Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2224858	05/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cardiac And Vascular Interventions Of New Jersey	303 George Street, New Brunswick, NJ	

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
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 lack of Proficiency Testing (PT) records and interview with the Chief Operations Officer (COO), the laboratory failed to enroll in an approved PT program for Routine Chemistry testing from 10/17/20 to the date of survey. The COO confirmed on 05/17/21 at 10:03 am the laboratory was not enrolled in PT testing.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: a) Based on surveyor observation of the lack of a Clinical Laboratory Improvement Amendment (CLIA) Certificate, iStat analyzer and interview with the Chief Operations Officer (COO), the laboratory failed to be in compliance with the Center for Medicaid and Medicare Services (CMS) CLIA regulations. The COO confirmed

	on 5/17/2021 at 10:30 am the laboratory did not have a CLIA certificate and was not in compliance with Federal regulations. b) Based on an in-office review of the laboratory's requirements for a State License, the laboratory failed to obtain a New Jersey State Clinical Laboratory License before the laboratory started patient testing. The Supervisor for the Clinical Laboratory Improvement Services (CLIS) confirmed on 5/21/21 that the laboratory did not obtain its CLIS license before the laboratory started testing.
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 lack of Performance Specifications (PS) records and interview with the Chief Operations Officer (COO), the laboratory failed to verify PS for Chemistry tests performed on the i-Stat analyzer from 10/17/20 to the date of survey. The COO confirmed on 5/17/20 at 10:05 pm that the PS were not performed.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the lack of Quality Control (QC) material and interview with Chief Operations Officer (COO), the laboratory failed to perform and document two levels of controls on each day of patient testing for Chemistry testing performed on the iStat analyzer from 10/17/20 to the date of survey. The findings include: 1. The COO stated "They where not running external controls " . 2. There was no documented evidence two levels of QC were run from 10/17/20 to the date of survey. 3. Approximately 75 patients were run and reported. 4. The COO confirmed on 5/17/21 at 10:30 am that two levels of QC were not performed every day of patient testing.
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 the lack of a Laboratory Director (LD) at the time of survey and interview with Chief Operations Officer (COO), the laboratory failed to have an (LD) who meets the qualification requirements of 493.1405 from 10/17/20 until the date of survey. The COO confirmed at 10:10 am on 5/17/21 the laboratory did not have an LD.
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 the lack of Performance Specification (PS) records and interview with the Chief Operations Officer (COO), the Laboratory Director (LD) failed to ensure that PS procedures for Chemistry tests performed on the iStat analyzer were not adequate from 10/17/20 to the date of survey. The COO confirmed on 5/17/21 at 10:20 am that PS records were not done.
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 the lack Proficiency Testing (PT) records and interview with the Chief Operations Officer (COO), the Laboratory Director (LD) failed to ensure that the laboratory was enrolled in an approved PT program from 10/17/20 to the date of the survey. The COO stated on 5/17/21 at 10:00 am the LD failed to ensure that the laboratory was enrolled in an approved PT program.
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 lack of Quality Control (QC) material, and interview with the Chief Operations Officer (COO), the Laboratory Director (LD) failed to ensure that the established QC program was maintained for laboratory services provided from 10/17 /20 to the date of the survey. The finding includes: 1. The COO stated the laboratory "was not running external controls on the iStat" 2. The COO confirmed on 5/17/21 at 10:30 am the LD did not ensure the QC plan was maintained.
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 lack of a Quality Assessment (QA) program and interview with the Chief Operations Officer (COO), the Laboratory Director failed to ensure that a QA program was established and maintained from 10/17/20 to the date of survey. The COO confirmed on 5/17/21 at 10:05 am that the laboratory did not have a QA program.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on the lack of Quality Control (QC) material and interview with the Chief Operations Officer (COO), the Testing Personnel (TP) failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the on the iStat analyzer analyzer from 10/17/20 to the date of survey. The COO confirmed on 5/17/21 at 10:20 am that trends and shifts were not reviewed.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

	This CONDITION is not met as evidenced by: Based on a interview with the Chief Operations Officer (COO), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from 10/17/20 to the date of the survey. 1. The LD failed to meet the qualification requirements of 493.1405. Cross refer D 6000. 2. The LD failed to ensure that Performance Specification procedures for Chemistry tests performed on the iStat analyzer were completed. Cross refer D 6013. 3. The LD failed to ensure that the laboratory was enrolled in an approved PT program. Cross refer D 6015. 4. The LD failed to ensure that the established Quality Control (QC) program was maintained. Cross refer D 6020. 5. The LD failed to ensure that a Quality Assurance (QA) program was established. Cross refer D 6021 6. The LD failed to identify problems that may affect test performance by not reviewing and evaluating trends and /or shifts. Cross refer D 6074