Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	45D2141401	06/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Mission Cardiac & Vascular Institute	479 Oxford, Suite 103, New Braunfels, 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	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES resulting in a finding of IMMEDIATE JEOPARDY: D5400 - 42 C.F.R. 493.1250 Condition: Analytic Systems D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director; moderate complexity D6033 - 42 C. F.R. 493.1409 Condition: Technical Consultant D6063 - 42 C.F.R. 493.1412 Condition: Testing Personnel; moderate complexity NOTE: The laboratory was asked to cease performing Activated Clotting Time testing utilizing the Abbott i-STAT analyzer. They agreed to cease testing. See the letter dated: Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's test records, review of patient medical records, and staff interview, it was revealed the laboratory failed to retain instrument printouts for samples tested for Activated Clotting Time (ACT) on the Abbott i-STAT analyzer.

	The findings were: 1. A review of the laboratory's ACT Results Log from September 2018 to March 2019 revealed the laboratory performed 15 ACT tests on 11 patients. They were: Date ID 09/11 18214 10/06 9-16-48 10/13 5-30-18 11/20 9-16-48 11/20 9-16-48 11/20 9-16-48 11/28 11-11-41 12/5 12-12-54 12/5 12-12-54 12/26 11-2-44 01/22 7403 01/31 3220 02/26 11-11-41 03/06 1472 03/06 1472 2. A review of patient medical records for each of the identified patients revealed the instrument printouts were not part of the patient's electronic medical record for each of the 11 patients tested. 3. The laboratory was asked to provide documentation of the instrument printouts for each of the identified tests. No documentation was provided. 4. An interview with the medical assistant on 06/13/2019 at 1230 hours in the office area revealed she did not know where the instrument printouts were. She stated they should have been scanned into the electronic medical records, but were not. This confirmed the findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for the analyte Activated Clotting Time (ACT) in 2018. The findings were: 1. A review of the laboratory's test menu revealed the laboratory performed Activated Clotting Time (ACT) testing utilizing the Abbott i-STAT analyzer in 2018. 2. A review of the laboratory's records revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for ACT testing in 2018. 3. The laboratory was asked to provide documentation of performing two accuracy assessments in 2018. No documentation was provided. 4. An interview with the Administrator on 06/13/2019 at 0945 hours in the office area revealed the laboratory was not enrolled in proficiency testing for ACT, nor did it have a mechanism in place to assess the accuracy of ACT results. This confirmed the findings.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment Plan, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of monitoring general laboratory systems. The findings were: 1. A review of the laboratory's Quality Assessment Plan (effective date: 6-29-18) revealed: "The goals of the QA program include assessment that all of the services provided by the laboratory contribute to the overall delivery of excellent medical care. This assessment will be derived from reviews and assessment of all aspects of laboratory

	operations, which will include: - General Laboratory Procedures - Pre-Analytic phase of Testing - Analytic phase of Testing - Post-Analytic phase of Testing" and, Quality Indicators for this facility have been defined as, but not limited to: GENERAL: a. Personnel qualifications, training and performance evaluation b. Periodic evaluation of physical environment for safety compliance c. Monitoring of Confidentiality of patient information d. Monitoring of patient and specimen identification and integrity e. Communication and complaint investigation f. Evaluation of Proficiency Testing and Split Sample Testing g. Retention of Records 2. A review of the laboratory's records from September 2018 to June 2019 (as of the day of the survey) revealed the laboratory failed to have documentation of monitoring the quality indicators specified in its policy. 3. The laboratory was asked to provide documentation of following its Quality Assessment Plan for general laboratory systems. No documentation was provided. 4. An interview with the medical assistant on 06/13/2019 at 1300 hours in the office area revealed the laboratory had not performed Quality Assessments for the laboratory. This confirmed the findings.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment Plan, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of monitoring Pre-Analytic systems. The findings were: 1. A review of the laboratory's Quality Assessment Plan (effective date: 6-29-18) revealed: "The goals of the QA program include assessment that all of the services provided by the laboratory contribute to the overall delivery of excellent medical care. This assessment will be derived from reviews and assessment of all aspects of laboratory operations, which will include: - General Laboratory Procedures - Pre-Analytic phase of Testing - Analytic phase of Testing - Post-Analytic phase of Testing" and, Quality Indicators for this facility have been defined as, but not limited to: PRE-ANALYTIC PHASE: a. Test tracking (requisitions) b. Specimen handling, collection, and labeling c. Specimen referral process 2. A review of the laboratory's records from September 2018 to June 2019 (as of the day of the survey) revealed the laboratory failed to have documentation of monitoring the quality indicators specified in its policy. 3. The laboratory was asked to provide documentation of following its Quality Assessment Plan for pre-analytic systems. No documentation was provided. 4. An interview with the medical assistant on 06/13/2019 at 1300 hours in the office area revealed the laboratory had not performed Quality Assessments for the laboratory. This 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 meet the requirements in analytic systems. The findings were: 1. The laboratory failed to have documentation of the laboratory director approving the procedure manual (refer to D5407) 2. The laboratory failed to have documentation of performing verification studies (refer to D5421). 3. The laboratory failed to have documentation of performing required function checks (refer to D5433). 4. The laboratory failed to monitor quality control to detect immediate errors (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 have documentation of following its Quality Assessment Plan for analytic testing (refer to D5791).
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 test menu, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing verification studies for Activated Clotting Time testing on the Abbott i-STAT analyzer. The findings were: 1. A review of the laboratory's test menu revealed the laboratory started performing Activated Clotting Time (ACT) testing on the Abbott i-STAT analyzer in September 2018. 2. A review of the laboratory's records revealed the laboratory failed to have documentation of performing verification studies to ensure a accurate and reliable test results. The following studies were not performed: Accuracy Precision 3. The laboratory was asked to provide documentation of performing the required verification studies. No documentation was provided. 4. The laboratory's patient test records revealed the laboratory performed 15 ACT tests on 11 patients from September 2018 to March 2019. They were: Date ID 09/11 18214 10/06 9-16-48 10/13 5-30-18 11/20 9-16-48 11/20 9-16-48 11/20 9-16-48 11/28 11-11-41 12/5 12-12-54 12/5 12-12-54 12/26 11-2-44 01/22 7403 01/31 3220 02/26 11-11-41 03/06 1472 03/06 1472 5. An interview with the Administrator on 06/13/2019 at 0925 hours in the office area revealed the laboratory did not perform verification studies. This confirmed the findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a

	maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Abbott i-STAT analyzer, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing the required function checks every six months. The findings were: 1. A review of the manufacturer's instructions for the Abbott i-STAT analyzer (Art: 714376-00U, Rev. Date: 27-Jan-17) revealed: "A quality check is performed on the thermal probes each time the external Electronic Simulator is used... Therefore, i-STAT recommends that the thermal probe check be verified every six months." and, "Thermal Probe Check The handheld's thermal probes should be check every six months." 2. A review of the laboratory's records revealed the laboratory documented a check of the thermal probes on 08/01/2018. Thus the next thermal probe check was due by 04/01/2019. 3. The laboratory was asked to provide documentation of a thermo probe checks being performed after the one done on 08/01/2019. No documentation was provided. 4. An interview with the Administrator on 06/13/2019 at 1045 hours in the office area revealed she could not find documentation of a thermal probe check being performed. This 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 Activated Clotting Time quality control records, review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of evaluating quality control results for acceptability prior to reporting patient result. The findings were: 1. A review of the laboratory's Activated Clotting Time (ACT) quality control records from October 2018 to June 2019 revealed the laboratory tested two levels of quality control material 3 times. The dates and quality control results were: Date Results 10/2 ACT 1: 204 ACT 2: 570 2/19 ACT 1: 209 ACT 2: 570 6/10 ACT 1: 204 ACT 2: 651 2. A review of patient test records from September 2018 to March 2019 revealed the laboratory performed 15 patient tests. 3. The laboratory was asked to provide documentation of the acceptable ranges for the results as provided by the manufacturer. No documentation was provided. 4. An interview with the medical assistant on 06/13/2019 at 1230 hours in the office area revealed the laboratory tested the control material, but did not evaluate the results to

	determine if they were acceptable or not. She was unaware the acceptable ranges for each control were available on the manufacturer's website. This 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 Activated Clotting Time quality control records, review of the laboratory's Activated Clotting Time test records, and staff interview, it was revealed the laboratory failed to have documentation of performing quality control testing each day of patient testing. The findings were: 1. A review of the laboratory's Activated Clotting Time (ACT) quality control records from October 2018 to June 2019 revealed the laboratory tested two levels of quality control material 3 times. The dates and quality control results were: Date Results 10/2 ACT 1: 204 ACT 2: 570 2/19 ACT 1: 209 ACT 2: 570 6/10 ACT 1: 204 ACT 2: 651 2. A review of the laboratory's ACT Results Log from September 2018 to March 2019 revealed the laboratory performed ACT testing on the following days: Date ID 09/11 18214 10 /06 9-16-48 10/13 5-30-18 11/20 9-16-48 11/28 11-11-41 12/5 12-12-52 12/26 11-2-44 01/22 7403 01/31 3220 02/26 11-11-41 03/06 1472 3. The laboratory was asked to provide documentation of performing quality control testing each day of patient testing, or of developing an Individualized Quality Control Plan (IQCP) to modify the frequency of control testing. No documentation was provided. 4. An interview with the medical assistant on 06/13/2019 at 1230 hours in the office area revealed the laboratory tested control material with each shipment. The laboratory did not performed quality control testing each day of patient testing, nor did it develop an IQCP to modify the frequency. This confirmed the findings.
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 review of the laboratory's Quality Assessment Plan, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of monitoring Analytic systems. The findings were: 1. A review of the laboratory's Quality Assessment Plan (effective date: 6-29-18) revealed: "The goals of the QA program include assessment that all of the services provided by the laboratory contribute to the overall delivery of excellent medical care. This assessment will be derived from reviews and assessment of all aspects of laboratory operations, which will include: - General Laboratory Procedures - Pre-Analytic phase of Testing -

	Analytic phase of Testing - Post-Analytic phase of Testing" and, Quality Indicators for this facility have been defined as, but not limited to: ANALYTIC PHASE: a. Review and update of procedure manual b. Monitoring supply and storage of reagents, test equipment, instruments, materials c. Instruments, with verification of calibration, quality control and maintenance d. Review of reference ranges e. Test records 2. A review of the laboratory's records from September 2018 to June 2019 (as of the day of the survey) revealed the laboratory failed to have documentation of monitoring the quality indicators specified in its policy. 3. The laboratory was asked to provide documentation of following its Quality Assessment Plan for analytic systems. No documentation was provided. 4. An interview with the medical assistant on 06/13 /2019 at 1300 hours in the office area revealed the laboratory had not performed Quality Assessments for the laboratory. This confirmed the findings.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of providing reference range to providers. The findings were: 1. A review of the laboratory's test menu revealed the laboratory started performing Activated Clotting Time (ACT) testing in September 2018. 2. A review of the laboratory's ACT Results Log from September 2018 to March 2019 revealed the laboratory performed 15 ACT tests on 11 patients. They were: Date ID Result 09/11 18214 222 10/06 9-16-48 196 10/13 5-30-18 253 11/20 9-16-48 261 11/20 9-16-48 266 11/20 9-16-48 148 11/28 11-11-41 200 12/5 12-12-54 212 12/5 12-12-54 144 12/26 11-2-44 196 01/22 7403 233 01/31 3220 144 02/26 11-11-41 186 03/06 1472 237 03/06 1472 221 3. The laboratory was asked to provide documentation of the reference range provided for the interpretation of the results. No documentation was provided. 4. An interview with the medical assistant on 06/13/2019 at 1315 hours in the office area revealed the laboratory only provided the result to the doctor. She stated she did not know what the laboratory's reference range was for the Activated Clotting Time test. This confirmed the findings.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment Plan, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of monitoring Post-Analytic systems. The findings were: 1. A review of the laboratory's Quality Assessment Plan (effective date: 6-29-18) revealed: "The goals of the QA program include assessment that all of the services provided by the laboratory contribute to the overall delivery of excellent medical care. This

	assessment will be derived from reviews and assessment of all aspects of laboratory operations, which will include: - General Laboratory Procedures - Pre-Analytic phase of Testing - Analytic phase of Testing - Post-Analytic phase of Testing" and, Quality Indicators for this facility have been defined as, but not limited to: POST-ANALYTIC PHASE: a. Result reporting, verification of records and procedure for corrected reports b. Documentation and notification of critical values and turn-around time evaluation 2. A review of the laboratory's records from September 2018 to June 2019 (as of the day of the survey) revealed the laboratory failed to have documentation of monitoring the quality indicators specified in its policy. 3. The laboratory was asked to provide documentation of following its Quality Assessment Plan for analytic systems. No documentation was provided. 4. An interview with the medical assistant on 06/13/2019 at 1300 hours in the office area revealed the laboratory had not performed Quality Assessments for the laboratory. This 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 overall management 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 the laboratory's quality control plan was followed (refer to D6020). 3. The laboratory director failed to ensure the laboratory's quality assessment plan was followed (refer to D6021). 4. The laboratory director failed to ensure reference ranges for Activated Clotted Time were available to providers (refer to D6026). 5. The laboratory director failed to ensure testing personnel met requirements (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 quality control plan, review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure the laboratory's quality control program was followed. The findings were: 1. A review of the laboratory's quality control plan (effective date: 6-29-2019) revealed: "Because this test is FDA classified as moderately complex, two levels of controls are required each day of patient testing..." 2. This was not followed (refer to D5447). 3. A review of the laboratory's quality control plan (effective date: 6-29-2019) revealed: "Control results are reviewed for each testing event by testing personnel." 4. This was not followed (refer to D5441).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment Plan, review of the laboratory's records, and staff interview, it was revealed the laboratory director failed to ensure the laboratory's Quality Assessment Plan was followed. The findings were: 1. The laboratory director failed to ensure the laboratory's Quality Assessment Plan for laboratory general systems was followed (refer to D5291). 2. The laboratory director failed to ensure the laboratory's Quality Assessment Plan for pre-analytic systems was followed (refer to D5391). 3. The laboratory director failed to ensure the laboratory's Quality Assessment Plan for analytic systems was followed (refer to D5791). 4. The laboratory director failed to ensure the laboratory's Quality Assessment Plan for post-analytic systems was followed (refer to D5891).
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 records and staff interview, it was revealed the laboratory director failed to ensure reference ranges for Activated Clotted Time were available to providers (refer to D5807).
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 records, and staff interview, it was revealed the laboratory director failed to ensure testing personnel met requirements. The findings were: 1. The laboratory director failed to ensure 1 of 3 testing personal had documentation of education to perform testing (refer to D6065). 2. The laboratory director failed to ensure 3 of 3 testing personal had documentation of training to perform testing (refer to D6066).
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 records, and staff interview, it was revealed the technical consultant failed meet the qualifications and failed to provide technical oversight for the laboratory. The findings were: 1. The laboratory failed to have documentation of education to qualify the technical consultant (refer to D6035). 2. The technical consultant failed to ensure verification studies were performed (refer to D6040). 3. The technical consultant failed to ensure the laboratory's quality control plan was followed (refer to D6042). 4. The technical consultant failed to ensure testing personnel had documentation of education (refer to D6045).
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, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 1 technical consultants. The findings were: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 1 technical consultant. 2. A review of the laboratory's personnel files revealed the laboratory failed to have documentation of education to qualify the technical consultant. 3. The laboratory was asked to provide the required documentation. No documentation was provided. 4. An interview with the administrator on 06/13/2019 at 1000 hours in the office area revealed the laboratory did not have education records for the technical consultant. This confirmed the findings.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the technical consultant failed to ensure verification studies were performed (refer to D5421).

D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of the laboratory quality control plan, review of the laboratory's records and staff interview, it was revealed the technical consultant failed to ensure the laboratory's quality control program was followed. The findings were: 1. A review of the laboratory's quality control plan (effective date: 6-29-2019) revealed: "Because this test is FDA classified as moderately complex, two levels of controls are required each day of patient testing..." 2. This was not followed (refer to D5447). 3. A review of the laboratory's quality control plan (effective date: 6-29-2019) revealed: "Control results are reviewed for each testing event by testing personnel." 4. This was not followed (refer to D5441).
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on review of personnel records, and staff interview, it was revealed the technical consultant failed to identify the need for training for 3 of 3 testing personnel (refer to D6066).
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 laboratory's records and staff interview, it was revealed testing personnel failed to meet the qualifications and failed to performed required functions. The finding were: 1. The laboratory failed to have documentation to qualify 1 of 3 personnel to perform testing (refer to D6065). 2. The laboratory failed to have documentation of training for 3 of 3 testing personnel (refer to D6066). 3. Testing personnel failed to retain instrument printouts (refer to D6070). 4. Testing personnel failed to follow the laboratory's quality control plan (refer to D6072).
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 laboratory's records and staff interview, it was revealed the laboratory failed to have documentation to qualify 1 of 3 personnel to perform testing (refer to D6065). The findings were: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 3 testing personnel. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education for 1 of 3 testing personnel. The person without documentation of education was (as listed on Form CMS 209): Testing personnel number 2 3. The laboratory was asked to provide documentation of education. No documentation was provided. 4. An interview with the Administrator on 06/13/2019 at 1000 hours in the office area revealed the laboratory did not have education records for testing personnel number 2. This 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 laboratory's records and staff interview, it was revealed the laboratory failed to have documentation of training for 3 of 3 testing personnel. The findings were: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 3 testing personnel. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training for 3 of 3 testing personnel who performed ACT testing on the Abbott i-STAT analyzer. They were (as listed on Form CMS 209): Testing personnel number 1 Testing personnel number 2 Testing personnel number 3 3. The laboratory was asked to provide documentation of training. No documentation was provided. 4. An interview with the Administrator on 06/13/2019 at 1000 hours in the office area revealed the laboratory did not have documentation on training. This confirmed the findings.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and

	maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed testing personnel failed to retain instrument printouts to ensure accurate result reporting (refer to D3031).
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed testing personnel failed to follow the laboratory's quality control plan. The findings were: 1. A review of the laboratory's quality control plan (effective date: 6-29-2019) revealed: "Because this test is FDA classified as moderately complex, two levels of controls are required each day of patient testing..." 2. This was not followed (refer to D5447). 3. A review of the laboratory's quality control plan (effective date: 6-29-2019) revealed: "Control results are reviewed for each testing event by testing personnel." 4. This was not followed (refer to D5441).