Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1080580	09/08/2021
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 on-site CLIA recertification survey was conducted at Northern Virginia Hematology Oncology Associates, PC on September 8, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on August 12, 2021 and virtual record review conducted on September 3, 2021. The laboratory was surveyed under 42 C.F.R. part 493 CLIA Regulations. The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D5400 - 42 C.F.R. 493.1250 Condition: Analytic Systems and D6000 - 42 C.F.R. 493.1403 Condition: Moderate complexity laboratory director.
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, the CASPER 155 report and interview, the laboratory failed to participate in the first PT event of 2021 and received scores of "0" for 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). Findings include: 1. Review of the American

	Proficiency Institute (API) PT records and the CASPER 155 report revealed API reported the 2021 1st event as: 0% "failure to participate" for 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). 2. In an interview with testing personnel A (TP A) on September 8, 2021 at approximately 10:30 AM, the testing personnel stated the laboratory forgot to enroll with API for 2021. 3. In an exit interview with testing personnel A (TP A) and office manager on September 8, 2021 at approximately 12:30 PM, the above findings were confirmed.
D2100	ENDOCRINOLOGY CFR(s): 493.843(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, the CASPER 155 report and interview, the laboratory failed to participate in the first PT event of 2021 and received scores of "0" for thryoid stimulating hormone (TSH). Findings include: 1. Review of the American Proficiency Institute (API) PT records and the CASPER 155 report revealed API reported the 2021 1st event as: 0% "failure to participate" for TSH. 2. In an interview with the primary testing personnel on September 8, 2021 at approximately 10:30 AM, the Testing Personnel A (TP A) stated the laboratory forgot to enroll with API for 2021. 3. In an exit interview with the testing personnel A (TP A) and office manager on September 8, 2021 at approximately 12:30 PM, the above findings were confirmed.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, policy and procedures, lack of documentation, and an interview, the laboratory failed to document evaluation taken for one (1) unacceptable prostatic specific antigen (PSA) score on American Proficiency Institute (API) 2020 Event 1. Findings include: 1. Review of the laboratory's API records (2019 Events 2 & 3, 2020 Events 1-3 and 2021 Events 1 & 2), a total of seven (7) events, revealed no evidence of remedial action taken for the unsatisfactory 2020 Event 1 PSA analyte score of 50%. 2. Review of the laboratory's procedures revealed a policy, "Procedure for Proficiency Testing", which stated

	"REVIEW OF RETURNED SUMMARY SHEETS...4. Unacceptable results will be investigated and corrective actions will be documented. 5. A score of 80% is acceptable. A score of 60% is not acceptable and requires immediate action." 3. Review of the laboratory's PT records revealed no evaluation or corrective action documentation for the unacceptable PSA score listed above. The surveyor requested to review documentation of the corrective actions taken for the unsatisfactory PSA score. The laboratory provided no documentation to review. 4. In an exit interview with testing personnel A (TP A) and office manager on September 8, 2021 at approximately 12:30 PM, the above findings were confirmed.
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, 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 A & B); 2. to document calibration procedures for the Medica EasyRA (see D5437); 4. 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); 5. verify new lot numbers of QC material used to monitor the accuracy of analytes on the TOSOH A1A 900 and Medica EasyRA (see D5469); 6. identify and address analytic issues within the specialties of chemistry, and hematology (see D5791).
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 the review of the laboratory's policies and procedures, operator's guides, instrument maintenance logs, lack of documentation, and interviews, the laboratory failed to follow their established policy and document the monthly maintenance for the TOSOH A1A-900 from June 2020 until March 2021, a total of ten (10) months, and quarterly maintenance from January 2020 until the date of the survey, September 8, 2021, a total of twenty (20) months. Findings include: 1. Review of the TOSOH A1A-900 operator's guide and maintenance schedule revealed the following maintenance procedures to be performed monthly to include "Clean Sample Area with Ethanol, Replace B/F Wash Probe Tip, Replace wash/diluent reservoir filters"; and quarterly maintenance to include "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." 2. Review of the "TOSOH A1A-900 Maintenance Schedule" revealed a lack of documentation of the performance of the monthly maintenance procedures from June 2020 until March 2021, a total of 10 months. The surveyor requested to review documentation of the TOSOH monthly maintenance. The laboratory provided no documentation to review. 3. Review of the "TOSOH A1A-900 Maintenance Schedule" revealed a lack of documentation of the performance of the quarterly maintenance procedures from January 2020 until the date of the survey on September 8, 2021, a total of 20 months. The surveyor requested to review documentation of the TOSOH quarterly maintenance. The laboratory provided no documentation to review 4. In an exit interview with testing personnel A (TP A) and office manager on September 8, 2021 at approximately 12:30 PM, the above findings were confirmed. B. Based on the review of the laboratory's policies and procedures, instrument maintenance logs, lack of documentation, and interview, the laboratory failed to follow their established policy and document the monthly maintenance for the Medonic M-Series Hematology Analyzer from September 2020 until December 2020, a total of four (4) months. Findings include: 1. Review of the "Medonic M-Series Hematology Analyzer" log revealed the following maintenance procedures to be performed monthly to include "Monthly Cleaning (Hypochlorite)", and "Clot Prevention (Enzymatic)". 2. Review of the "Medonic M-Series Hematology Analyzer" logs revealed a lack of documentation of the performance of the monthly maintenance procedures from September 2020 until December 2020, a total of 4 months. The surveyor requested to review documentation of the Medonic monthly maintenance. The laboratory provided no documentation to review. 3. In an exit interview with testing personnel A (TP A) and office manager on September 8, 2021 at approximately 12:30 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 policies and procedures, calibration records, lack of documentation, and interviews, the laboratory failed to document calibration procedures for patient Chemistry testing on the Medica EasyRA Chemistry Analyzer when new lot numbers or complete change of reagents occur, or when there was a major preventive maintenance occurrence from June 2019 until August 31, 2021, a total of twenty-seven months. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a policy, "Calibration/Calibration Verification", with a statement, "Calibration is also performed when new lot numbers or complete change of reagents occur, or if there is a major preventive maintenance occurrence." 2.

	Review of the laboratory's calibration records from June 2019 until the date of the survey on September 8, 2021 revealed a lack of documentation of the calibrations performed on the EasyRA Chemistry analyzer from June 2019 until August 31, 2021, a total of 27 months. The surveyor requested to review documentation of the calibration records for the 27 months listed above. The laboratory provided no documentation to review. Testing personnel A (TP A) stated at approximately 11:30 AM: "I didn't know I needed to printout the calibration reports after each calibration. The instrument only saves the last two calibrations." 3. In an exit interview with testing personnel A (TP A) and office manager on September 8, 2021 at approximately 12:30 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, 2019 plan of correction, lack of documentation and interviews, the laboratory failed to follow their 2019 plan of correction, and established policy to perform calibration verification studies every 6 months in calendar year 2020 until the date of the inspection on September 8, 2021. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a "Quality Assurance (QA)" policy which stated "Quantitative test systems require calibration verification be performed every 6 months to ensure instrument settings are successfully able to provide accurate test results throughout the test ranges..." 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 July 2019 until the date of the survey on September 8, 2021 revealed the verification studies were performed as listed below: CEA - 10/18/2019: Ferritin - 10/18/2019; PSA - 7/30/2019. The surveyor requested to review the documentation of the every 6 month calibration verifications for 2020 and 2021 for

	CEA, PSA and Ferritin. The laboratory provided no documentation for review. 4. Review of the laboratory's 2019 Plan of Correction on Form CMS-2567 (dated 3/25 /2019) and supporting documentation revealed the laboratory completed calibration of above listed analytes on 2/25/2019 and "Future calibration verification is scheduled to be completed by 9/25/19 and every six months after that date or at a minimum, at least twice per calendar year." 5. In an exit interview with the testing personnel A (TP A) and office manager on September 8, 2021 at approximately 12:30 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, 2019 plan of correction, lack of documentation and interviews, the laboratory failed to follow their 2019 plan of correction, and established policy to perform calibration verification studies every 6 months in calendar year 2020 until the date of the inspection on September 8, 2021. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a "Quality Assurance (QA)" policy which stated "Quantitative test systems require calibration verification be performed every 6 months to ensure instrument settings are successfully able to provide accurate test results throughout the test ranges..." 2. Review of the laboratory's EasyRA analyzer verification records from July 2019 until the date of the survey on September 8, 2021 revealed the verification studies were performed as listed below: 08/23/2019-BUN, Calcium, Creatinine, Iron, Glucose, Magnesium, Total Iron Binding Capacity (TIBC); 10/15/2019-Total Protein; 10/16/2019-Albumin, Carbon Dioxide; 10/18/2019-Chloride, Potassium, Sodium, Total Bilirubin; 10/30/2019-Alkaline Phosphotase, Alanine Transaminase (ALT), Aspartate Aminotransferase (AST), Lactate Dehydrogenase (LDH). 06/15/2020-Carbon Dioxide; 07/06/2020-Total Bilirubin; 08 /03/2020-BUN, Calcium, Creatinine, Iron, Glucose, Magnesium, Albumin, Total Protein. The surveyor requested to review the documentation of the every 6 month calibration verification for the following analytes for 2020: Total Iron Binding Capacity (TIBC), Chloride, Potassium, Sodium, Alkaline Phosphotase, Alanine Transaminase (ALT), Aspartate Aminotransferase (AST), Lactate Dehydrogenase (LDH). The laboratory provided no documentation to review for the above listed analytes. The surveyor requested to review the documentation of the every 6 month calibration verification for the following analytes for 2021: BUN, Calcium, Creatinine, Iron, Glucose, Magnesium, Total Iron Binding Capacity (TIBC), Total Protein, Albumin, Carbon Dioxide, Chloride, Potassium, Sodium, Total Bilirubin, Alkaline Phosphotase, Alanine Transaminase (ALT), Aspartate Aminotransferase (AST), Lactate Dehydrogenase (LDH). The laboratory provided no documentation to review for the above listed analytes. 3. Review of the laboratory's 2019 Plan of Correction on Form CMS-2567 (dated 3/25/2019) and supporting documentation revealed the laboratory completed calibration of above listed analytes on 2/25/2019 and "Future calibration verification is scheduled to be completed by 9/25/19 and every six months after that date or at a minimum, at least twice per calendar year." 4. In an exit interview with testing personnel A (TP A) and office manager on September 8, 2021 at approximately 12:30 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:
A. Based on a review of the laboratory's policies and procedures, quality control (QC) records, lack of documentation, and interviews, the laboratory failed to perform evaluations to verify nine (9) of 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-nine (29) months reviewed. Findings include: 1. Review of the laboratory's procedure manual revealed a policy, "Quality Control", which stated "Parallel testing of new lot numbers of QC should be performed for preferably 5 days to confirm validity of new controls before being put into use. This should be documented accordingly." 2. Review of the laboratory's QC records from March 2019 to August 2021 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: 40341, 40342, 40343, 40361, 40362, 40363, 40381, 40382 and 40383. The surveyor requested to review documentation that each of the QC lot numbers outlined above were confirmed (verified). The laboratory provided no documentation to review. 3. In an exit interview with the testing personnel A (TP A) and office manager on September 8, 2021 at approximately 12:30 PM, the above findings were confirmed. B. Based on a review of the laboratory's policies and procedures, quality control (QC) records, lack of documentation, and interviews, the laboratory failed to perform evaluations to verify six (6) of 6 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-nine (29) months reviewed. Findings include: 1. Review of the laboratory's procedure manual revealed a policy, "Quality Control", which stated "Parallel testing of new lot numbers of QC should be performed for preferably 5 days to confirm validity of new controls before being put into use. This should be documented accordingly." 2. Review of the laboratory's QC records from March 2019 to August 2021 revealed the following 6 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: 19140, 19141, 20086, 20087, 20266, and 202067. The surveyor requested to review documentation that each of the QC lot numbers outlined above were confirmed (verified). The laboratory provided no documentation to review. 3. In an exit interview with the testing personnel A (TP A) and office manager on September 8, 2021 at approximately 12:30 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** A. Based on review of the laboratory's policies and procedures, Quality Control (QC) records, and an interview, the laboratory failed to follow their 2019 plan of correction and a written policy for QC statistics review for their hematology and chemistry analyzers for twenty-nine (29) of 29 months reviewed. Findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "Quality Management and Quality Assessment", which stated "QUALITY CONTROL-Levy Jennings graphs will be printed and reviewed for shifts and trends and any corrective actions necessary will be determined." 2. Review of QC records from March 2019 to August 2021 revealed a lack of documentation of the review of the Levey-Jennings graphs for the Medonic hematology analyzer, TOSOH A1A and Medica EasyRA chemistry analyzers from March 2019 until August 2021. The inspector requested to review the Levey-Jennings graph reviews for the above listed instruments. The laboratory provided no documentation to review. The lead testing personnel stated, at approximately 10:30 AM on September 8, 2021, "I did not know I needed to print the graphs for review." 3. Review of the laboratory's 2019 Plan of Correction on Form CMS-2567 (dated 3/25/2019) and supporting documentation revealed the following statement, "The Laboratory Director will ensure that Levey Jennings Graphs will be printed and reviewed for all required testing systems and for each test performed. QC and Levey Jennings graphs will be reviewed at monthly Quality Assessment meetings." 4. In an exit interview with testing personnel A (TP A) and office manager on September 8, 2021 at approximately 12:30 PM, the above findings were confirmed. B. Based on the review of the laboratory's "Quality Assessment (QA) Plan", policies and procedures, instrument maintenance records, calibration and calibration verification records, quality control (QC) records, lack of documentation and interviews, the laboratory failed to follow their established Quality Assessment (QA) plan and identify and address analytic issues within the specialties of diagnostic chemistry, and hematology (Cross Reference D 5429 A & B, 5437, 5439, and 5469) from March 2019 to August 2021. Findings include: 1. Review of the laboratory's "Quality Assessment (QA)", policies and procedures, instrument maintenance records, calibration and calibration verification records, and quality control (QC) records revealed the analytic issues listed below. The laboratory failed to: -perform monthly and quarterly maintenance on the TOSOH A1A 900 (see D5429 A & B); -document calibration procedures for the Medica EasyRA (see D5437); -follow their established policy and 2019 plan of correction to perform calibration verification for the analytes tested on the TOSOH A1A 900 and Medica EasyRA (D5439 A & B); -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); 2. Review of the laboratory's "Quality Management and Quality Assessment" policy revealed the following statement, "Quality Assessment-Pre-analytic, analytic and post-analytic laboratory systems will be monitored on an ongoing basis with varying frequencies to ensure quality test performances are occurring and to ensure regulatory compliance. Monthly: monitoring testing and storage conditions present in laboratory, instrument and system maintenance, review

	of quality control, waived testing performance, review of QA logs reflecting actions taken in the laboratory (Panics, Rejections, Complaints, Incidents, Communications, etc.) Quarterly: Evaluation of Proficiency Testing performances, Patient Test Management reviews. Bi-annually: Calibrations and Calibration Verification performances, LIS evaluation (if applicable). Annually: Competency/personnel review, review of Procedure Manual, review of QA Plan, review of OSHA and safety concerns. Reviews will be via review of charts, logs, records, and files in use at the laboratory facility and documented accordingly." 3. Review of the laboratory's 2019 Plan of Correction on Form CMS-2567 (dated 3/25/2019) revealed the following statement, "The Laboratory Director will ensue that the Quality Assessment Program in place for the laboratory will be maintained and reviewed on a monthly basis... Monthly Quality Assessment meetings will be scheduled to promptly review documentation from the prior month to ensure timely and effective corrective actions." 4. Review of the laboratory's QA documentation revealed a lack of documentation of "Monthly Quality Assessment" meetings from March 2019 until the date of the survey on September 8, 2021. The surveyor requested to review documentation of the "Monthly Quality Assessment" meetings. The laboratory provided no documentation to review. 5. In an exit interview with the testing personnel A (TP A) and office manager on September 8, 2021 at approximately 12:30 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, Quality Control (QC) records, the Centers for Medicare and Medicaid Services Laboratory Personnel Report form, laboratory personnel files, 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 specialties of chemistry and hematology (See D6021); 3. testing personnel had documented training and initial competency (D6029).
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 2019 Plan of Correction and

	established QC policy to print out Levey Jennings graphs monthly for review for twenty-nine (29) of 29 months reviewed from March 2019 to August 2021. (See D5791.)
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, 2019 plan of correction, and interviews, the Laboratory Director failed to ensure the established QA policy was maintained from March 2019 to August 2021. (See D5791 and D6020.)
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, policies and procedures and interviews, the laboratory director failed to ensure one (1) of 1 new TP had documented training and initial competency assessments prior to performing patient testing procedures. Findings include: 1. Review of CLIA CMS-209 form revealed TP A was hired since the last CLIA inspection on 2/27/19. 2. Review of 2019, 2020 and 2021 TOSOH A1A 900 and Medica EasyRA Quality Control (QC) records revealed TP A performed testing on the TOSOH and EasyRA beginning in June 2019. 3. Review of the laboratory's policies and procedures revealed a policy,"Training and Competency Requirements", which stated, "Comprehensive "hands-on" training for Quality Control, Quality Assurance, maintenance and record keeping will be performed and documented for each procedure the employee performs. Competency testing will be performed after initial training for procedures, at 6 months of independent work, annually thereafter." 4. Review of TP A's personnel records revealed the following lack of: -Training documentation for the Medonic M-series Hematology analyzer, TOSOH A1A and Medica EasyRA chemistry analyzers; and -Initial TOSOH A1A and Medica EasyRA competency documentation. The surveyor requested to review

	documentation of the training and initial competencies for TP A. The laboratory provided no documentation for review. 5. In an exit interview with TP A and office manager on September 8, 2021 at approximately 12:30 PM, the above findings were confirmed.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for 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 Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, quality control records, and an interview, the technical consultant (TC) failed to follow their established policy and assess the semi-annual TOSOH A1A and Medica EasyRA chemistry competency for one (1) of (1) testing personnel in 2019. Findings include: 1. Review of the CMS 209 personnel form and personnel records revealed the laboratory director also performs the duties of TC and a new testing personnel (TP A) was hired on 6/3 /2019 with an initial competency performed on 6/10/2019. 2. Review of 2019, 2020 and 2021 TOSOH A1A and EasyRA Quality Control (QC) records revealed TP A performed testing on the TOSOH and EasyRA. 3. Review of the laboratory's policies and procedures revealed a policy,"Training and Competency Requirements", which stated, "Competency testing will be performed after initial training for procedures, at 6 months of independent work, annually thereafter." 4. Review of the available personnel records revealed a lack of documentation of TP A's semi-annual TOSOH A1A and EasyRA chemistry analyzer competency assessments. The surveyor requested to review the semi-annual competency assessments for the above listed instruments. The laboratory provided no documentation to review. 5. In an exit interview with testing personnel A (TP A) and office manager on September 8, 2021 at approximately 12:30 PM, the above findings were confirmed.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, Quality Assessment policy, and an interview, the technical consultant (TC) failed to follow the laboratory's established policy and document annual competency evaluations for one (1) of 1 testing personnel in 2020. Findings include: 1. Review of the CMS Form 209 revealed that the laboratory director (LD) also performs the duties of TC and that there is one testing personnel (TP) who performed moderate complexity testing in 2020. 2. Review of the laboratory's policies and procedures revealed a policy,"Training and Competency Requirements", which stated, "Competency testing will be performed after initial training for procedures, at 6 months of independent work, annually

	thereafter." 3. Review of the laboratory personnel files revealed testing personnel (TP A) was hired on 6/3/2019 with an initial competency performed on 6/10/2019. TP A's file lacked documentation of their 2020 annual competency evaluations. The surveyor requested to review documentation of the 2020 annual competency for TP A. The laboratory provided no documentation for review. 4. In an exit interview with testing personnel A (TP A) and office manager on September 8, 2021 at approximately 12:30 PM, the above findings were confirmed.