Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2210544	05/20/2026
Name of Provider or Supplier	**Street Address, City, State**	
National Cardiovascular Surgery Center, Llc	10825 W Mcdowell Rd, Ste 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
D0000	An onsite validation survey was conducted on 05/20/2026. The laboratory was found to be in compliance with condition level deficiencies. The following standard-level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory quality management policy, personnel competency records and an interview with the Technical Consultant #1 (TC1), the laboratory failed to perform competency assessments for two of two TCs. 1. A review of the Quality Management, Training & Competency Assessment, SOP#3, identified the following statement: "Initial training is completed for all technical consultants and includes competency evaluation. Competency assessment is evaluated six months after training and annually thereafter." 2. A review of personnel competency records revealed six-month competency assessments were not performed and documented for TC1 and Technical Consultant #2 (TC2). 3. In an interview on 05/20/2026 at 9:45 AM, TC1 confirmed six-month competency assessments for both TC1 and TC2 were not performed.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 laboratory observation, review of test cartridge manufacturer's Instructions For Use (IFU), room temperature logs, and an interview with the Technical Consultant #1 (TC1), the laboratory failed to record and monitor the room temperature for five of seven days in April 2026. 1. During a tour of Lab 2 Control Room on 05/20/2026 at 11:20 AM, the following i-STAT test cartridges were observed stored in a tray next to the i-STAT instrument: i-STAT CHEM 8+ LOT # H26044 Expiration Date: 2026-08-12 Amended Expiration Date (for room temperature): 6/2/26 Quantity = 2 packets i-STAT Kaolin Activated Clotting Time (ACT) LOT # R26067 Expiration Date: 2026-09-04 Amended Expiration Date (for room temperature): 6/2/26 Quantity = 2 packets 2. A review of the manufacturer's IFUs for the i-STAT test cartridges revealed the following room temperature requirements for storage: iSTAT CHEM 8+ Room Temperature at 18-30C (64-86F). i-STAT Kaolin ACT Room Temperature at 18-30C (64-86F). 3. A review of the room temperature logs for Lab 2 Control Room identified five of seven days in April 2026 where the room temperature was not recorded and monitored. April 2, 2026 April 8, 2026 April 16, 2026 April 21, 2026 April 29, 2026 4. In an interview on 05/20/2026 at 11:15 AM, the TC1 confirmed findings stated above.