Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2210184	10/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
National Cardiovascular Associates, Llc	10825 W Mcdowell Rd, Suite 320, Avondale, AZ	

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
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 review of i-Stat test records and interview with the Technical Consultant (TC-1), the laboratory failed to perform and document the electronic simulator check performed on the i-Stat analyzer each day of patient testing. Findings include: 1. The laboratory began performing patient testing using the i-Stat analyzer on 03/23/21 with an annual test volume of 12, 385. 2. The laboratory uses Chem8+, ACT, and PT/INR cartridges for patient testing. The manufacturer's Instructions For Use for the i-Stat state, "Verify the performance of each handheld in the i-STAT 1 System using the internal or external Electronic Simulator every 24 hours of use, or as needed for regulatory compliance." 3. No documentation was presented for review during the survey to indicate the laboratory performed and documented the electronic simulator check on the analyzer prior to testing patients on 11/04/2021 and 08/12/2022. On each of these days, two patients were tested on the i-Stat analyzer. 4. The TC-1 interviewed on 10/19/23 at 10:30 AM confirmed the laboratory failed to have documentation of the electronic simulator check for the dates indicated above.
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 review of the laboratory's quality control (QC) records, lack of QC lot correlation documentation and interview with the Technical Consultant (TC-1), the laboratory failed to verify the criteria for acceptability of quality control materials. Findings include: 1. The laboratory began patient testing using the i-Stat analyzer on 3 /23/21. The reported annual test volume is 12,385. 2. No documentation was presented for review to indicate the laboratory verified the criteria for acceptability of each lot of control material used on the i-Stat from 3/23/21 through the date of the survey on 10/19/23. 3. The laboratory's "Quality Control Log" form states, "To verify the accurate operation of this instrument and test cartridges, two levels of quality control must be tested with values reporting within the manufacturer's acceptable range. These controls must be tested: - At the start of each new lot number or shipment of test cartridges." 4. The TC-1 interviewed on October 19, 2023 at 10:50 AM confirmed the laboratory failed to verify and document the criteria for acceptability of each control lot used on the i-Stat analyzer 5. The number of QC lots used on the analyzer from 3/23/2021 through the date of the survey could not be determined at the time of the survey.
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 review of quality assessment (QA) documentation and interview with the Technical Consultant (TC-1), the laboratory's QA processes failed to monitor, identify and correct errors found in the analytic systems specified in 493.1251 through 493.1283. Findings include: 1. The laboratory began utilizing the i-Stat for patient testing on 03/23/21, with an annual test volume of 12,385. 2. The laboratory performs a quarterly QA review, including a review of the electronic simulator logs for the i-Stat analyzer. The Quality Assessment Review forms presented for review for the time periods of October - December 2021 and April - August of 2022 indicated the Electronic Simulator (internal) was verified each day of patient testing. 3. The laboratory's quarterly QA process referenced above failed to identify errors found with the failure to perform the Electronic Simulator (internal) check on the i-Stat analyzer prior to testing patient specimens each day of testing. See D5431 for

	findings. 4. The TC-1 interviewed on October 19, 2023 at 11:00AM confirmed the laboratory's QA processes failed to identify and correct issues found with the electronic simulator check on the i-Stat.