Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2150723	11/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Cardiovascular Association, Pllc	18450 Hwy 59 N, Humble, TX	

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 announced survey of the laboratory was conducted on 11/13/2025. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute (API) proficiency testing records, and staff interview, the laboratory failed to have documentation of performing a self-evaluation of analytes that were 'not graded' by the proficiency testing program for three of six Chemistry-Core and three of six Hematology/Coagulation proficiency testing events in 2024 and 2025. Findings include: 1. A review of the American Proficiency Institute's Performance Evaluation revealed the following: "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes. Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for analytes that have not been graded." 2. A review of the laboratory's API results from 2024 and 2025 revealed the following Hematology/Coagulation and Chemistry-Core proficiency testing events that included analytes that were scored as 'not graded' and the laboratory failed to have documentation of a self-evaluation: a) 2024 Chemistry - Core- 1st Event - Bilirubin Total Samples CH-02, CH-03, CH-05 b) 2024 Hematology/Coagulation- 1st Event - Nucleated RBCs Sample COU-02 c) 2024 Hematology/Coagulation- 2nd Event - Nucleated RBCs Sample COU-06 d) 2024

	Hematology/Coagulation- 3rd Event - Nucleated RBCs Sample COU-12 e) 2025 Chemistry- Core- 2nd Event - BNP Sample CM-07 - Troponin I Samples CM-06, CM-07, CM-08, CM-09, CM-10 - Bilirubin Total Samples CM-07, CM-09, CM-10 f) 2025 Chemistry- Core - 3rd Event - BNP Sample CM-15 - Bilirubin Total Samples CM-12, CM-15 3. In an interview on 11/13/25 at 9:45 a.m. in the conference room, after review of the records, the laboratory director confirmed the above findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor's observations, review of manufacturer instructions and staff interview, the laboratory failed to document open and/or amended expiration dates on three of three COULTER 6C hematology controls in use, Control Level 1, 2 and 3. Findings included: 1. Surveyor's observations on 11/13/2025 at 1030 hours in the laboratory revealed three of three COULTER 6C hematology controls in use: Control Level 1- Lot 123176150; Expiration date: 2025-11-29; A62072-AB Control Level 2- Lot 123176150; Expiration date: 2025-11-29; A62073-AB Control Level 3- Lot 123176150; Expiration date: 2025-11-29; A62087-AB The three vials did not have documentation of open and/or amended expiration dates. 2. Review of manufacturer's instructions included in the Beckman Coulter controls' package insert the "Table of Expected Results" (document C82641-AC) revealed: "Assumes that the Instructions for Use section of the package insert is performed a maximum of 18 times within 16 days." 3. In an interview on 11/13/2025 at 1030 hours in the laboratory, testing person number two (as indicated on submitted Form CMS 209) stated that they document piercings on a monthly date spreadsheet, but they do not document open dates on the control vials to indicate start of use. This confirmed the findings.