Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1075467	03/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Carient Heart & Vascular	415 Church Street Ne, Suite 203, Vienna, VA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced initial CLIA survey was conducted at Carient Heart & Vascular on March 14, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. During the course of the initial survey, Immediate Jeopardy (IJ) was identified. The Immediate Jeopardy was removed when Carient Heart & Vascular voluntarily ceased testing in the specialty of Hematology. The laboratory was not in compliance with the following 42 CFR part 493 CLIA CONDITION Regulations: D2000 - 42 C.F.R. 493-801 Condition: Enrollment and testing of samples, D5400 - 42 C.F.R. 493-1250 Condition: Analytic Systems-Immediate Jeopardy; D6000 - 42 C.F. R. 493-1403 Condition: Moderate Complexity, Laboratory Director-Immediate Jeopardy, and D6063 - 42 C.F.R. 493-1421 Condition: Moderate Complexity, Testing Personnel. Specific deficiencies cited are as follows.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of instrument and patient records, lack of documentation and interviews, the laboratory failed to enroll in a Proficiency Testing (PT) program for Activated Clotting Time (ACT) from August 10, 2022 until the date of the survey on March 14, 2023. Findings include: 1. During an entrance interview with the Clinical

	Manager (CM) on March 14, 2023 at approximately 11:05 AM, the CM stated the laboratory uses the Hemochron Signature Elite Whole Blood Microcoagulation System to perform Low Range Activated Clotting Time (ACT-LR) on patient specimens during procedures. The surveyor inquired when the laboratory began patient testing. The CM stated they started working at the facility in October 2022 and the laboratory was using the Hemochron ACT for patients at that time. 2. Review of the Hemochron Signature Elite instrument (serial number 21354 7/31/2021) database revealed the first patient specimen ACT results recorded were on August 10, 2022. 3. A review of the laboratory's records revealed a lack of documentation of PT testing enrollment for ACT from August 10, 2022 until the date of the survey on March 14, 2023. During an interview with the Clinical Manager on March 14, 2023 at approximately 2:00 PM, the surveyor requested documentation of the laboratory's enrollment in a PT program from August 2022 until March 14, 2023. The laboratory provided no proof of enrollment for the surveyor to review. 4. In exit interviews with the Laboratory Director on March 14, 2023 at approximately 3:00 PM and Clinical Manager on March 14, 2023 at approximately 3:30 PM, the findings were confirmed.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a tour, review of the laboratory's policies and procedures, laboratory records, instrument records, patient records, lack of documentation and interviews, the laboratory failed to: 1. include in their Low Range Activated Clotting Time (ACT-LR) procedure requirements for specimen labeling, criteria for acceptability and rejection, preparation of quality control materials, interpretation of results, reportable range, quality control procedures (QC), corrective action to take when QC results fail to meet laboratory criteria for acceptability, limitations of methodology, reference ranges, critical values, system for reporting results and actions to take when the ACT test is unavailable on the Hemochron Signature Elite Whole Blood Microcoagualtion System (see D5403); 2. obtain review and approval of the laboratory's policy and procedure manual by the laboratory director prior to testing of patients on August 10, 2022 until the date of the survey on March 14, 2023 (D5407); 3. monitor and document the room temperature (RT) where the Hemochron Elite was operated from August 10, 2022 until the date of the survey on March 14, 2023 (see D5411); 4. monitor the refrigerator temperature to ensure manufacturer's storage requirements were followed for quality control (QC) materials utilized for Low Range Activated Clotting Time (ACT-LR) patient testing from August 10, 2022 until the date of the survey on March 14, 2023 (see D5413); 5. ensure that two (2) of 2 "directCheck Whole Blood Control" boxes stored in the laboratory for use with the Hemochron Signature Elite Whole Blood Microcoagualtion System were within the manufacturer's expiration dates as observed on the date of the survey on March 14, 2023 (see D5417); 6. verify the manufacturer's performance specifications of the Low-Range Activated Clotting Time (ACT-LR) test prior to reporting two-hundred forty-seven (247) patient results from August 10, 2022 until the date of the survey on

	March 14, 2023 (see D5421); 7. perform at least two levels of external QC materials every eight (8) hours for the Low Range Activated Clotting Time (ACT-LR) test from August 10, 2022 until the date of the survey on March 14, 2023 while reporting two-hundred forty-seven (247) patient results (see D5545); 8. establish and follow a written policy to identify and address analytic issues in order to monitor, assess and correct problems in the speciality of Hematology from August 10, 2022 until the date of the survey on March 14, 2023 (see D5791); 9. include the unit of measurement (UOM) for 3 of 3 ACT-LR test results reviewed (see D5805); and 10. include reference intervals for 3 of 3 ACT test results reviewed (see D5807).
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 a review of instrument records and the laboratory's policy and procedure manual, and interviews, the laboratory's procedure at the time of the survey on 3/14 /23 for Activate Clotting Time (ACT) failed to include: requirements for specimen labeling, criteria for acceptability and rejection, preparation of quality control materials, interpretation of results, reportable range, quality control procedures (QC), corrective action to take when QC results fail to meet laboratory criteria for acceptability, methodology limitations, reference ranges, critical values, system for reporting results and actions to take when the ACT test is unavailable on the Hemochron Signature Elite Whole Blood Microcoagualtion System. The findings include: 1. During an entrance interview with the Clinical Manager (CM) on March 14, 2023 at approximately 11:05 AM, the CM stated the laboratory uses the Hemochron Signature Elite Whole Blood Microcoagulation System to perform Low Range Activated Clotting Time (ACT-LR) on patient specimens during procedures. The surveyor inquired when the laboratory began patient testing. The CM stated they started working at the facility in October 2022 and the laboratory was using the Hemochron ACT for patients at that time. 2. Review of the Hemochron Signature Elite instrument (serial number 21354 7/31/2021) database revealed the first patient specimen ACT results recorded were on August 10, 2022. 3. Review of the laboratory's policies and procedures revealed a procedure, "Activated Clotting Time Workflow", for ACTs performed on the Hemochron Signature Elite which lacked

	documentation of the following: Requirements for specimen labeling, criteria for acceptability and rejection; Preparation of QC materials; Interpretation of results; Reportable range; QC procedures to include number, type and frequency, criteria to determine acceptable control results and corrective actions to take when QC is unacceptable; Limitations of the ACT method; Reference ranges; Critical values; System for reporting results, and What to do if ACT method is unavailable. The surveyor requested to review documentation of the procedure requirements outlined above. The laboratory provided no documentation for review. 4. In exit interviews with the Laboratory Director on March 14, 2023 at approximately 3:00 PM and Clinical Manager on March 14, 2023 at approximately 3:30 PM, the findings were confirmed.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, instrument records and interviews, the laboratory failed to document lab director review and approval of the laboratory's policy and procedure manual prior to testing of patients on August 10, 2022 until the date of the survey on March 14, 2023. The findings include: 1. During an entrance interview with the Clinical Manager (CM) on March 14, 2023 at approximately 11:05 AM, the CM stated the laboratory uses the Hemochron Signature Elite Whole Blood Microcoagulation System to perform Low Range Activated Clotting Time (ACT-LR) on patient specimens during procedures. The surveyor inquired when the laboratory began patient testing. The CM stated they started working at the facility in October 2022 and the laboratory was using the Hemochron ACT for patients at that time. 2. The surveyor requested to review the procedure for the Hemochron Signature Elite Whole Blood Microcoagulation System ACT-LR test. The laboratory provided a document titled, "Activated Clotting Time Workflow." Review of the document revealed a lack of documentation of the the laboratory director's (LD) review and approval of the ACT procedure. The surveyor requested to review documentation of the LD's review and approval. The laboratory provided no documentation for review. 3. Review of the Hemochron Signature Elite instrument (serial number 21354 7/31/2021) database revealed the first patient specimen ACT results recorded were on August 10, 2022. 4. In an exit interview with the Laboratory Director (LD) on March 14, 2023 at approximately 3:00 PM, the findings were confirmed. During the exit interview, the LD stated they did not know they were the LD. In an exit interview with the Clinical Manager on March 14, 2023 at approximately 3:30 PM, the findings were confirmed.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on a review of laboratory records, manufacturer's requirements, lack of documentation and interviews, the laboratory failed to monitor and document the room temperature (RT) where the Hemochron Elite was operated from August 10, 2022 until the date of the survey on March 14, 2023. The findings include: 1. During an entrance interview with the Clinical Manager (CM) on March 14, 2023 at approximately 11:05 AM, the CM stated the laboratory uses the Hemochron Signature Elite Whole Blood Microcoagulation System to perform Low Range Activated Clotting Time (ACT-LR) on patient specimens during procedures. The surveyor inquired when the laboratory began patient testing. The CM stated they started working at the facility in October 2022 and the laboratory was using the Hemochron ACT for patients at that time. 2. Review of the Hemochron Signature Elite instrument (serial number 21354 7/31/2021) database revealed the first patient specimen ACT results recorded were on August 10, 2022. 3. Review of the Hemochron Signature Elite's Operator Manual revealed a manufacturer defined "Operating Environment" temperature of 15 degrees Celsius to 30 degrees Celsius. The surveyor requested to review documentation of the room temperature where the Hemochron Signature Elite was operated from August 10, 2022 until March 14, 2023. The laboratory provided no documentation to review. 4. In exit interviews with the Laboratory Director on March 14, 2023 at approximately 3:00 PM and Clinical Manager on March 14, 2023 at approximately 3:30 PM, the findings were confirmed.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a tour, manufacturer's user guide/package inserts, lack of documentation and interviews, the laboratory failed to monitor the refrigerator temperature to ensure manufacturer's storage requirements were followed for quality control (QC) materials utilized for Low Range Activated Clotting Time (ACT-LR) patient testing from August 10, 2022 until the date of the survey on March 14, 2023. The findings include: 1. During an entrance interview with the Clinical Manager (CM) on March 14, 2023 at approximately 11:05 AM, the CM stated the laboratory uses the Hemochron Signature Elite Whole Blood Microcoagulation System to perform Low Range Activated Clotting Time (ACT-LR) on patient specimens during procedures. The surveyor inquired when the laboratory began patient testing. The CM stated they started working at the facility in October 2022 and the laboratory was using the Hemochron ACT for patients at that time. 2. Review of the Hemochron Signature Elite instrument (serial number 21354 7/31/2021) database revealed the first patient specimen ACT results recorded were on August 10, 2022. 3. During a tour of the laboratory on March 14, 2023 at approximately 12:30 PM, the surveyor noted two boxes of "directCheck Whole Blood Control" vials stored in a refrigerator in the laboratory. The Clinical Manager (CM) stated the controls were for use with the ACT-LR testing. The surveyor noted no external or internal thermometer in the refrigerator.

	The surveyor inquired regarding the laboratory's protocol for recording refrigerator temperatures. The Clinical Manager stated, "We should be taking temperature." The surveyor requested to review documentation of the temperatures of the laboratory refrigerator from August 10, 2022 until the date of the survey on March 14, 2023. The laboratory provided no documentation of the refrigerator temperatures to review. 4. Review of the "directCheck Whole Blood Control" manufacturer's package insert revealed the following storage requirements: "When refrigerated (2-8C) the vials are stable until the marked expiration date. The quality control product should never be exposed to temperatures in excess of 37C." 5. In exit interviews with the Laboratory Director on March 14, 2023 at approximately 3:00 PM and Clinical Manager on March 14, 2023 at approximately 3:30 PM, the findings were confirmed.
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 a tour, review of manufacturer's user guide/package inserts, and interviews, the laboratory failed to ensure that two (2) of 2 "directCheck Whole Blood Control" boxes stored in the laboratory for use with the Hemochron Signature Elite Whole Blood Microcoagualtion System were within the manufacturer's expiration dates as observed on the date of the survey on March 14, 2023. The findings include: 1. During an entrance interview with the Clinical Manager (CM) on March 14, 2023 at approximately 11:05 AM, the CM stated the laboratory uses the Hemochron Signature Elite Whole Blood Microcoagulation System to perform Low Range Activated Clotting Time (ACT-LR) on patient specimens during procedures. The surveyor inquired when the laboratory began patient testing. The CM stated they started working at the facility in October 2022 and the laboratory was using the Hemochron ACT for patients at that time. 2. Review of the Hemochron Signature Elite instrument (serial number 21354 7/31/2021) database revealed the first patient specimen ACT-LR results were recorded on August 10, 2022. 3. During a tour of the laboratory on March 14, 2023 at approximately 12:30 PM, the surveyor noted two boxes of "directCheck Whole Blood Control" vials stored in the laboratory refrigerator: one box of Lot #G1DLA009 expiration date 9/30/2022 and one box of Lot #J1DLA011 expiration date 10/31/2022. A total of 2 boxes of expired control materials were observed on March 14, 2023. The CM stated the controls were to be used with the ACT-LR test. 4. Review of the manufacturer package insert for the "directCheck Whole Blood Control" vials revealed a statement, "...The marked expiration date must not be exceeded..." 5. In exit interviews with the Laboratory Director on March 14, 2023 at approximately 3:00 PM and Clinical Manager on March 14, 2023 at approximately 3:30 PM, the findings were confirmed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)

	(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the laboratory's records, instrument records, lack of documentation and interviews, the laboratory failed to verify the manufacturer's performance specifications of the Low-Range Activated Clotting Time (ACT-LR) test performed on the Hemochron Signature Elite, prior to reporting two-hundred forty-seven (247) patient results from August 10, 2022 until the date of the survey on March 14, 2023. The findings include: 1. During an entrance interview with the Clinical Manager (CM) on March 14, 2023 at approximately 11:05 AM, the CM stated the laboratory uses the Hemochron Signature Elite Whole Blood Microcoagulation System to perform Low Range Activated Clotting Time (ACT-LR) on patient specimens during procedures. The surveyor inquired when the laboratory began patient testing. The CM stated they started working at the facility in October 2022 and the laboratory was using the Hemochron ACT for patients at that time. 2. Review of the Hemochron Signature Elite instrument (serial number 21354 7/31 /2021) database revealed the first patient specimen ACT-LR results were recorded on August 10, 2022 with 247 patient tests from August 10, 2022 until the date of the survey on March 14, 2023. 3. Review of the laboratory's records revealed a lack of documentation of the verification of the Hemochron Signature Elite Whole Blood Microcoagulation System Low Range Activated Clotting Time (ACT-LR) test's accuracy, precision, reportable range and reportable range prior to the reporting of 247 patients from August 10, 2022 until March 14, 2023. The surveyor requested to review the documentation of the verification of the ACT-LR test prior to patient testing. The laboratory provided no documentation to review. 4. In exit interviews with the Laboratory Director on March 14, 2023 at approximately 3:00 PM and Clinical Manager on March 14, 2023 at approximately 3:30 PM, the findings were confirmed.
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 a review of the CLIA Laboratory Improvement Amendments (CLIA) Application for Certification (CMS-116), instrument records, lack of documentation and interviews, the laboratory failed to perform at least two levels of external QC materials every eight (8) hours for the Low Range Activated Clotting Time (ACT-LR) test from August 10, 2022 until the date of the survey on March 14, 2023 while reporting two-hundred forty-seven (247) patient results. The findings include: 1. During an entrance interview with the Clinical Manager (CM) on March 14, 2023 at approximately 11:05 AM, the CM stated the laboratory uses the Hemochron Signature Elite Whole Blood Microcoagulation System to perform Low Range Activated Clotting Time (ACT-LR) on patient specimens during procedures. The surveyor inquired when the laboratory began patient testing. The CM stated they started

	working at the facility in October 2022 and the laboratory was using the Hemochron ACT for patients at that time. 2. Review of the Hemochron Signature Elite instrument (serial number 21354 7/31/2021) database revealed the first patient specimen ACT-LR results were recorded on August 10, 2022 with 247 patient tests from August 10, 2022 until the date of the survey on March 14, 2023. 3. Review of CMS-116 form revealed hours of operation of the laboratory as follows: Monday 7:00 AM- 12:00 PM (5 hours): Tuesday and Wednesday 7:00 AM to 5:30 PM (10.5 hours each day); and Friday 07:00 AM to 5:30 PM (10.5 hours). 4. Review of the laboratory's records revealed a lack of documentation of the performance of two levels of QC materials every 8 hours each day of patient testing for the Hemochron Signature Elite Whole Blood Microcoagulation System Low Range Activated Clotting Time (ACT-LR) test from August 10, 2022 until March 14, 2023. The surveyor requested to review the documentation of the QC performance from August 10, 2022 until March 14, 2023. The laboratory provided no documentation to review. 5. In an interview with the Clinical Manager (CM) on March 14, 2023 at approximately 12:30 PM, the CM stated, "We can't find any records of the quality control performance. I know we need to perform controls. We have ordered quality controls." 6. In exit interviews with the Laboratory Director on March 14, 2023 at approximately 3:00 PM and Clinical Manager on March 14, 2023 at approximately 3:30 PM, the findings were confirmed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual, lack of documentation, and interviews, the laboratory failed to establish and follow a written policy to identify and address analytic issues in order to monitor, assess and correct problems in the speciality of Hematology from August 10, 2022 until the date of the survey on March 14, 2023. Findings include: 1. Review of the laboratory's "Activated Clotting Time Workflow" revealed no quality assurance (QA) plan to monitor, assess and correct issues within the hematology test procedure. 2. The surveyor requested to review the laboratory's QA protocols for specimen and reagent storage conditions, equipment /instrument/test/system maintenance and function checks, establishment and verification of method performance specifications, review of quality controls, and corrective/remedial action plans. The laboratory provided no documentation for review. 3. In exit interviews with the Laboratory Director on March 14, 2023 at approximately 3:00 PM and Clinical Manager on March 14, 2023 at approximately 3: 30 PM, the findings were confirmed.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units

	of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review three (3) randomly selected patient Low Range Activated Clotting Time (ACT-LR) reports from the electronic medical record (EMR), instrument records, lack of documentation and interviews, the laboratory's hematology report failed to include the unit of measurement (UOM) for 3 of 3 ACT-LR tests reviewed. The findings include: 1. Review of 3 randomly selected patient ACT-LR reports from the NextGen EMR revealed no UOM for the ACT-LR test. 2. Review of the Hemochron Signature Elite instrument (serial number 21354 7/31/2021) database revealed two-hundred forty-seven (247) patient tests from August 10, 2022 until the date of the survey on March 14, 2023. 3. In exit interviews with the Laboratory Director on March 14, 2023 at approximately 3:00 PM and Clinical Manager on March 14, 2023 at approximately 3:30 PM, the findings were confirmed.
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 a review three (3) randomly selected patient Low Range Activated Clotting Time (ACT-LR) reports from the electronic medical record (EMR), lack of documentation and interviews, the laboratory's hematology report failed to include reference intervals for 3 of 3 ACT tests reviewed. The findings include: 1. Review of 3 randomly selected patient ACT-LR reports from the NextGen EMR revealed no reference intervals for the ACT-LR test. 2. Review of the Hemochron Signature Elite instrument (serial number 21354 7/31/2021) database revealed two-hundred forty-seven (247) patient tests from August 10, 2022 until the date of the survey on March 14, 2023. 3. In exit interviews with the Laboratory Director on March 14, 2023 at approximately 3:00 PM and Clinical Manager on March 14, 2023 at approximately 3:30 PM, the findings were confirmed.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a tour, review of the laboratory's policies and procedures, laboratory records, patient records, testing personnel records, lack of documentation, and interviews, the laboratory director failed to ensure: 1. the verification of the accuracy, precision, reportable range and reference ranges of the Low-Range Activated Clotting Time performed on the Hemochron Signature Elite Whole Blood Microcoagulation

	System (See D6013); 2. Proficiency Testing enrollment for Low-Range Activated Clotting Time (ACT-LR) (See D6015); 3. Quality Control (QC) policies and procedures were established and maintained for the Low-Range Activated Clotting Time test from August 10, 2022 until March 14, 2023 (See D6020); 4. the establishment of a quality assessment plan to identify and address analytic issues within the specialty of hematology (See D6021); and 5. documentation of the performance, review, and approval of initial training and competency assessments for two (2) of 2 Testing Personnel prior to patient testing (see 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 a record review, lack of documentation and interviews, the Laboratory Director failed to ensure the verification of the accuracy, precision, reportable range and reference ranges of the Low-Range Activated Clotting Time performed on the Hemochron Signature Elite Whole Blood Microcoagulation System prior to reporting two-hundred forty-seven (247) patient results from August 10, 2022 until the date of the survey on March 14, 2023 (see D5421).
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on a review of laboratory records, lack of documentation, and interviews, the laboratory director failed to ensure Proficiency Testing enrollment for Low-Range Activated Clotting Time (ACT-LR) from August 10, 2022 until the date of the survey on March 14, 2023 (see D2000).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

	director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, instrument records, lack of documentation, and interviews, the Laboratory Director failed to ensure Quality Control (QC) policies and procedures were established and maintained for the Low-Range Activated Clotting Time test from August 10, 2022 until March 14, 2023 (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 a review of the laboratory's policies and procedures, instrument records, lack of documentation and interviews, the laboratory director failed to ensure the establishment of a quality assessment plan to identify and address analytic issues within the specialty of hematology from August 10, 2022 until the date of the survey on March 14, 2023 (See D5791).
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 a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), testing personnel (TP) records, and interviews, the laboratory director (LD) failed to document the performance/review/approval of the initial training and initial competency assessment for two (2) of two TP prior to patient testing. (See Personnel Code Sheet.) The findings include: 1. Review of the CMS 209 form revealed that the LD identified two new testing personnel (TP A and TP B) as responsible for moderate complexity Hematology testing from August 2022 until the date of the survey on March 14, 2023. 2. In an interview with the Clinical Manager (CM) and TP B on March 14, 2023, at approximately 12:10 PM, the CM stated TP A started working at the facility on 12/15/2022 and TP B started on 8/1

	/2022. 3. Review of TP records revealed no evidence of the LD's performance/review /approval of the training and competency assessments for TP A and TP B. The surveyor requested to review documentation of TP A and TP B's training and initial competency. The laboratory provided not documentation for review. 4. In exit interviews with the Laboratory Director on March 14, 2023 at approximately 3:00 PM and Clinical Manager on March 14, 2023 at approximately 3:30 PM, the findings were confirmed.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), testing personnel records, and interviews, the laboratory failed to retain documentation of education qualifications for two of two testing personnel responsible for reporting moderate complexity Low-Range Activated Clotting Time (ACT-LR) patient testing from August 10, 2022 until the date of the survey on March 14, 2023. See D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), personnel records, lack of documentation, and interviews, the laboratory director (LD) failed to retain documentation of education qualifications for two of two testing personnel (TP) from August 10, 2022 until the date of the survey on March 14, 2023. The findings include: 1. Review of the CMS 209 Laboratory Personnel Report revealed that the LD identified 2 TP as qualified to perform moderate complexity ACT-LR testing. 2. Review of the available laboratory personnel records of TP A and TP B for evaluation of education documentation revealed no record of TP A and TP B's education qualifications. See attached Personnel Code Sheet. The surveyor requested to review the education documentation for TP A and TP B. The laboratory provided no documentation to review. 3. In exit interviews with the Laboratory Director on March 14, 2023 at approximately 3:00 PM

	and Clinical Manager on March 14, 2023 at approximately 3:30 PM, the findings were confirmed.