2018 EasyRA calibration verification records revealed the calibration verification studies were performed on 7/12/17. No documentation was found for 2018 until the date of the survey. The surveyor requested documentation of calibration verifications for 2018. At approximately 12:30 PM, testing personnel A (TPA) stated he/she did not perform calibration verification for the analytes tested on the Easy RA. He/she stated that he/she had completed a calibration verification for the analytes on 2/22/19. 3. Review of the EasyRA analyzer's online test data revealed the following 17 analytes were analyzed on patient samples from 7/22/17 until the date of the survey: Albumin, Alkaline Phosphotase, Alanine Aminotranferase, Aspatate Aminotransferase, Blood Urea Nitrogen, Calcium, Chloride, Carbon Dioxide, Creatinine, Glucose, Iron, Lactate Dehydrogenase, Magnesium, Potassium, Sodium, Total Bilirubin, and Total Protein. 4. Review of the laboratory's Laboratory Information System (LIS), Medlinks, revealed two thousand fifteen (2,015) patients samples were tested on the Easy Medica from 7/12/17 until the date of the survey. 5. In an interview at approximately 2:00 PM, TP A confirmed the above listed findings. B. Based on a review of the laboratory's policy and procedure manuals, TOSOH A1A 900 calibration verification records, analyzer's online test data, patient test logs, and interviews, the laboratory failed to perform twice annual calibration verification studies on the TOSOH A1A 900 in calendar year 2018. Findings include: 1. Review of the laboratory's procedure manual revealed a Quality Assurance (QA) policy which states "Quantitative test systems require calibration verification be performed every 6 months..." 2. Review of the laboratory's 2017 and 2018 TOSOH A1A 900 analyzer verification records revealed the verification studies were performed on 7/12/17. No documentation was found for 2018 until the date of the survey. The surveyor requested documentation of calibration verifications for 2018. At approximately 12:30 PM, testing personnel A (TPA) stated he/she did not perform calibration verification for the analytes tested on the TOSOH A1A 900. He/she stated that he/she had completed a calibration verification for the analytes performed on the TOSOH A1A on 2/22/19. 3. Review of the TOSOH analyzer's online test data revealed 2 analytes, Ferritin and CEA, were analyzed on the TOSOH A1A 900 for patient samples from 7

	/22/17 until the date of the survey. 4. Review of the laboratory's Laboratory Information System (LIS), Medlinks, revealed two thousand one hundred forty-six (2,146) patients samples were tested on the TOSOH from 7/12/17 until the date of the survey. 5. In an interview at approximately 2:00 PM, TP A confirmed the above listed findings
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 calibration verification records, policy and procedure manual, Quality Control records, Quality Assessment records and interviews, the laboratory director failed: to ensure calibration verifications were performed every 6 months (Cross Reference D5439-REPEAT DEFICIENCY); and to ensure monthly Levy Jennings graphs were printed and reviewed (Cross Reference D6020).
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: Based on the review of policy and procedure manual, Quality Control (QC) records, Quality Assessment (QA) records and interview, the laboratory director failed to ensure the staff followed the established QC policy to print out Levy Jennings graphs monthly for review for nineteen (19) of nineteen (19) months reviewed from July 2017 to date of the survey. Findings: 1. Review of the policy and procedure manual revealed a policy, Quality Control, which stated "Levy Jennings graphs will be printed and reviewed for shifts and trends and corrective actions necessary will be determined." 2. Review of the laboratory's QC records revealed no documentation of Levy Jennings graphs for the Medonic M Series Hematology analyzer from July 2017 until date of survey (19 months). The surveyor requested documentation of the Levy Jennings graphs for the Medonic analyzers. At approximately 12:30 PM, TP A stated, "I do not printout the Medonic Levy Jennings monthly or when I changes of lots. I review QC daily." 3. Review of the policy and procedure manual revealed a "Quality Assessment Review" checklist which stated "Monthly-Levy Jennings graphs printed monthly for evaluation. YES, NO, N/A" 4. Review of the QA records revealed a QA checklist for July 2017 until the date of survey (19 checklists) signed and dated by the Laboratory Director. Nineteen (19) of 19 checklist were checked "YES" for "Monthly-Levy Jennings graphs printed monthly for evaluation." 5. At approximately 2:00 PM, TPA confirmed the above listed findings.

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: Based on review of policy and procedure manual, Quality Control (QC) records, Quality Assurance (QA) records, and interviews with Testing Personnel A at approximately 12:30 PM and 2:00 PM, the laboratory director failed to ensure the established QA policy was maintained from July 2017 until the date of the survey. (Cross Reference D5439 and D6020).