Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2169260	03/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
Modern Vascular Fairfax	2812 Old Lee Highway Bldg Suite 100-B, Fairfax, 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 initial survey was conducted at Modern Vascular Fairfax on March 24, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on February 24, 2021 and virtual record review conducted on March 18, 2021. The laboratory was surveyed under 42 C.F.R. part 493 CLIA Regulations. The specific deficiencies are as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D2000 - 42 C.F.R. 493.801 Condition: Enrollment and Testing of Samples, D5400 - 42 C.F.R. 493.1250 Condition: Analytic Systems, D6000 - 42 C.F. R. 493.1403 Condition: Moderate Complexity Laboratory Director, D6063 - 42 C.F. R. 493.1421 Condition: Laboratory Testing Personnel. Modern Vascular Fairfax is performing SARS CoV-2 (COVID-19) testing and is in compliance with the applicable COVID-19 reporting requirements. .
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of patient records, lack of documentation of proficiency testing (PT) records, and interview, the laboratory failed to enroll in a PT program for Sodium (Na), Potassium (K), Chloride (Cl), Carbon Dioxide (CO2), Ionized Calcium

	(iCa), Blood Urea Nitrogen (BUN), Glucose (Glu), Creatinine (Cre), Hemoglobin (Hgb) and Hematocrit (Hct) from May 2020 until March 18, 2021. Findings include: 1. A review of the laboratory's records revealed a lack of documentation of PT testing enrollment for Na, K, Cl, CO2, iCa, BUN, Glu, Cre, Hgb and Hct from May 2020 until March 18, 2021. 2. During a virtual interview with Testing Personnel A (TP A) on March 18, 2021 at approximately 10:05 AM, the surveyor requested documentation of the laboratory's enrollment in a PT program from May 2020 until March 18, 2021. The laboratory provided no proof of enrollment for the surveyor to review. 3. In a virtual interview with the primary testing personnel on March 18, 2021 at approximately 10:05 AM the 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 laboratory tour, review of the laboratory's policy and procedure manual, manufacturer's operators guide, temperature logs, validation/verification records, i-STAT calibration verification records, quality control (QC) test logs quality assessment documents, lack of documentation and interviews, the laboratory failed to: 1. follow their six (6) month calibration verification protocol for the i-STAT chemistry and hematology analytes from May 2020 until March 23, 2021 (Cross Reference D5401); 2. monitor the daily room temperature and relative humidity percent (%) for the i-STAT analyzer laboratory (Cross Reference D5413); 3. verify the performance specifications for the Chem 8+ cartridge analytes from May 2020 until March 24, 2021 while reporting forty-seven (47) patients (Cross Reference D5421); 4. perform at least two levels of external QC materials each day of patient testing for the non-waived Abbott i-STAT Chem 8+ cartridge analytes from May 2020 to March 24, 2021 (Cross Reference D5447); and 5. identify and address analytic issues within the specialties of chemistry and hematology (Cross Reference D5791).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the laboratory's procedures, Abbott i-STAT chemistry analyzer records, lack of documentation, and interviews, the laboratory failed to follow their six (6) month calibration verification procedure for the i-STAT chemistry and hematology analytes from May 2020 until March 24, 2021. Findings include: 1.

	Review of the laboratory's procedures revealed a procedure, "Chemistry Testing Using the i-STAT, Chem8+ Cartridge Type", which stated "Calibration: 3. Calibration Verification/Analytical Measurement Ranges are validated by lab/POC staff after each CLEW software update at six month intervals. The test levels within this linearity kit cover the complete measurement range of the test cartridge parameters. Record data on the Post CLEW 6 month Calibration Verification Log Sheet." 2. Review of the laboratory's i-STAT analyzer records for Chem8+ analytes, Sodium (Na), Potassium (K), Chloride (Cl), Total Carbon Dioxide (TCO2), Ionized Calcium (iCa), Glucose (Glu), Blood Urea Nitrogen (BUN), Creatinine (Creat), Hemoglobin (Hgb) and Hematocrit (Hct) reported on the i-STAT analyzer (Serial Number 409902, installed 9/2019), revealed the lack of calibration validation and verification from May 2020 until March 2021. The inspector requested to review documentation of calibration verification performed from May 2020 until March 2021 for Na, K, Cl, TCO2, iCa, Glu, BUN, Creat, Hgb, and Hct on the i-STAT. The laboratory provided no documentation for review. Testing Personnel A (TP A) stated they didn't know they were to perform the calibration verification. 3. In an exit interview with TP A on March 24, 2021 at approximately 11:00 AM, the above findings were confirmed.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 tour, daily temperature/environment logs, manufacturer's user guide, lack of documentation, and interviews, the laboratory failed to monitor the daily room temperature and relative humidity percent (%) to ensure manufacturer's operating requirements were followed for the i-STAT chemistry analyze utilized for patient testing from May 2020 until the date of the survey, March 24, 2021. Findings include: 1. During a tour of the laboratory on March 24, 2021 at approximately 9:00 AM, the inspector noted an Abbott i-STAT analyzer system, Serial Number (SN) 409902, in use for chemistry testing of Sodium (Na), Potassium (K), Chloride (Cl), Total Carbon Dioxide (TCO2), Ionized Calcium (iCa), Glucose (Glu), Blood Urea Nitrogen (BUN), Creatinine (Creat), Hemoglobin (Hgb) and Hematocrit (Hct). 2. Review of the iSTAT's user guide revealed the following "Operating requirement 16-30C for i-STAT cartridge testing" and "environmental conditions for running instrument is humidity levels less than 80% non-condensing". 3. Review of the daily temperature /environmental logs from May 1, 2020 to March 23, 2021 revealed a lack of the documentation of the room temperature and humidity monitoring. The inspector requested documentation of the room temperatures and humidity from May 2020 until March 24, 2021. The laboratory provided no documentation for review. Testing Personnel A (TP A) stated they did not record the room temperatures or humidity of the laboratory. 4. In an exit interview with TP A on March 24, 2021 at approximately 11:00 AM, the above findings were confirmed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

	CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the review of the laboratory's records, patient test records, lack of documentation and interviews, the laboratory failed to verify the performance specifications for the Chem 8+ cartridge analytes from May 2020 until March 24, 2021 while reporting forty-seven (47) patients. Findings include: 1. During a virtual record review with Testing Personnel A on March 18, 2021 at approximately 10:30 AM, TP A stated the facility was using the Abbott i-STAT Chem 8+ test system (serial number 409902, installed 9/2019) for patient testing of Sodium (Na), Potassium (K), Chloride (Cl), Total Carbon Dioxide (TCO2), Ionized Calcium (iCa), Glucose (Glu), Blood Urea Nitrogen (BUN), Creatinine (Creat), Hemoglobin (Hgb) and Hematocrit (Hct). 2. Review of the laboratory's records for the Abbott i-STAT test system's (serial number 409902, installed 9/2019) documentation revealed a lack of documentation of the verification of the performance characteristics (accuracy, precision, reportable ranges and normal values) of the Chem 8+ cartridge. The surveyor requested documentation of the verification of the performance characteristics of the Chem 8+ cartridge. The laboratory provided no documentation of the verification of the performance characteristics for the Chem 8+ cartridge for the surveyor to review. 3. A review of the laboratory's patient records revealed forty-seven (47) patients were tested and resulted with the Chem 8+ cartridge from May 2020 until March 24, 2021. 4. In an interview with Testing Personnel A (TP A) on March 24, 2021 at approximately 11:00 AM, the findings were confirmed.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review laboratory's procedures, quality control (QC) test logs, patient records, lack of documentation, and an interviews, the lab failed to perform at least two levels of external QC materials each day of patient testing for the non-waived Abbott i-STAT Chem 8+ cartridge analytes from May 2020 to March 24, 2021 while reporting forty-seven (47) patients. Findings include: 1. Review of the "Chemistry Testing Using the i-Stat Chem8+ Cartridge Type" revealed "F. QUALITY CONTROL: Frequency of Use: The staff verifies each new lot number and new shipment of cartridges using Level 1 and Level 3 QC samples, prior to use for patient testing. The lab staff is responsible for completing the liquid quality control testing

	samples every month." 2. Review the QC test logs for the non-waived Abbott i-STAT Chem 8+ cartridges analytes (Sodium (Na), Potassium (K), Chloride (Cl), Total Carbon Dioxide (TCO2), Ionized Calcium (iCa), Glucose (Glu), Blood Urea Nitrogen (BUN), Creatinine (Creat), Hemoglobin (Hgb) and Hematocrit (Hct)) revealed the laboratory performed external QC procedures on the following dates: 7/31/2020, 8/12 /20, 9/9/2020, 2/24/2021 and 3/9/2021. 3. In an interview with Testing Personnel A (TP A) on March 18, 2021 at approximately 10:45 AM, TP A stated "We do not run Quality Control on the i-STAT analyzer each day of patient testing. We run Quality Control when receive a new shipment, lot number and every month." 4. Review of the patient records revealed 47 patient were tested from May 2020 until May 24, 2021. 5. In an exit interview with Testing Personnel A (TP A) on March 24, 2021 at approximately 11:00 AM, 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: Based on the review of the laboratory's "Quality Management Program", policies and procedures, i-STAT analyzer records, quality control (QC) records, patient records, and interviews, the laboratory's established Quality Assurance (QA) plan failed to identify and address analytic issues within the specialties of chemistry and hematology (Cross Reference D 5401, 5413, 5421, 5447). Findings include: 1. Review of the laboratory's "Quality Management Program", policies and procedures, i-STAT analyzer records, quality control (QC) records, patient records, revealed the following analytic issues: -No documentation of the laboratory following their established procedure for performing calibration verification of the i-STAT analyzer every six (6) months; -No documentation of the laboratory monitoring the room temperature and relative humidity % of the laboratory; -No documentation of the laboratory performing the verification of performance characteristics for the i-STAT analyzer (Serial number 409902 installed 9/2019). - No documentation of the laboratory performing external QC each day of patient testing for the i-STAT analyzer Chem 8+ cartridge from May 2020 until March 24, 2021. 2. Review of the Quality Management Program revealed no statement of a mechanism used by the laboratory to monitor and address issues in the specialties of hematology and chemistry. 3. In an exit interview with Testing Personnel A (TP A) on March 24, 2021 at approximately 11:00 AM, the 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 tour, review of instrument validation documents, policy and procedure

	manual, Quality Control (QC) records patient records, temperature logs, the Centers for Medicare and Medicaid Services Laboratory Personnel Report form, laboratory personnel files, lack of documentation and an interviews, the laboratory director failed to: 1. verify of the accuracy, precision, reportable range and reference ranges of the Chem 8+ cartridge analytes (Sodium (Na), Potassium (K), Chloride (Cl), Total Carbon Dioxide (TCO2), Ionized Calcium (iCa), Glucose (Glu), Blood Urea Nitrogen (BUN), Creatinine (Creat), Hemoglobin (Hgb) and Hematocrit (Hct)) performed on the i-STAT chemistry analyzer(Cross Reference D6013); 2. enroll in Proficiency Testing (PT) for Sodium (Na), Potassium (K), Chloride (Cl), Total Carbon Dioxide (TCO2), Ionized Calcium (iCa), Glucose (Glu), Blood Urea Nitrogen (BUN), Creatinine (Creat), Hemoglobin (Hgb) and Hematocrit (Hct) from May 2020 until March 2021 (Cross Reference D6015); 3. establish and maintain quality control policies and procedures for the non-waived Abbott i-STAT Chem 8+ cartridge analytes from May 2020 to March 24, 2021 (Cross Reference D6020); 4. establish a quality assessment plan to identify and address analytic issues within the specialties of chemistry and hematology (Cross Reference D6021); 5. ensure monitoring and documentation of room temperature, and relative humidity of the laboratory (Cross Reference D6023); 6. ensure education documentation was available for two (2) of six (6) new personnel performing patient testing with the i-STAT chemistry analyzer on March 24, 2021(Cross Reference D6029A); 7. ensure six (6) of six (6) new Testing Personnel had documented training and competency assessments prior to performing patient testing procedures from May 2020 until March 24, 2021 (Cross Reference D6029B); 8. ensure a policy for competency assessment of testing personnel (TP) on a semi-annual basis was established and followed for 6 of 6 testing personnel who were performing patient testing procedures from May 2020 until March 2021 (Cross Reference D6030).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on record review, lack of documentation and interview, the Laboratory Director failed to ensure the verification of the accuracy, precision, reportable range and reference ranges of the Chem 8+ cartridge analytes (Sodium (Na), Potassium (K), Chloride (Cl), Total Carbon Dioxide (TCO2), Ionized Calcium (iCa), Glucose (Glu), Blood Urea Nitrogen (BUN), Creatinine (Creat), Hemoglobin (Hgb) and Hematocrit (Hct)) performed on the i-STAT chemistry analyzer (Cross Reference D5421).
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on a review of laboratory records, lack of documentation, and interviews, the laboratory director failed to ensure Proficiency Testing enrollment for Sodium (Na), Potassium (K), Chloride (Cl), Total Carbon Dioxide (TCO2), Ionized Calcium (iCa), Glucose (Glu), Blood Urea Nitrogen (BUN), Creatinine (Creat), Hemoglobin (Hgb) and Hematocrit (Hct) from May 2020 until March 2021 (Cross reference D2000).
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 review of laboratory's procedures, quality control (QC) logs, patient records, lack of documentation, and interviews, the Laboratory Director failed to ensure Quality Control (QC) policies and procedures were established and maintained for the non-waived Abbott i-STAT Chem 8+ cartridge analytes from May 2020 to March 24, 2021 (Cross reference D5447).
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 the review of the laboratory's "Quality Management Program", policies and procedures, i-STAT analyzer records, Quality Control (QC) records, patient records, and interviews, the laboratory director failed to ensure the established quality assessment plan identified and addressed analytic issues within the specialties of chemistry and hematology (Cross reference D5791).
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on the review of manufacturer operator's guide, available temperature documentation, and interviews, the laboratory director failed to ensure the monitoring and documentation of room temperature, and relative humidity of the laboratory (Cross reference D5413).
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: A. Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), personnel records, and interviews, the laboratory director failed to provide documentation of education for two (2) of six (6) new personnel performing patient testing with the i-STAT chemistry analyzer on March 24, 2021(Cross Reference D6065.) B. Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, policy and interview with Testing Personnel (TP) A, the laboratory director failed to ensure six (6) of six (6) new TP had documented training and competency assessments prior to performing patient testing procedures from May 2020 until March 24, 2021. Findings include: 1. Review of CLIA CMS-209 form revealed that TP A, B, C, D, E and F were new TP hired in May 2020 (See attached TP Code Sheet). 2. Review of the testing personnel competency records revealed a lack of training documentation and competency assessments available for review for TP A, B, C, D, E and F. The surveyor requested documentation of the training and competencies for TP A, B, C, D, E and F. The laboratory provided no documentation for review. 3. In an exit interview with TP A on March 24, 2021 at approximately 11:00 AM, the findings were confirmed.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to

	process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), personnel records, policies, and interviews, the laboratory director failed to establish and follow a policy for performing competency assessment of testing personnel (TP) on a semi-annual basis for six (6) of six (6) TP performing patient testing from May 2020 until March 24, 2021. Findings include: 1. Review of the CMS 209 form revealed and an interview with TP A on March 18, 2021 at approximately 10:00 AM revealed there were 6 new TP hired in May 2020. (See attached TP code sheet.) 2. Review of the laboratory's personnel records revealed a lack of documentation of the semi-annual competency assessments for TP A, B, C, D, E and F. The surveyor requested documentation of the semi-annual competency assessments for TP A, B, C, D, E and F. The laboratory provided no documentation for review. 3. Review of the laboratory's policies and procedures revealed a lack of policy for performing competency of new testing personnel on a semi-annual basis. The surveyor requested to review the laboratory's competency policy. The laboratory provided no competency policy to review. 4. In an exit interview with TP A on March 24, 2021 at approximately 11:00 AM, the findings were confirmed.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), testing personnel records, and interviews, the laboratory failed to retain documentation of education qualifications for two (2) of six (6) testing personnel (TP) responsible for reporting moderate complexity testing on the i-STAT analyzer from May 2020 until March 24, 2021 (Cross Reference D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

	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), testing personnel records, lack of documentation and interviews, the laboratory failed to retain documentation of education qualifications for two (2) of six (6) testing personnel (TP) responsible for reporting moderate complexity testing on the i-STAT analyzer from May 2020 until March 24, 2021. Findings include: 1. Review of the CLIA CMS 209 form revealed there were 6 TP listed. Review of the laboratory's education documentation revealed education documents for TP A, D, E , F. No documentation of the highest level of education for TP B and C was noted (See Personnel code sheet). The surveyor requested documentation of the education documents for TP B and C. The laboratory provided no documentation for review. 2. In an interview with TP A on March 24, 2021 at approximately 9:30 AM, TP A stated the individuals listed on the CMS-209 performed patient testing utilizing the i-STAT Chem 8+ cartridge since May 2020. 3. In an exit interview with TP A on March 24, 2021 at approximately 11:00 AM, the findings were confirmed.