Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2233110	07/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
Cardiovascular Lab Of Arizona, Llc	16638 N 90th St, Scottsdale, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records from 2022, 2023 and 2024 and interview with the Technical Consultant (TC-1), the laboratory failed to test PT samples by testing personnel who routinely perform patient testing in the laboratory, using the laboratory's routine methods. Findings include: 1. The laboratory participates in PT for testing performed in the specialty of Chemistry. 2. The CMS-209, Laboratory Personnel Form presented during the survey conducted on July 16, 2024 listed 15 testing personnel who routinely perform patient testing. 3. Review of PT records from 2022, 2023 and 2024 indicated the same testing personnel (TP-1) tested the PT samples during each testing event as evidenced below: 2022-1 - PT samples performed by TP-1 and 1 other TP. 2022-2 - PT samples performed by TP-1 and 2 other TP. 2022-3 - PT samples performed by TP-1 and 2 other TP. 2023-1 - PT samples performed by TP-1 and 3 other TP. 2023-2 - PT samples performed by only TP-1. 2023-3 - PT samples performed by only TP-1. 2024-1 - PT samples performed by only TP-1. 2024-2 - PT samples performed by only TP-1. 4. TC-1 interviewed on 7 /12/24 at 2:10 PM confirmed that the same testing personnel (TP-1) participated in each testing event as indicated above.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of

	collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of i-Stat test procedures, i-Stat instrument printouts and interview with the technical consultant (TC-1), the laboratory failed to follow established policies and procedures to ensure positive identification of the patient's specimen from the time of collection through completion of testing and reporting of results. Findings include: 1. The laboratory began ACT (Activated Clotting Time) testing on the i-Stat analyzer on 10/29/2021 in the specialty of Hematology, with an approximate annual test volume of 300. 2. The laboratory's established test procedure for the i-Stat analyzer states, "Follow handheld prompts. Enter Operator ID number as assigned to each user. Enter Patient ID number...Attach printout to Lab Report Form, verifying that patient ID numbers match." 3. The laboratory failed to enter the correct patient ID number into the i-Stat analyzer and failed to verify that the Patient ID numbers match for one out of two ACT tests performed on patient# 60178 on 7/11/2022. The i-Stat printout for ACT testing at 15:06 on 7/11/22 listed the patient ID as 06718. The patient ID as confirmed by other patient records and laboratory personnel is 60178. 4. The laboratory failed to follow established policies and procedures to ensure positive identification of the patient's specimen indicated above throughout the entire testing process on the i-Stat analyzer. 5. TC-1 interviewed on 7/12/24 at 3:05 PM confirmed the laboratory failed to follow established policies and procedures for positive specimen identification for testing performed on the i-Stat analyzer.