Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2174262	07/30/2021
Name of Provider or Supplier	**Street Address, City, State**	
Desert Cardiovascular Consultants	5785 S Fort Apache Rd Ste A-100, Las Vegas, NV	

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	This Statement of Deficiencies was created as a result of an on-site initial CLIA certification survey conducted at your facility July 30, 2021. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of the 2020 and 2021 American Proficiency Institute (API) proficiency testing (PT) Hematology/Coagulation records for the I-STAT Activated Clotting Time (ACT) test, and an interview with the Cardiac Catheterization Laboratory Charge Nurse, the laboratory failed to retain all of the proficiency testing records for at least two years. Findings include: 1. There were no records of proficiency testing for the API 2020 Hematology/Coagulation testing events One, Two, and Three, and for the API 2021 Hematology/Coagulation event one for the I-STAT ACT test available for review at the time of the survey. 2. Results for the 2020 Hematology/Coagulation testing event One for the I-STAT ACT were retrieved from the API website at the time of the survey. 3. The results and attestations for the 2020 Hematology/Coagulation testing events two and three, and the 2021 Hematology /Coagulation testing event one for the I-STAT ACT could not be retrieved from the API website. The results for those events were not submitted by the laboratory for evaluation. 4. The Cardiac Catheterization Laboratory Charge Nurse confirmed the findings during an interview conducted on July 30, 2021 at approximately 10:00 AM. The laboratory performs approximately 360 hematology tests annually.

D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing (PT) records for the 2020 and 2021 Hematology/Coagulation I-STAT Activated Clotting Time (ACT), and an interview with the Cardiac Catheterization Laboratory Charge Nurse, the laboratory failed to review and evaluate results from proficiency testing programs (refer to D5211), the laboratory failed to establish a mechanism, and failed to document the means used by the laboratory to verify the accuracy of the test for the events in which the laboratory received a zero score for non-participation in the proficiency testing events. (refer to D5215), and the laboratory failed to establish and follow written policies and procedures to monitor, assess, and correct problems identified in the general laboratory systems (refer to D5291).
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the 2020 American Proficiency Institute (API) proficiency testing (PT) Hematology/Coagulation report for the I-STAT Activated Clotting Time (ACT) test retrieved from the API website, a review of the API PT Hematology /Coagulation Event History for the I-STAT ACT 2020 test Events Two and Three, and the 2021 test Event One that was retrieved from the API website, and an interview with the Cardiac Catheterization Laboratory Charge Nurse, the laboratory failed to obtain and review the reports received for the 2020 test Events One, Two and Three, and the 2021 test Event One for the I-STAT ACT test to evaluate the laboratory's performance, and to identify any problems that require corrective action. Findings include: 1. The API 2020 Hematology/Coagulation I-STAT ACT test report for Event One were not reviewed and evaluated for acceptablility prior to the date of the survey. The result report was retrieved from the API website during the survey. 2. The API 2020 Hematology/Coagulation I-STAT ACT test report for Event Two and Event Three, and the API 2021 Hematology/Coagulation I-STAT ACT test report for Event One were not obtained and reviewed prior to the date of the survey. The test reports could not be retrieved from the API website. A review of the Event History revealed that the results were not submitted to API for evaluation, resulting in a score of zero for each event. 3. The findings were confirmed by the Cardiac Catheterization Laboratory Charge Nurse during an interview conducted on July 30, 2021 at approximately 11:00 AM. The laboratory performs approximately 360 hematology tests annually.

D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of the 2020 and 2021 American Proficiency Institute (API) proficiency testing (PT) Hematology/Coagulation Event History for the I-STAT Activated Clotting Time (ACT) test, a review of the laboratory policy and procedure manual, and an interview with the Cardiac Catheterization Laboratory Charge Nurse, the laboratory failed to establish a mechanism and document the means used by the laboratory to verify the accuracy of the I-STAT ACT test for the 2020 testing Events Two and Three, and the 2021 testing Event One in which the laboratory received a score of zero for non-participation for each event. Findings include: 1. A review of the 2020 and 2021 American Proficiency Institute (API) proficiency testing (PT) Hematology/Coagulation Event History that was retrieved from the API website on the day of the survey revealed that the laboratory failed to submit the PT test results for the I-STAT Activated Clotting Time (ACT) test during the 2020 test events two and three, and during the 2021 testing event one. 2. There was no director approved policy and procedure for proficiency testing that established a mechanism for the routine review of the API Hematology/Coagulation proficiency testing results for the I-STAT ACT test to ensure the accuracy of the test. 3. The laboratory failed to review the proficiency testing results for the API Hematology/Coagulation 2020 testing events two and three, and the API Hematology/Coagulation 2021 testing event one, for each of which the laboratory received a zero score for non-participation, and the laboratory failed to document the means by which the laboratory verified the accuracy of the I-STAT ACT test for the test events. 4. The finding was confirmed during an interview with the Cardiac Catheterization Laboratory Charge Nurse that was conducted on July 30, 2021 at approximately 10:30 AM. The laboratory performs approximately 360 hematology tests annually.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of the laboratory policy and procedure manual, a review of the American Proficiency Institute (API) laboratory event history for 2020 and 2021 Hematology/Coagulation I-STAT Activated Clotting Time (ACT) test, and an interview with the Cardiac Catheterization Laboratory Charge Nurse, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and where necessary, correct problems identified in the general laboratory systems requirements. Findings include: 1. There was no

	established policy and procedure to monitor, assess and correct the failure to submit results in the API 2020 Hematology/Coagulation I-STAT ACT test events two and three , and the 2021 Hematology/Coagulation I-Stat ACT test event one. 2. There was no documentation of quality assessment to identify and correct the failure to submit the results for the API 2020 Hematology/Coagulation I-STAT ACT test events two and three, and the 2021 Hematology/Coagulation I-STAT ACT test event one. 3. The findings were confirmed during an interview with the Cardiac Catheterization Laboratory Charge Nurse on July 30, 2021 at approximately 11:00 AM. The laboratory performs approximately 360 hematology tests annually.
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 review of the director approved policy and procedure entitled, "Kaolin Activated Clotting Time," the laboratory failed to monitor and document the established conditions for storage of the I-STAT Activated Clotting Time (ACT) test cartridges and control solutions (refer to D5413), a review of the manufacturer's package insert for the I-STAT ACT Level 2 Control Solution, lot number 27113, and the laboratory quality control log, the laboratory failed to ensure that the control solution was not used beyond the manufacturer's established expiration date (refer to D5417), a review of the I-STAT Operator's Manual, Chapter 14, the laboratory failed to perform function checks with the frequency required by the manufacturer (Refer to D5431), a review of the laboratory I-STAT ACT quality control log, the laboratory failed to verify the stated value of the I-STAT ACT quality controls level one, lot number 261126 and level two, lot number 271126 prior to placing them in use (refer to D5469), a review of the laboratory quality control log, the laboratory failed to perform two levels of quality control solutions every 8 hours of patient testing for the I-STAT ACT test (Refer to D5545), a review of the laboratory temperature logs, the laboratory failed to document corrective action for refrigerator temperature excursions outside the acceptable range established by the manufacturer of the I-STAT ACT test cartridges and control solutions (Refer to D5785), a review of the laboratory policy and procedure manual, the laboratory failed to establish a policy and procedure to monitor, assess, and take corrective action, and to document quality assessment activities to correct failures in the analytic phase of testing (Refer to D5791).
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 review of the director approved procedure entitled "Kaolin Activated Clotting Time" for the I-STAT Activated Clotting Time (ACT) test, a review of the laboratory refrigerator temperature logs between the dates of June, 2020 and July 2021 for the storage of the I-Stat Activated Clotting Time (ACT) test cartridges, observation of I-STAT ACT test cartridge storage conditions, a random patient audit between the dates of January 30, 2020 and July 21, 2021, and an interview with the Cardiac Catheterization Laboratory Charge Nurse, the laboratory failed to monitor and document the conditions for the storage of the ACT test cartridges. Findings include: 1. The director approved procedure entitled "Kaolin Activated Clotting Time" stated in the section entitled, "Preparation and Storage," 'Cartridges in sealed pouches are stable through the expiration date when stored refrigerated at 2-8 degrees Celsius (C), and for up to two weeks at room temperature (18-30 degrees C.).' 2. There were no room temperature logs available for review to ensure that the integrity of the cartridges was maintained during the room temperature storage. 3. Four I-STAT ACT test cartridges were observed in storage on the counter of the laboratory at the time of the survey. 4. A random patient audit between the dates of January 30, 2020 and July 21, 2021 revealed that there were no refrigerator temperature logs available for review for the test dates of January 30, 2020 and March 18, 2020. 5. A review of the refrigerator logs between the dates of June, 2020 and July 2021 revealed that the temperatures were not consistently recorded in either Celsius (C) or Fahrenheit (F) units in order to evaluate acceptability for the refrigerator storage of the I-STAT ACT test cartridges. 6. The findings were confirmed during an interview conducted with the Cardiac Catheterization Laboratory Charge Nurse on July 30, 2021 at approximately 1: 15 PM. The laboratory performs approximately 360 hematology tests annually.
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 review of the laboratory quality control logs for the I-STAT Activated Clotting Time test, and a review of the manufacturer's package insert for the I-STAT Level 2 Activated Clotting Time (ACT) Control solution, lot number 27113, the laboratory failed to ensure that the control solution was not used past the expiration date established by the manufacturer of the control material. Findings include: 1. The manufacturer's package insert for the I-STAT Level 2 ACT Control Solution, lot number 27113 stated that the expiration date was listed as May 31, 2020. 2. The laboratory quality control log obtained at the time of the survey indicated that the I-STAT Level 2 ACT Control Solution, lot number 27113 was used to perform quality control testing on June 23, 2020. The laboratory performs approximately 360 hematology tests annually.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of the I-STAT Operator's Manual, Chapter 14 entitled, "Quality Control," a review of the I-STAT maintenance logs, and an interview with the Cardiac Catheterization Laboratory Charge Nurse, the laboratory failed to ensure that the performance of the I-STAT analyzer was verified through the performance and documentation of the thermal probe check every six months, as required by the manufacturer. Findings include: 1. A review of the I-STAT Operator's Manual, Chapter 14 entitled, "Quality Control" stated, "A quality check is performed on the thermal probes each time the external Electronic Simulator is used. To complete this check, the surface temperature of the external Electronic Simulator must not fluctuate. If this condition is not met, the thermal probe check is not completed. Therefore, I-STAT recommends that the thermal probe check be verified every six months." 2. There were no logs documenting the I-STAT thermal probe checks for the years of 2020 and 2021 available for review at the time of the survey. 3. The findings were confirmed during an interview with the Cardiac Catheterization Laboratory Charge Nurse during an interview conducted on July 30, 2021 at approximately 1:30 PM. The laboratory performs approximately 360 hematology tests 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 a review of the laboratory quality control logs for the I-STAT Activated Clotting Time (ACT) test between the dates of January 24, 2020 and May 11, 2021, and an interview with the Cardiac Catheterization Laboratory Charge Nurse, the laboratory failed to verify the stated values of the commercially assayed control materials for the I-STAT ACT Level One quality control solution, lot number 261126, and the I-STAT ACT Level Two quality control solution, lot number 271126 prior to use. Findings include: 1. The laboratory failed to obtain the manufacturer's package insert for the I-STAT ACT Level One quality control solution, lot number 261126, and the I-STAT ACT Level Two quality control solution, lot number 271126, in order to verify the assay values assigned to the control materials prior to use. The control solutions were placed in use on March 9, 2021. 2. A review of the quality control logs

	revealed that the laboratory continued to use the acceptable ranges established by the manufacturer of the I-STAT ACT Level One quality control solution, lot number 261114, and the I-STAT ACT Level Two quality control solution, lot number 271113 that were no longer in use. 3. The findings were confirmed during an interview with the Cardiac Catheterization Laboratory Charge Nurse that was conducted on July 30, 2021 at approximately 1:45 PM. The laboratory performs approximately 360 hematology tests annually.
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 director approved procedure entitled, "Kaolin Activated Clotting Time," a review of the laboratory quality control records, a random patient audit between the dates of January 30, 2020 and July 21, 2021, and an interview with the Cardiac Catheterization Laboratory Charge Nurse, the laboratory failed to perform two levels of control material during each 8 hours of operation. Findings include: 1. The director approved procedure entitled, "Kaolin Activated Clotting Time" in the section entitled, "Liquid Quality Control," stated, "Two levels of liquid quality control are run on Monday, or the first day of testing for the week." 2. A random patient audit between the dates of January 30, 2020 and July 21, 2021 revealed that the I-STAT ACT quality controls were not performed on the date of patient testing on the dates of May, 28, 2020, May 24, 2021, and July 21, 2021 as required. The dates that the quality control was performed were, respectively, May, 14, 2020, and May 11, 2021. 3. The findings were confirmed during an interview with the Cardiac Catheterization Laboratory Charge Nurse on July 30, 2021 at approximately 1:30 PM. The laboratory performs approximately 360 hematology tests annually.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of the director approved procedure entitled, entitled "Kaolin Activated Clotting Time," a review of the laboratory refrigerator temperature logs, and an interview with the Cardiac Catheterization Laboratory Charge Nurse, the laboratory failed to document corrective action for temperature excursions outside the acceptable ranges for storage of the I-Stat ACT test cartridges and quality control solutions. Findings include: 1. The maximum refrigerator temperatures were outside the acceptable range of 2-8 degrees C or 36-46 degrees F with no documentation of corrective action during the following months: 11 of 15 days in August, 2020, 11 of 16 days in October, 2020, eight of eight days in November 2020, six of nine days in December 2020, six of six days in January and February, 2021, ten of ten days in

	March and April, 2021 12 of 12 days in May, 2021, six of six days in June, 2021, and eight of eight days in July, 2021. The maximum temperature for the dates in August, 2020 was recorded as 22.7 degrees. The maximum temperature recorded for the remaining dates was 23.3 degrees. 2. The minimum refrigerator temperatures were outside the acceptable range of 2-8 degrees C or 36-46 degrees F with no documentation of corrective action during the following months: 11 of 16 days in October, 2020, eight of eight days in November, 2020, nine of nine days in December, 2020, six of six days in January and February 2021, ten of ten days in March and April, 2021, 12 of 12 days in May, 2021, six of six days in June, 2021, and eight of eight days in July, 2021. The minimum temperature for the months of October, 2020 through April, 2021 was recorded as 1.1 degrees. The minimum temperature was recorded as -0.9 degrees on 10 of 12 days in May, 2021, five of six days in June, 2021, and eight of eight days in July, 2021. The minimum temperature was recorded as 0.2 degrees on one of 12 days, and as 1.2 degrees on one of 12 days in May, 2021, -1.1 degrees on one of six days in June, 2021, and as -0.9 degrees on eight of eight days in July, 2021. 3. One of nine maximum refrigerator temperatures recorded was not legible in order to evaluate acceptability for the storage of the I-Stat ACT cartridges during the month of December, 2020. The laboratory performs approximately 360 hematology tests annually.
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 policy and procedure manual, and an interview with the Cardiac Catheterization Laboratory Charge Nurse, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, document, and, when indicated, correct problems identified in the storage of the I-STAT ACT test supplies, the failure to perform the I-STAT analyzer thermal probe checks, the failure to perform two levels of ACT quality control every 8 hours of patient testing, and to verify the assigned values for the I-STAT ACT assayed control solutions. Findings include: 1. There was no director approved policy and procedure to monitor, assess, identify and correct the failures to properly store the I-STAT Activated Clotting Time (ACT) test cartridges and control solutions in accordance with the manufacturer's instructions, and no documentation of quality assessment to correct the failures when they occurred. 2. There was no director approved policy and procedure to monitor, assess, identify and correct the failures to perform the thermal probe checks for the I-STAT analyzer every six months as required by the manufacturer, and no documentation of quality assessment to correct the failures when they occurred. 3. There was no director approved policy and procedure to monitor, assess, identify and correct the failure to perform two levels of quality control every 8 hours of patient testing, and no documentation of quality assessment to correct the failures when they occurred. 4. There was no director approved policy and procedure to monitor, assess, identify and correct the failure to verify the assigned assay values of the I-STAT ACT Level One control solution lot number 261126, and Level two control solution, lot number 271126 prior to placing them in use, no documentation of quality assessment to correct the failures when they

	occurred. 5. The findings were confirmed during an interview with the Cardiac Catheterization Laboratory Charge Nurse conducted on July 30, 2021 at approximately 2:00 PM. The laboratory performs approximately 360 hematology tests annually.
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 review of the American Proficiency Institute (API) proficiency testing (PT) records for the 2020 and 2021 Hematology/Coagulation I-STAT Activated Clotting Time (ACT) testing events and test event histories retrieved from the API website, and a review of the laboratory policy and procedure manual, the director failed to ensure that the PT samples were tested as required (refer to D6016), the director failed to ensure that the PT sample results were returned to API by the established deadlines as required (refer to D6017), the director failed to ensure that the PT reports were received, and that the reports were reviewed by the appropriate staff and that the reports were evaluated to identify problems requiring corrective action (refer to D6018), the director failed to ensure that a corrective action plan was established and followed for the I-STAT ACT PT results that were unacceptable (refer to D6019), and the director failed to ensure that programs of quality control and quality assessment were established and maintained to identify and correct failures in quality as they occurred (refer to D6022).
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing 2020 and 2021 Hematology/Coagulation I-STAT Activated Clotting Time (ACT) event history retrieved from the API website on the date of the survey, the laboratory testing records, a review of the laboratory policy and procedure manual, and an interview with the Cardiac Catheterization Laboratory Charge Nurse, the director failed to ensure that the proficiency testing samples were tested as required. Findings include: 1. A review of the American Proficiency Institute (API) proficiency testing 2020 and 2021 Hematology/Coagulation I-STAT Activated Clotting Time (ACT) event history retrieved from the API website on the day of the survey revealed that the PT testing results for the 2020 Hematology/Coagulation test events two and three, and the 2021 Hematology/Coagulation test Event One were not submitted to API by the deadline established by the proficiency testing agency. 2. There were no records of the

	proficiency testing available for review to determine if the specimens were tested for the 2020 Hematology/Coagulation test events two and three, and the 2021 Hematology /Coagulation test event one. 3. There was no director approved policy and procedure established for the testing of proficiency test samples. 4. The findings were confirmed during an interview conducted with the Cardiac Catheterization Laboratory Charge Nurse on July 30, 2021 at approximately 10:00 AM. The laboratory performs approximately 360 hematology tests annually.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing 2020 and 2021 Hematology/Coagulation event history retrieved from the API website on the date of the survey, a review of the 2020 and 2021 API shipping schedules, a review of the laboratory policy and procedure manual, and an interview with the Cardiac Catheterization Laboratory Charge Nurse, the director failed to ensure that the proficiency testing results were submitted by the deadlines established by the API proficiency testing agency. Findings include: 1. A review of the American Proficiency Institute (API) proficiency testing 2020 and 2021 Hematology/Coagulation event history retrieved from the API website on the day of the survey revealed that the PT testing results for the 2020 Hematology/Coagulation I-STAT Activated Clotting Time (ACT) test events two and three, and the 2021 Hematology/Coagulation test event one results were not submitted to API by the deadline established by the proficiency testing agency. 2. A review of the API 2020 shipping schedule revealed that the 2020 Hematology/Coagulation test event two was shipped on July 6, 2020. A complete 2020 schedule was not available at the time of the survey to determine the deadline for submission of the results to API. 3. A review of the API 2020 shipping schedule revealed that the 2020 Hematology/Coagulation test event three was shipped on November 2, 2020. A complete 2020 schedule was not available at the time of the survey to determine the deadline for submission of the results to API. 4. A review of the API 2021 shipping schedule revealed that the 2021 Hematology/Coagulation test event one was shipped on March 8, 2021. The results for the 2021 Hematology /Coagulation test event one were due by the deadline of March 31, 2021. 5. The findings were confirmed during an interview with the Cardiac Catheterization Laboratory Charge Nurse that was conducted on July 30, 2021 at approximately 10:00 AM. The laboratory performs approximately 360 hematology tests annually.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of the 2020 American Proficiency Institute (API) proficiency testing (PT) Hematology/Coagulation test report for the I-STAT Activated Clotting Time (ACT) test retrieved from the API website, the API PT Hematology /Coagulation Event History for the 2020 test events two and three, and the 2021 test event one that was retrieved from the API website at the time of the survey, and an interview with the Cardiac Catheterization Laboratory Charge Nurse, the director failed to ensure that the reports for the 2020 test events one, two and three, and for the 2021 test event one for the I-STAT ACT test were received and reviewed by the appropriate staff to evaluate the laboratory's performance, and to identify any problems that require corrective action. Findings include: 1. The API 2020 Hematology/Coagulation I-STAT ACT test report for event one were not reviewed and evaluated for acceptablility prior to the date of the survey. The result report was retrieved from the API website during the survey. 2. The API 2020 Hematology /Coagulation I-STAT ACT test report for event two and three, and the API 2021 Hematology/Coagulation I-STAT ACT test report for event one were not reviewed prior to the date of the survey. The test reports could not be retrieved from the website. A review of the Event History revealed that the results were not submitted to API for evaluation, resulting in a score of "0" for each event. 3. The findings were confirmed by the Cardiac Catheterization Laboratory Charge Nurse during an interview conducted on July 30, 2021 at approximately 11:00 AM. The laboratory performs approximately 360 hematology tests annually.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on a review of the laboratory policy and procedure manual, a review of the American Proficiency Institute (API) proficiency testing (PT) Hematology /Coagulation Event History for the 2020 test events two and three, and the 2021 test event one that was retrieved from the API website at the time of the survey, a review of the 2020 and 2021 API Hematology/Coagulation shipping schedules, and an interview with the Cardiac Catheterization Laboratory Charge Nurse, the director failed to ensure that a corrective action plan was established and followed for the I-STAT Activated Clotting Time (ACT) proficiency testing results that were unacceptable. Findings include: 1. There was no director approved policy and procedure established for the testing of proficiency testing samples, and for the performance of corrective action when the proficiency testing results are unacceptable. 2. There was no documentation of corrective action for the failure to submit the proficiency testing results to API for the 2020 Hematology/Coagulation I-

	STAT ACT test events two and three, for each of which the laboratory received a score of zero. The complete 2020 shipping schedule was not available for review to determine the deadlines for submission of the results. 3. There was no documentation of corrective action for the failure to submit the proficiency testing results to API for the 2021 Hematology/Coagulation I-STAT ACT test event one, for which the laboratory received a score of zero. The deadline for the submission of the test results for the 2020 Hematology/Coagulation test event one was March 31, 2021. 4. The findings were confirmed during an interview with the Cardiac Catheterization Laboratory Charge Nurse that was conducted on July 30, 2021 at approximately 11: 00. The laboratory performs approximately 360 hematology tests annually.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of the laboratory policy and procedure manual, the director approved policy and procedure entitled "Kaolin Activated Clotting Time," the laboratory quality control records for the I-STAT Activated Clotting Time (ACT) test, the lack of documentation of quality assessment records, and an interview with the Cardiac Catheterization Laboratory Charge Nurse, the director failed to ensure that the quality control and quality assessment programs were established and maintained to identify failures in quality when the occur. Findings include: 1. There was no director approved quality control policy and procedure established for the performance of two levels of quality control every 8 hours of patient testing as required by the applicable regulations for the I-STAT ACT test. A review of the director approved procedure entitled, "Kaolin Activated Clotting Time" revealed that in the section entitled, "Liquid Quality Control," it was stated, "Two levels of liquid quality control are run on Monday, or the first day of testing for the week." 2. There was no director approved quality assessment program established to monitor, assess, identify and correct failures in the quality of the laboratory testing, and no documentation of quality assessment activities to correct those failures for the I-STAT ACT testing performed by the laboratory. 3. The findings were confirmed during an interview with the Cardiac Catheterization Laboratory Charge Nurse that was conducted on July 30, 2021 at approximately 2:30 PM. The laboratory performs approximately 360 hematology tests annually.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on a review of the laboratory refrigerator temperature logs between the dates of

	June 2020 and July 2021 and the documented corrective action for the storage of the I-STAT Activated Clotting Time (ACT) test cartridges and the quality controls, and an interview with the Cardiac Catheterization Laboratory Charge Nurse, the technical consultant failed to assess the competency of the testing personnel for the ability to trouble shoot and correct problems with monitoring of the refrigerator temperatures. Findings include: 1. The corrective action taken to correct the refrigerator temperature excursions was ineffective to correct the minimum and maximum temperature excusions during the following months: two of two days in June and July, 2020, one of 11 days in August, two of ten days in April, 2021, and seven of 12 days in May, 2021. 2. The corrective action taken to correct the current refrigerator temperatures was ineffective on one of two days on which action was taken in April, 2021. 3. During the survey, the Cardiac Catheterization Charge Nurse changed the battery in the thermometer at approximately 2:00 PM. The Cardiac Catheterization Charge Nurse confirmed that the thermometer appeared to be working properly at the time the survey ended at approximately 4:45 PM. The laboratory performs approximately 360 hematology tests annually.