Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2142233	(X3) Date Survey Completed 08/06/2018
Name of Provider or Supplier Mid City Specialty Center, Llc	**Street Address, City, State** 3600 Florida Blvd, Suite 2000, Baton Rouge, LA	

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 INITIAL CERTIFICATION SURVEY was performed at Mid City Specialty Center, LLC - CLIA # 19D2142233 on August 6, 2018. Mid City Specialty Center was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1215 CONDITION: Hematology. 42 CFR 493.1403 CONDITION: Laboratory Director performing moderate complexity testing. 42 CFR 493.1409 CONDITION: Technical Consultant. 42 CFR 493.1421 CONDITION: Testing Personnel.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a record review, and interview with personnel, the laboratory failed to ensure the quality of testing in the specialty of Hematology. Findings: 1. The laboratory failed to maintain a complete policy and procedure manual. Refer to D5401 and D5403. 2. The laboratory failed to ensure that Direct Check Whole Blood Control for Hemochron Microcoagulation Systems for ACT testing is not used beyond their expiration dates. Refer to D5417. 3. The laboratory failed to verify performance specifications for the two (2) Hemochron Signature Elite Analyzer for Activated Clotting Time (ACT) testing. Refer to D5421. 4. The laboratory failed to establish means and ranges for Quality Control (QC) material used for the Hemochron Signature Elite Analyzer for Activated Clotting Time (ACT) testing as required by the manufacturer for eight (8) of eight (8) lots of quality control material. Refer to D5469. 5. The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for Activated Clotting Time (ACT) performed on the Hemochron Signature Elite Analyzer, for two (2) of two (2) patients reviewed. Refer to D5545. 6.

	The laboratory's Quality Assurance monitors failed to identify and correct quality issues in Hematology. Please refer to D5793.
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 record review and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory did not have detailed instructions for: Proficiency Testing (PT): a) Ordering and ensuring that you are enrolled for Proficiency Testing. b) What to do when you receive samples from the PT Provider. c) How to handle the samples; who will test, when to test, how do you assure no inter and intra laboratory communication takes place d) How to record results to send into the PT Provider to be scored. e) What records to maintain. f) How to evaluate when you receive your scores from the PT Provider. g) What steps to take if corrective action is needed. h) What steps are required when the laboratory has their first and second two (2) out of three (3) failures. 2. Interview with personnel 3 on August 6, 2018 confirmed the policy and procedure manual was incomplete
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory failed to have policies and

	procedures for each test/analyzer that includes: Quality Control policies and procedures to include establishing of means and ranges for quality control material, to include but not limited to: How to establish ranges for quality control material and/or verification of quality control material; who is to monitor and how changes are to be made to the ranges of quality control material; and that the correct means and ranges are available to testing personnel. Also to include what quality control is required for each instrument and what the acceptability criteria is for all. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. Reference intervals (normal values). Imminently life-threatening test results, or panic or alert values. 2. Interview with personnel 3 on August 6, 2018 confirmed the laboratory failed to have a complete policy and procedure manual.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory failed to ensure that Direct Check Whole Blood Control for Hemochron Microcoagulation Systems for ACT testing is not used beyond their expiration dates. Findings: 1. Review of Quality Control Records revealed the laboratory utilized the following expired Direct Check Whole Blood Control for Hemochron Microcoagulation Systems for ACT testing: June 1, 2018 - July 1, 2018 Abnorm Control lot number M7DLA034 with an expiration date of 5/31/2018. August 1, 2018 - July 1, 2018 Abnorm Control lot number M7DLA034 with an expiration date of 5/31/2018. 2. Interview with personnel 3 on August 6, 2018 confirmed the quality control material documented in the Monthly ACT - LR Cuvette Validation Log was being used for patient testing. 3. Review of Patient Test Records revealed Patient 1 was tested and reported on June 21, 2018 utilizing expired control material.
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 observation, record review and interview with personnel, the laboratory failed to verify performance specifications for the two (2) Hemochron Signature Elite Analyzer for Activated Clotting Time (ACT) testing. Findings: 1. Observation by surveyor on August 6, 2018 revealed the laboratory maintained two (2) Hemochron Signature Elite Analyzers for ACT testing (Serial numbers SE3587 and SE3702). 2. Review of the Laboratory's Policy and Procedure Manual revealed under "Method

	Validation" policies and procedures for the "establishment and verification of performance specifications for non-waived and waived test systems to include validation of a new method or new analyzer and for intermittent testing put into production." Further review of the policy revealed detailed written policies and procedures for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges. The Laboratory Policy and Procedure Manual revealed the laboratory allowed the manufacturers representative to verify accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges. The Laboratory Policy and Procedure Manual failed to ensure prior to patient testing policies and procedures for the laboratory to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges. 3. Review of the ACT Hemochron Signature Elite Method Validation Manual submitted to the surveyor on August 6, 2018 revealed studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges performed by another laboratory in July 2010. 4. Interview with Personnel 3 on August 6, 2018 confirmed the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges. Personnel 3 revealed that patient testing began in June of 2018. 5. Review of patient test records from June 21, 2018 through August 6, 2018 revealed the laboratory had performed only two (2) ACT tests as follows: On June 21, 2018 - Patient 1 On July 5, 2018 - Patient 2. Review of the Task 1 and 3 Form submitted to the surveyor on August 6, 2018 revealed the laboratory is expecting to perform approximately 520 ACT annually.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to establish means and ranges for Quality Control (QC) material used for the Hemochron Signature Elite Analyzer for Activated Clotting Time (ACT) testing as required by the manufacturer for eight (8) of eight (8) lots of quality control material. Findings: 1. Observation by the surveyor on August 6, 2018 revealed the laboratory utilized the Hemochron Signature Elite Analyzer for ACT testing. Further observation

	by the surveyor noted the laboratory utilized Direct Check Whole Blood Control for Hemochron Microcoagulation Systems for ACT testing. 2. Review of the Direct Check Whole Blood Control for Hemochron Microcoagulation Systems for ACT testing package insert revealed under Performance Characteristics: Expected Values: ITC recommends that each instrument establish its own expected range of response based on the mean +/- 2 standard deviations of at least 20 repeated test results. The local mean values establish should fall within the manufacturer's acceptable performance range. Studies show that intra-laboratory variation in test results should produce a coefficient of variation of approximately 14% or less for coagulation control tests." 3. Review of the Laboratory's Policy and Procedure Manual revealed testing personnel are to utilize the manufacturer's ranges for quality control . Further review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to establish written policies for the establishment of means and ranges for ACT testing performed on the Hemochron Signature Elite Analyzer. 4. Review of Quality Control Records revealed the laboratory utilized the manufacturer's ranges for the following eight (8) lots of Direct Check Whole Blood Control for Hemochron Microcoagulation Systems for ACT testing: March 8, 2018 - May 31, 2018 Norm Control lot number J7DNL028 with an expiration date of 5/31/2018. March 8, 2018 - April 9, 2018 Abnormal Control lot number C7 DLA015 with an expiration date of 7/31/2018. April 10, 2018 - May 31, 2018 Abnormal Control lot number K7 DLA030 with an expiration date of 7/31/2018. June 1, 2018 - July 1, 2018 Norm Control lot number A8DNL001 with an expiration date of 10/30/2018. June 1, 2018 - July 1, 2018 Abnorm Control lot number M7DLA034 with an expiration date of 5/31/2018. July 2, 2018 - August 6, 2018 Norm Control lot number E8DNL008 with an expiration date of 2/28/2019. July 2, 2018 - August 1, 2018 Abnorm Control lot number D8DLA004 with an expiration date of 7/31/2019. August 1, 2018 - July 1, 2018 Abnorm Control lot number M7DLA034 with an expiration date of 5/31/2018. 5. Interview with personnel 3 on August 6, 2018 revealed she was unaware the laboratory had to establish their own ranges. Personnel 3 confirmed the laboratory failed to establish ranges for the eight (8) lots of Direct Check Whole Blood Control for Hemochron Microcoagulation Systems for ACT testing.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for Activated Clotting Time (ACT) performed on the Hemochron Signature Elite Analyzer, for two (2) of two (2) patients reviewed. Findings: 1. Observation by the surveyor on August 6, 2018 during the tour of the laboratory noted the laboratory maintained two (2) Hemochron Signature Elite Analyzers for the testing and reporting of Activated Clotting Time (ACT) testing. 2. Review of the Laboratory's Policy and Procedure Manual revealed personnel are to perform electronic quality control every eight (8) hours of patient testing and perform two levels of liquid quality control every month, and with each new shipment/lot number for patient ACT testing. 3. Interview with personnel 3 and 6 on August 6, 2018 revealed the laboratory just started testing

	around June 2018 and revealed they were unaware the laboratory had to perform liquid quality control every eight (8) hours and prior to patient testing. Personnel 3 and 6 revealed testing personnel were performing the electronic quality control every eight (8) hours of patient testing and performing two levels of liquid quality control every month, and with each new shipment/lot number for patient ACT testing. 4. Review of ACT Patient Test Records and Quality Control Records from June 21, 2018 through August 6, 2018 revealed testing personnel documented performance of: a) The electronic control every eight (8) hours of patient testing b) Two (2) levels of liquid quality control every month and with each new lot/shipment. However for the two (2) patients below the laboratory failed to document the performance of two (2) levels of liquid quality control every eight (8) hours and prior to patient testing. On June 21, 2018 - Patient 1. On July 5, 2018 - Patient 2. 5. Interview with personnel 3 and 6 on August 6, 2018 confirmed the laboratory failed to perform two (2) levels of liquid quality control prior to patient testing and within eight (8) hours of performing the patient.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review, and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues in Hematology. Findings: 1. A review of patient test records and quality control records indicated problems with the analytic system as follows: a) The laboratory failed to maintain a complete policy and procedure manual. Refer to D5401 and D5403. b) The laboratory failed to ensure that Direct Check Whole Blood Control for Hemochron Microcoagulation Systems for ACT testing is not used beyond their expiration dates. Refer to D5417. c) The laboratory failed to verify performance specifications for the two (2) Hemochron Signature Elite Analyzer for Activated Clotting Time (ACT) testing. Refer to D5421. d) The laboratory failed to establish means and ranges for Quality Control (QC) material used for the Hemochron Signature Elite Analyzer for Activated Clotting Time (ACT) testing as required by the manufacturer for eight (8) of eight (8) lots of quality control material. Refer to D5469. e) The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for Activated Clotting Time (ACT) performed on the Hemochron Signature Elite Analyzer, for two (2) of two (2) patients reviewed. Refer to D5545. 2. The laboratory has a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory; however, the monitors failed to identify any of the deficiencies identified with the analytic systems. 3. Interview with personnel 3 and 6 on August 6, 2007 confirmed the laboratory failed to identify the deficiency cited above.
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 observation, record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure that verification procedures are performed to determine accuracy, precision, reportable and reference ranges for the Hemochron Signature Elite Analyzer for Activated Clotting Time (ACT) testing. Refer to D6013. 2. The Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Refer to D6014. 3. The Laboratory Director failed to ensure that quality control programs were established to assure the quality of laboratory testing. Refer to D6020. 4. The Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D6021. 5. The Laboratory Director failed to ensure that all personnel have the appropriate education and experience to accurately report patient test results. Refer to D6029. 6. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6031.
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 observations, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that verification procedures are performed to determine accuracy, precision, reportable and reference ranges for the Hemochron Signature Elite Analyzer for Activated Clotting Time (ACT) testing. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed

	to ensure laboratory personnel performed testing as required for accurate and reliable results. Findings: 1. The laboratory failed to ensure that Direct Check Whole Blood Control for Hemochron Microcoagulation Systems for ACT testing is not used beyond their expiration dates. Refer to D5417. 2. Interview with personnel 3 on August 6, 2018 confirmed the quality control material documented in the Monthly ACT - LR Cuvette Validation Log was being used for patient testing.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that quality control programs were established to assure the quality of laboratory testing. Findings: 1. The laboratory failed to verify performance specifications for the two (2) Hemochron Signature Elite Analyzer for Activated Clotting Time (ACT) testing. Refer to D5421. 2. The laboratory failed to establish means and ranges for Quality Control (QC) material used for the Hemochron Signature Elite Analyzer for Activated Clotting Time (ACT) testing as required by the manufacturer for eight (8) of eight (8) lots of quality control material. Refer to D5469. 3. The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for Activated Clotting Time (ACT) performed on the Hemochron Signature Elite Analyzer, for two (2) of two (2) patients reviewed. Refer to D5545.
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 observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Findings: 1. A review of patient test records and quality control records indicated problems with the analytic system as follows: a) The laboratory failed to maintain a complete policy and procedure manual. Refer to D5401 and D5403. b) The laboratory failed to ensure that Direct Check Whole Blood Control for Hemochron Microcoagulation Systems for ACT testing is not used beyond their expiration dates. Refer to D5417. c) The laboratory failed to verify performance specifications for the two (2) Hemochron Signature Elite Analyzer for Activated Clotting Time (ACT)

	testing. Refer to D5421. d) The laboratory failed to establish means and ranges for Quality Control (QC) material used for the Hemochron Signature Elite Analyzer for Activated Clotting Time (ACT) testing as required by the manufacturer for eight (8) of eight (8) lots of quality control material. Refer to D5469. e) The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for Activated Clotting Time (ACT) performed on the Hemochron Signature Elite Analyzer, for two (2) of two (2) patients reviewed. Refer to D5545. 2. The laboratory has a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory; however, the monitors failed to identify any of the deficiencies identified with the analytic systems. Refer to D5793. 3. Interview with personnel 3 and 6 on August 6, 2007 confirmed the laboratory failed to identify the deficiency cited above.
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 laboratory personnel records and interview with laboratory personnel, the Laboratory Director failed to ensure that all personnel have the appropriate education and experience to accurately report patient test results. Findings: 1. The laboratory failed to maintain documentation of Technical Consultant qualifications for two (2) of three (3) Technical Consultants. Refer to D6035. 2. The laboratory failed to provide documentation that testing personnel met the educational qualifications for performing moderate complexity testing for two (2) of seven (7) testing personnel. Refer to tag D6065.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings: 1. Review of the policy and procedure manual revealed the laboratory did not have detailed policies and procedures for the following: Proficiency Testing (PT): a) Ordering and ensuring

	that you are enrolled for Proficiency Testing. b) What to do when you receive samples from the PT Provider. c) How to handle the samples; who will test, when to test, how do you assure no inter and intra laboratory communication takes place d) How to record results to send into the PT Provider to be scored. e) What records to maintain. f) How to evaluate when you receive your scores from the PT Provider. g) What steps to take if corrective action is needed. h) What steps are required when the laboratory has their first and second two (2) out of three (3) failures. Quality Control policies and procedures to include establishing of means and ranges for quality control material, to include but not limited to: How to establish ranges for quality control material and/or verification of quality control material; who is to monitor and how changes are to be made to the ranges of quality control material; and that the correct means and ranges are available to testing personnel. Also to include what quality control is required for each instrument and what the acceptability criteria is for all. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. Reference intervals (normal values). Imminently life-threatening test results, or panic or alert values. 2. Interview with personnel 3 on August 6, 2018 confirmed the laboratory failed to have a complete policy and procedure manual.
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 observation, record review, and interview with personnel, the Technical Consultants failed to meet the qualifications and provide technical oversight of the laboratory. Findings: 1. The laboratory failed to maintain documentation of Technical Consultant qualifications for two (2) of three (3) Technical Consultants. Refer to D6035. 2. The Technical Consultant failed to provide technical and scientific oversight for the laboratory. Refer to D6036.
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 personnel records and interview with personnel, the laboratory failed to maintain documentation of Technical Consultant qualifications for two (2) of three (3) Technical Consultants. Findings: 1. Review of personnel records revealed the laboratory failed to maintain: a) For Personnel 3: the laboratory failed to maintain documentation of 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. b) For Personnel 4: the laboratory failed to maintain documentation of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and 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. 2. Interview with Personnel 3 on August 6, 2018 confirmed the laboratory failed to maintain documentation of education, and experience for both Personnel 3 and 4.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight for the laboratory. Findings: 1. Review of the FORM CMS 209 submitted to the surveyor on August 6, 2018 revealed that personnel 1, 3 and 4 fulfilled the duties for Technical Consultant. 2. Observation, record review and interview with personnel revealed the Technical Consultant failed to address the following problems identified in the laboratory: a) The laboratory failed to maintain a complete policy and procedure manual. Refer to D5401 and D5403. b) The laboratory failed to ensure that Direct Check Whole Blood Control for Hemochron Microcoagulation Systems for ACT testing is not used beyond their expiration dates. Refer to D5417. c) The laboratory failed to verify performance specifications for the two (2) Hemochron Signature Elite Analyzer for Activated Clotting Time (ACT) testing. Refer to D5421. d) The laboratory failed to

	establish means and ranges for Quality Control (QC) material used for the Hemochron Signature Elite Analyzer for Activated Clotting Time (ACT) testing as required by the manufacturer for eight (8) of eight (8) lots of quality control material. Refer to D5469. e) The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for Activated Clotting Time (ACT) performed on the Hemochron Signature Elite Analyzer, for two (2) of two (2) patients reviewed. Refer to D5545. f) The laboratory has a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory; however, the monitors failed to identify any of the deficiencies identified with the analytic systems. Refer to D5793. 3. Interview with personnel 3 on August 6, 2007 confirmed the laboratory failed to identify the deficiency cited above.
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 record review and interview with laboratory personnel, the laboratory failed to ensure testing personnel met the qualifications of education and licensure to perform moderate complexity testing. Findings: 1) The laboratory failed to provide documentation that testing personnel met the educational qualifications for performing moderate complexity testing for two (2) of seven (7) testing personnel. Refer to tag D6065. 2) Interview with Personnel 3 on August 6, 2018 confirmed the above findings
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 record review and interview with personnel, the laboratory failed to provide documentation that testing personnel met the educational qualifications for performing moderate complexity testing for two (2) of seven (7) testing personnel. Findings: 1. Review of personnel records on August 6, 2018 revealed the laboratory failed to maintain documentation of at least a High School Diploma or equivalent for moderate complexity laboratory testing for Personnel 5, and 10. 2. Interview with Personnel 3 on August 6, 2018 confirmed the laboratory failed to maintain

	documentation of the highest level of education for personnel 5, and 10 as indicated above.