Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1107364	10/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Fayetteville Heart Center, Pc	2301 Robeson Street, Suite 301, Fayetteville, NC	

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	A scheduled initial survey was conducted 10/9/19 at Fayetteville Heart Center, PC. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Clinical Laboratories. Based on survey findings, an Immediate Jeopardy situation was identified. The laboratory was notified at approximately 1:15 p.m. 10/9/19. The laboratory failed to validate the performance specifications of the ACT analyzer in use before beginning patient testing and had not performed quality control for the ACT testing performed since April of 2017. The following Conditions were not met: D5024-Hematology 493.1215 D6000-Laboratories performing moderate complexity testing; laboratory director 493.1403
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 review of laboratory records, review of operator's manual, review of manufacturer's instructions (package inserts), and interviews with testing personnel number one (TP #1) and laboratory owner 10/9/19, the laboratory failed to meet all specified requirements for the performance of activated clotting time (ACT) testing in the speciality of Hematology. Findings: The laboratory performs ACT testing on the Hemochron Signature Elite analyzer using Low Range Activated Clotting Time (ACT-LR) cuvettes. The laboratory began testing in April of 2017. 1. The laboratory failed to have a complete and current procedure manual. See D5403. 2. The laboratory failed to define, monitor and document essential storage conditions for reagents and essential temperature conditions for the operation of the Hemochron Signature Elite analyzer. See D5413. 3. The laboratory failed to establish and verify performance specifications for the ACT testing on the Hemochron Signature Elite analyzer. See

	D5421. 4. The laboratory failed to perform and document calibration verifications every 6 months as required for the ACT testing performed. See D5439. 5. The laboratory failed to establish quality control procedures, and failed to perform and document quality control for the ACT testing performed as required. See D5545. Based on TP #1 and laboratory owner interviews, the laboratory performs ACT testing during peripheral angiogram procedures. The facility performs the peripheral angiogram procedures two days a week, two patients a day for a total of approximately 16 patients a month. Total number of patients tested since April of 2017 until time of survey, 30 months, is approximately 480 patients.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory records, review of testing personnel (TP) records, and interview with TP #1 10/9/19, the laboratory failed to establish competency policies and procedures that meet the regulations as stated in section 493.1413(b)(8) of the 42 CFR Part 493 Requirements for Laboratories. Section 493.1413(b)(8) states: "The procedures for evaluation of the competency of the staff (testing personnel) must include, but are not limited to.... Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; Monitoring the recording and reporting of test results; Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; Direct observation of performance of instrument maintenance and function checks; Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and Assessment of problem solving skills; Review of laboratory records revealed no competency procedures for the assessment of TP. Review of TP records revealed no competency records were available for previous TP. TP#1 had started employment in May of 2019 and has not had a competency assessment at time of survey. Interview with TP #1 at approximately 10:45 a.m. confirmed she began employment in May of 2019.
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 laboratory records and interview with TP #1 and laboratory owner 10/9/19, the laboratory failed to verify the accuracy of the ACT testing as least twice annually. Findings: Review of laboratory records revealed no documentation that the laboratory had verified the accuracy of the ACT testing at least twice annually since testing began in April of 2017 until time of survey, a period of approximately 30 months in which verification of accuracy had not been performed. Interview with TP #1 at approximately 12:45 p.m. confirmed the laboratory had not performed a

	verification of the accuracy of the ACT testing. She stated she began employment in May of 2019 and had been unable to find any record documenting a performance of a verification of accuracy and was unaware that it was required until preparing for the survey. Interview with laboratory owner at approximately 2:00 p.m. confirmed the laboratory began testing on the Hemochron Signature Elite analyzer in April of 2017.
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 laboratory records, review of operator's manual and interview with TP #1 10/9/19, the laboratory failed to have a complete and current procedure manual for the ACT testing performed. Findings: The surveyor obtained a copy of the operator's manual via manufacturer's website. A package insert for the ACT-LR cuvettes used for the ACT testing was obtained from a box of cuvettes by TP #1 at time of survey. 1. Review of laboratory records revealed a copy of the operator's manual for the "Hemochron Models 801 and 401", there was no current procedure or operator's manual for the Hemochron Signature Elite analyzer in use since April of 2017. Interview with TP #1 at approximately 10:45 a.m. confirmed the operator's manual was for the Hemochron Models 801 and 401 and not for the Hemochron Signature Elite analyzer in use. She stated she was unaware that the operator's manual was not for the current analyzer. 2. Review of laboratory records revealed the laboratory failed to have the following procedures and or policies for performance of the ACT test on the Hemochron Signature Elite analyzer: a. A procedure describing specimen collection, labeling and the criteria used to determine specimen acceptability and rejection. b. A step-by-step procedure for the performance of the ACT test on the Hemochron Signature Elite analyzer including the interpretation of results. c. A procedure for the preparation of calibrators, controls, and reagents (cuvettes) used for testing. d. A calibration verification procedure to include what type of reagent is used for calibration verification, the frequency of calibration verification and the criteria used to determine if calibration is acceptable. e. A quality control (QC) procedure to include the type of QC used, the levels of QC to use, the frequency of QC, how QC is documented, and the criteria used to determine if QC is acceptable. f. A procedure for the corrective action to take if calibration or QC results fail to meet

	the laboratory's criteria for acceptability. g. A procedure for entering results in the patient record and reporting results including the protocol for reporting imminently life threatening results, panic and/or alert values. h.. A procedure for the course of action to take if the Hemochron Signature Elite analyzer becomes inoperable. i.. The reportable range for ACT test results established and/or verified by the laboratory. j. The reference intervals (normal values) for the ACT test. k. The imminently life-threatening test results, or panic or alert values established by the laboratory for the ACT test.
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 operator's manual, review of manufacturer's package insert, review of laboratory records and interview with TP #1 10/9/19, the laboratory failed to define, monitor and document the conditions essential for proper storage of ACT-LR cuvettes for the ACT testing, and failed to define, monitor and document the conditions essential for accurate and reliable testing for the Hemochron Signature Elite analyzer. Findings: 1. Review of operator's manual for the Hemochron Signature Elite analyzer revealed the specifications for the operating environment to be 15 degrees celsius (C) to 30 degrees C. Review of laboratory records revealed no documentation of the monitoring of the operating environment temperature when performing patient testing on the ACT analyzer. Interview with TP #1 at approximately 1:00 p.m. confirmed the laboratory had not monitored or documented the operating environment temperature when performing the ACT test. She stated she was unaware that it was required. 2. Review of package insert for the ACT-LR cuvettes revealed under section "Storage and Stability". "When refrigerated (2-8 degrees C), the foil pouched ACT-LR cuvettes are stable until the marked expiration date." Review of laboratory records revealed no documentation of the monitoring of the refrigerator temperatures in which the ACT-LR cuvettes were stored. Interview with TP #1 at approximately 1:00 p.m. confirmed the laboratory was storing the ACT-LR cuvettes in the refrigerator, but they had not been monitoring or recording the refrigerator temperatures. She also stated the facility did not have a thermometer in the refrigerator where the ACT-LR cuvettes are stored.
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 laboratory records and interview with TP #1 and laboratory owner 10/9/19, the laboratory failed to establish and verify the performance specifications for the activated clotting time (ACT) testing on the Hemochron Signature Elite analyzer before reporting patient test results. Findings: The laboratory performs ACT testing on the Hemochron Signature Elite analyzer using the ACT-LR cuvettes. The laboratory began testing on the Hemochron Signature Elite analyzer in April of 2017. The laboratory performs ACT testing during peripheral angiogram procedures. The laboratory performs performs peripheral angiograms two days a week, two patients per day for a total of approximately 16 patients a month. Total number of patients tested since April of 2017 until time of survey, 30 months, is approximately 480 patients. Review of laboratory records revealed no documentation that the laboratory had established or verified the following performance specifications for the ACT testing performed on the Hemochron Signature Elite analyzer before patient testing began in April of 2017. a. Accuracy b. Precision c. Reportable range of test results for the test system. d. Reference intervals (normal values) are appropriate for the laboratory's patient population. Interview with TP #1 at approximately 1:15 p.m. confirmed the laboratory performs ACT testing during peripheral angiogram procedures two days a week, two patients a day. Interview with laboratory owner at approximately 2:00 p.m. confirmed the laboratory had not established or verified the performance specifications for the ACT testing on the analyzer before reporting patient test results. He also confirmed that the laboratory began testing on the analyzer in April of 2017.
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 review of operator's manual, review of manufacturer's instructions and

	review of laboratory records 10/9/19, the laboratory failed to perform and document calibration verifications every 6 months for the ACT testing performed. Findings: Review of operator's manual for the Hemochron Signature Elite analyzer and review of manufacturer's instructions (package insert) for the ACT-LR cuvette revealed no manufacturer requirements for calibration verification. Review of laboratory records revealed the laboratory had no documentation of the performance of calibration verifications for the ACT testing performed since testing began in April of 2017 until time of survey, a period of approximately 30 months is which calibration verification was not performed.
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 review of operator's manual, review of manufacturer's instructions, review of laboratory records and interviews with TP #1 and laboratory owner 10/9/19, the laboratory failed to perform and document quality control (QC) using the number and frequency specified by the manufacturer and as required for the ACT testing performed. Findings: The laboratory performs ACT testing on the Hemochron Signature Elite analyzer using ACT-LR cuvettes. The laboratory began testing on the Hemochron Signature Elite analyzer in April of 2017. The laboratory performs the ACT testing during peripheral angiograms procedures, two days a week, two patients per day for a total of approximately 16 patients a month. Total number of patients tested since April of 2017 until time of survey, 30 months, is approximately 480 patients. Review of operator's manual for the Hemochron Signature Elite analyzer revealed "QC of Instrument Performance...The instrument should be tested at two levels once every eight hours of operation." Review of manufacturer's instructions (package insert) for the ACT-LR cuvette revealed "Quality Control (QC)...Daily QC of the Instrument...The Hemochron Jr. should be quality controlled at two levels of control once every 8 hours of operation...QC of the Hemochron Jr. Test Cuvettes... Each lot of Hemochron Jr. ACT-LR cuvettes should be validated for performance at two liquid quality control levels:...When a new shipment is received, AND...Once per 30 calendar days thereafter." Review of laboratory records revealed no documentation for the performance of QC as required since time testing began in April of 2017 until time of survey, a period of approximately 30 months in which approximately 480 patients were tested. Interview with TP #1 at approximately 12:00 p.m. confirmed the laboratory had no documentation for the performance of QC. She stated she was unaware that QC was supposed to be performed for the ACT testing until one month ago when she found one level of QC reagent in the refrigerator. She stated she had recently ordered the second level of QC reagent needed, but they had not started running the QC yet and had continued testing on the analyzer. Interview with TP #1 at approximately 1:15 p.m. confirmed the laboratory performs ACT testing during peripheral angiogram procedures two days a week, two patients per day. Interview with laboratory owner at approximately 2:00 p.m. confirmed the laboratory began testing on the Hemochron Signature Elite analyzer in April of 2017.
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 laboratory procedures, review of laboratory records and interviews with TP#1 and laboratory owner 10/9/19, the laboratory director failed to provide overall management and direction for the laboratory services provided. Findings: The laboratory performs activated clotting time (ACT) testing on the Hemochron Signature Elite analyzer using the Low Range Activated Clotting Time (ACT-LR) cuvettes. The laboratory began testing in April of 2017. The laboratory performs ACT testing during peripheral angiogram procedures. The laboratory performs performs peripheral angiograms two days a week, two patients per day for a total of approximately 16 patients a month. Total number of patients tested since April of 2017 until time of survey, 30 months, is approximately 480 patients. 1. The laboratory director failed to establish performance verification procedures required for the ACT testing performed. See D6013. 2. The laboratory director failed to ensure a quality control program was established and maintained to assure the quality of the ACT testing performed. See D6020. 3. The laboratory director failed to ensure quality assessment policies and procedures were established to identify and correct problems within the laboratory system. See D6021. 4. The laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for the ACT testing performed. See D6023. 5. The laboratory director failed to ensure TP #1 was properly trained before she began testing on the Hemochron Signature Elite analyzer. See D6029. 6. The laboratory director failed to ensure competency policies and procedure were established. See D6030. 7. The laboratory director failed to ensure a complete and current procedure manual, approved by the laboratory director, was available to TP. See 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 review of laboratory records and interview with TP#1 and laboratory owner 10/9/19, the laboratory director failed to ensure performance verification procedures were established and adequate to determine the accuracy and precision of the activated clotting time (ACT) testing on the Hemochron Signature Elite analyzer before reporting patient test results. Findings: 1. Review of laboratory records revealed the laboratory director had not established performance verification procedures for the following: a. The laboratory director failed to establish a performance verification procedure required to determine the biannual accuracy of the

	ACT testing by either establishing a performance verification procedure or by enrolling in a proficiency testing program. See D5217. b. The laboratory director failed to establish a performance verification procedure required to determine the accuracy and precision of the Hemochron Signature Elite analyzer and to determine the reportable range and normal values of the ACT testing before reporting patient test results. See D5421. c. The laboratory director failed to establish calibration verification procedures required to verify the biannual calibration of the Hemochron Signature Elite analyzer. See D5439.
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 operator's manual, review of manufacturer's instructions, review of laboratory records and interviews with TP #1 and laboratory owner 10/9/19, the laboratory director (LD) failed to ensure a quality control (QC) program was established and maintained to assure the quality of the activated clotting time (ACT) testing performed. Findings: See 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 review of laboratory records and lack of quality assessment documentation 10/9/19, the laboratory director failed to ensure quality assessment policies and procedures were established to assure the quality of the laboratory services provided. Findings: Review of laboratory records revealed no quality assessment procedures were established for the pre-analytical, analytical and post-analytical assessment of the laboratory services provided. For example, there was no quality assessment procedures to assess if testing personnel were properly trained, if quality control was being performed as required and within range before testing, if calibrations were being performed, if temperatures were being monitored, it patient test results correlated to the patient's clinical condition, and if the patient test results were being entered correctly into the patients medical record. Review of laboratory records revealed no documentation that quality assessments were performed for pre-analytical, analytical and post-analytical laboratory services from the time testing began in April of 2017 until time of survey, a period of approximately 30 months.

D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews with TP #1 and laboratory owner 10/9/19, the laboratory director failed to ensure the establishment and the maintenance of acceptable levels of analytical performance for the ACT testing performed. Findings: 1. The laboratory director failed to ensure bi-annual verifications were performed and documented to verify the accuracy of the ACT testing performed. See D5217. 2. The laboratory director failed to ensure performance verifications were performed and documented before patient testing began. See D5421. 3. The laboratory director failed to ensure bi-annual calibration verifications were performed and documented as required. See D5439. 4. The laboratory director failed to ensure quality control was performed and documented as required. See D5545. 5. The laboratory director failed to ensure acceptable temperature ranges were monitored and documented for the performance of the ACT testing as required. See D5413.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with TP #1 10/9/19, the laboratory director failed to ensure TP #1 received the appropriate training for the ACT testing performed on the Hemochron Signature Elite analyzer before TP #1 began patient testing. Findings: Review of laboratory records revealed no training documentation for TP #1. Interview with TP #1 at approximately 9:30 a.m. confirmed TP #1 had no training documentation, she stated she had previously performed ACT testing at another facility, but had never received any additional training in regards to the maintenance and quality control that was also required. She stated she had been in contact with the nearby hospital in preparation for the upcoming survey, and it was then that she realized many requirements for performing the ACT testing were not being met.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of laboratory records, review of TP records, and interview with TP #1 10/9/19, the laboratory director failed to ensure the establishment of competency policies and procedures that meet the regulations as stated in section 493.1413(b)(8) of the 42 CFR Part 493 Requirements for Laboratories to assure TP are competent, maintain their competency and can identify needs for remedial training or continuing education to improve skills. Findings: Review of laboratory records and review of TP competency records revealed no policies or procedures had been established for the assessment of TP competency for the activated clotting time (ACT) testing performed. See D5209.
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 review of laboratory records, review of operator's manual and interview with TP #1 10/9/19, the laboratory director failed to have a complete and current procedure manual for the ACT testing performed that was approved, signed, dated by the laboratory director and available to all personnel responsible for any aspect of the ACT testing process. Findings: 1. Review of laboratory records revealed a copy of the operator's manual for the "Hemochron Models 801 and 401", there was no operator's manual approved, signed and dated by the current laboratory director for the Hemochron Signature Elite analyzer in use. The operator's manual for the "Hemochron Models 801 and 401" was also not approved, signed and dated by the current laboratory director. Interview with laboratory owner at approximately 2:00 p. m. confirmed the laboratory began testing on the Hemochron Signature Elite analyzer in April of 2017. 2. Review of laboratory records revealed no documentation a complete and current procedure manual was available to all personnel responsible for any aspect of the ACT testing process. See D5403.