Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2172130	04/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Modern Vascular Of San Antonio	9819 Huebner Road Building 4, San Antonio, TX	

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 unannounced complaint investigation was conducted on 04/22/2021. Please see event VLJX11 for the full CMS-2567. Complaint intake TX00363887 was unsubstantiated.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: I. Based on surveyor observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions when using the TRUE METRIX glucometer for multiple patient use. The findings were: 1. Surveyor observation made on April 22, 2021 at 09: 20 hours in the laboratory found 1 TRUE METRIX glucometer. 2. Review of the manufacturer's instructions for the TRUE METRIX glucometer (RE4NPDO3) stated, "Multiple patient use devices such as blood glucose meters should be used on only one patient and not shared. If dedicating blood glucose meters to a single patient is not possible, the meters must be properly cleaned and disinfected after every use following the guidelines found in Meter Care, Cleaning/Disinfecting." 3. The laboratory was asked to provide documentation of following the manufacturer's requirements to clean and disinfect the glucometer after every use. No documentation was provided. 4. An interview with the Clinical Director on April 22, 2021 at 10:15 hours in Patient Exam Room #3 confirmed the findings. She confirmed that the glucometer is cleaned after each use but that it is not documented. II. Based on surveyor observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for monitoring revised expiration dates for TRUE METRIX glucometer

	test strips. The findings were: 1. Surveyor observation made on April 22, 2021 at 09: 20 hours in the laboratory found 1 opened vial of TRUE METRIX glucometer test strip available for patient use. Lot #ZX4177S Expiration Date: 06-15-2021 No open or revised expiration date 2. Review of the manufacturer's instructions for the TRUE METRIX glucometer (RE4NPDO3) stated, "Write date first opened on vial label. Discard vial and unused test strips if either 4 months after first opening or date printed next to EXP on vial label has passed, whichever comes first." and; "Caution! Use of test strips or control solution past the Expiration Dates may give incorrect test results. Discard out-of-date products and test with new products." 3. The laboratory was asked to provide documentation of the following the manufacturer's instructions to monitor revised expiration dates of TRUE METRIX test strips. No documentation was provided. 4. An interview with the Clinical Director on April 22, 2021 at 10:15 hours in Patient Exam Room #3 confirmed the findings.
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 review of the laboratory's records, and staff interview, it was revealed the facility failed to have documentation of enrolling in proficiency testing for 2020 and 2021. The findings were: 1. A review of the laboratory's records revealed the facility started performed moderate complexity testing on the Abbott i-STAT in July 2020. They performed testing utilizing the CHEM8+ cartridges which tested for the following regulated analytes: Sodium Potassium Cloride Total CO2 Glucose BUN /Urea Creatinine Hematocrit 2. The laboratory was asked to provide documentation of being enrolled for proficiency testing in 2020 and 2021 for the listed analytes. No documentation was provided. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 04/22/2021 at 1600 hours confirmed the findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Abbott i-STAT analyzer, review of laboratory records, and staff interview, it was revealed the laboratory failed

	to have documentation of monitoring the temperature of shipments of cartridges as required by the manufacturer. The findings were: 1. A review of the manufacturer's instructions for the Abbott i-STAT (Art: 714258-00Q, Rev Date: 15-APR-2018) under the section titled "Cartridge and Test Information" revealed: "Verify Newly Received Cartridges and Control Materials Verify that the transit temperatures were satisfactory using the four-window temperature indicator strip included in the shipping container." 2. The laboratory was asked to provide documentation of verifying the temperature of each shipment of cartridges. No documentation was provided. 3. An interview with testing personnel number 1 (as listed on CMS 209) on 04/22/2021 at 1600 hours in her office confirmed the findings.
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 review of the laboratory's records and staff interview, it was revealed the laboratory failed to be in compliance with analytic systems. The findings were: 1. The laboratory failed to provide documentation of establishing and monitoring an acceptable room temperature (refer to D5413). 2. The laboratory failed to have documentation of performing verification studies (refer to D5421). 3. The laboratory failed to have documentation of performing calibration verification (refer to D5439). 4. The laboratory failed to have control procedures that monitored accuracy and precision (refer to D5441). 5. The laboratory failed to have documentation of performing quality control testing each day of patient testing (refer to D5447). 6. The laboratory failed to provide documentation of performing corrective action (refer to D5785).
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 review of review of manufacturer's technical specifications and confirmed in interview of facility personnel, the laboratory failed to provide documentation of establishing and monitoring an acceptable room temperature in order to monitor the environment where the Abbott i-STAT1 is operated. The findings were: 1. Review of the manufacturer's technical specifications for the Abbott i-STAT1 available at

	https://www.pointofcare.abbott/us/en/offerings/istat/istat-handheld revealed the operating temperature of the analyzer is 16 to 30 degrees Celsius. 2. The laboratory was asked to provide documentation of establishing an acceptable room temperature in order to monitor the environment where the Abbott i-STAT1 is operated. No documentation was provided. a. The laboratory had not established an acceptable room temperature. Therefore, the laboratory did not have a mechanism in place to monitor the environment where the Abbott i-STAT1 is operated. 3. An interview with the Clinical Director on April 22, 2021 at 10:45 hours in her office confirmed the findings. She agreed room temperatures were not documented.
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 review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing verification studies for the CHEM8+ cartridges tested on the Abbott i-STAT analyzer. The findings were: 1. A review of the laboratory's records revealed the laboratory started testing CHEM8+ cartridges on the Abbott i-STAT analyzer in July 2020. 2. The laboratory was unable to provide documentation of performing verification studies to include: accuracy precision reportable range verification of patient normal ranges 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 04/22/2021 at 1600 hours in her office confirmed the findings.
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: Based on the review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing calibration verification for CHEM8+ testing performed on the Abbott i-STAT. The findings were: 1. A review of the laboratory's records revealed the facility started performing testing of the CHEM8+ cartridges on the Abbott i-STAT system in July 2020. The test cartridge contained the following tests: Sodium (Na) Potassium (K) Chloride (Cl) TCO2 Ionized Calcium (iCa) Glucose (Glu) Urea Nitrogen (BUN)/Urea Creatinine (Crea) Hematocrit (Hct) 2. The i-STAT analyzer performed a singe point calibration and two levels of control material were to be tested each day of patient testing. Thus, calibration verification was required. 3. The laboratory was asked to provide documentation of performing calibration verification during the 8 months since testing had started. No documentation was provided. 4. An interview with testing personnel number 1 (as listed on Form CMS 209) on 04/22/2021 at 1600 hours in her office confirmed the findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing, review of the laboratory's policies, and staff interview, it was revealed the laboratory failed to have control procedures that monitored the accuracy and precision of the testing performed on the Abbott i-STAT analyzer. The findings were: 1. The laboratory started performed testing utilizing the CHEM8+ cartridge on the Abbott i-STAT analyzer in July 2020. 2. The laboratory was asked to provide documentation of a policy or procedure which defined the frequency of control testing, acceptability criteria, result monitoring and troubleshooting. No policy was provided. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 04/22/2021 at 1600 hours in her office confirmed the findings.
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 of the laboratory's testing, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing quality control testing each day of patient testing for the CHEM8+ cartridge performed on the Abbott i-STAT analyzer. The findings were: 1. The laboratory started performed testing utilizing the CHEM8+ cartridge on the Abbott i-STAT analyzer in July 2020. 2. The laboratory was asked to provide documentation of performed external quality control testing each day of patient testing. No policy was provided. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 04/22/2021 at 1600 hours in her office confirmed the findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, review of the laboratory's refrigeration records, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of performing corrective action when temperatures were documented out of range. The findings were: 1. Surveyor observation on April 22, 2021 at 09:20 hours during the initial tour of the facility found the following item located in the Medication Room in the Medication Refrigerator: CalVer 1-5 Tri-Control CalibratorsLot Number: 19184 Expiration Date: 11-30-2020 2. Review of the manufacturer's instructions found on the package labeling of the CalVer 1-5 TriControls stated the storage temperature of the reagents was "2-8 degrees Celsius." Note that this range in degrees Fahrenheit is 35.6 to 46.4. 3. Review of the laboratory's Refrigerator Temperatures Log stated, "...If temperature is out of range, an Incident Report must be completed. For example: 8am - temperature is 35 degrees - POA: increased thermostat by 1 degree and will re-check in 1 hr. 9am - temperature is 38 degrees - Corrected - no further action is needed." 4. Review of the laboratory's refrigeration records from September and October 2020 and January and February 2021 found the following days when the temperature was documented out of manufacturer's specifications and no corrective action was documented: Date Temperature Comments/POA 09-08-2020 34 degrees none 10-12-2020 34/34 degrees No change 10-13-2020 34 degrees No change 10-14-2020 32/33 degrees No Change 10-15-2020 33/35 degrees Arrow up 10-16-2020 33 degrees Arrow up 10-19-2020 34/34 degrees none 10-20-2020 35/34 degrees none 10-21-2020 34/34 degrees none 10-22-2020 33/33 degrees none 10-23-2020 33/33 degrees none 10-26-2020 34/34 degrees none 10-27-2020 34/34 degrees none 10-28-2020 33/34 degrees none 10-29-2020 33 degrees none 01-07-2021 32 degrees none 01-11-2021 26 degrees Comment made to increase temperature, no documentation that temperature was re-checked and found in range 01-12-2021 30 degrees none 01-13-2021 30 degrees none 01-14-2021 28 degrees none 01-15-2021 30 degrees none 01-18-2021 30 degrees none 01-19-2021 28 degrees none 01-20-2021 26 degrees none 01-29-2021 26 degrees Comment made to increase temperature, no documentation

	that temperature was re-checked and found in range 02-01-2021 32 degrees none 02-02-2021 32 degrees none 02-03-2021 34 degrees No change 02-05-2021 32 degrees none 02-23-2021 32 degrees none 02-24-2021 34 degrees none 02-25-2021 34 degrees none 5. The laboratory was asked to provide documentation of performing corrective action for the dates found when the refrigerator's temperature was documented out of range. No documentation was provided. 6. An interview with the Clinical Director on April 22, 2021 at 11:00 hours in her office confirmed the findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and staff interview, it was revealed the laboratory failed to provide documentation of including the name and address of the testing facility for results which were available to providers. The findings were: 1. A review of random patient test records from November 2020 through April 2021 revealed 6 of 6 reports failed to have documentation of the name and address of the facility. They were as follows: Date Account # / Specimen ID 11-20-2020 75239 04-02-2021 104044 04-05-2021 104876 04-06-2021 100753 04-12-2021 77898 04-22-2021 106748 2. The laboratory was asked to provide documentation of including the name and address of the facility on patient tests reports. No documentation was provided. 3. An interview with the clinical director on April 22, 2021 at 11:15 hours in her office confirmed the findings.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing, review of the laboratory's policies, and staff interview, it was revealed the laboratory failed to have a policy which defined panic values and the documentation of the notification of the panic values. The findings were: 1. The laboratory started performed testing utilizing the CHEM8+ cartridge on the Abbott i-STAT analyzer in July 2020. 2. The laboratory was asked to provide documentation of a policy which defined panic values for the testing performed and the procedure to document the notification of the panic values to the

	provider. No policy was provided. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 04/22/2021 at 1600 hours in her office confirmed the 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 review of the laboratory's records and staff interview, it was revealed the laboratory director failed to provide oversight for the laboratory. The findings were: 1. The laboratory director failed to ensure verification studies were performed (refer to D6013). 2. The laboratory director failed to ensure control procedures were written and followed (refer to D6020). 3. The laboratory director failed to ensure the facility provided pertinent information on patient reports (refer to D6026). 4. The laboratory director failed to ensure testing personnel had the appropriate education (refer to D6029).
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 review of the laboratory's records, and staff interview, it was revealed the laboratory director failed to ensure verification studies were performed (refer to D5421).
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 the laboratory's testing, review of the laboratory's policies, and staff interview, it was revealed the laboratory director failed to ensure control

	procedures were written and followed that monitored the accuracy and precision of the testing performed on the Abbott i-STAT analyzer (refer to D5441 and D5447).
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing, review of the laboratory's policies, and staff interview, it was revealed the laboratory director failed to ensure the facility had a policy which defined panic values and, thus, that these values were properly identified on patient reports (refer to D5813).
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 review of the laboratory's personnel files and staff interview, it was revealed the laboratory director failed to ensure testing personnel had the appropriate education to perform moderate complexity testing (refer to D6065).
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, and staff interview, it was revealed the facility did have a technical consultant for the laboratory (refer to D6035).
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411

	(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, and staff interview, it was revealed the facility did not identify a technical consultant for the laboratory. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 04/22/2021) revealed the facility did not identify a technical consultant. 2. An interview with testing personnel number 1 (as listed on Form CMS 209) revealed the facility did not have a person who met the qualifications to perform the duties of a technical consultant. This confirmed the findings.
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 review of the submitted Form CMS 209, review of the laboratory's

	personnel files and staff interview, it was revealed the laboratory failed have documentation of education to qualify 4 of 4 testing personnel who performed moderate complexity testing (refer to 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 review of the submitted Form CMS 209, review of the laboratory's personnel files and staff interview, it was revealed the laboratory failed have documentation of education to qualify 4 of 4 testing personnel who performed moderate complexity testing. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 04/22/2021) revealed the laboratory identified 4 testing testing personnel performing moderate complexity testing on the Abbott i-STAT analyzer. 2. The laboratory was asked to provide documentation of education to qualify each of the 4 testing personnel. No documentation was provided. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 04/22/2021 at 1600 hours in her office confirmed the findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the submitted Form CMS 209, review of the laboratory's personnel files and staff interview, it was revealed the laboratory failed have documentation of training for 4 of 4 testing personnel who performed moderate complexity testing on the Abbott i-STAT. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 04/22 /2021) revealed the laboratory identified 4 testing testing personnel performing moderate complexity testing on the Abbott i-STAT analyzer. 2. The laboratory was asked to provide documentation of training for each of the 4 testing personnel. No documentation was provided. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 04/22/2021 at 1600 hours in her office confirmed the findings.