Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2150723	02/13/2024
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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review the laboratory's American Proficiency Institute (API) proficiency testing records from 2023, the laboratory's records, and staff interview, the laboratory failed to have documentation of performing twice annual accuracy assessments in 2023 for one of one non-regulated analyte tested on the Beckman Coulter DxI 600 chemistry analyzer. Findings include: 1. A review of the laboratory's API proficiency testing records from 2023 revealed the laboratory failed to have documentation of the analyte B-Type Natriuretic Peptide (BNP) being tested in any of the 3 API chemistry events in 2023. 2. A review of the laboratory's records revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for BNP testing on the Beckman Coulter DxI 600 chemistry analyzer in 2023. 3. Further review of the laboratory's records revealed the laboratory performed an estimated 600 patient BNP tests in 2023. 4. In an interview on 2/13/24 at 11:05 a.m. in the conference room, after review of the records, the technical consultant (as indicated on the CMS 209 form) confirmed the above findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other

	supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (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, laboratory's policies/procedures and staff interview, the laboratory failed to document amended expiration or open/preparation dates to ensure reagent stability for 5 of 5 controls /reagents in use observed. Findings included: 1. Surveyors observations on 02/13 /2024 at 0915 hours in the laboratory revealed the following 5 of 5 controls/reagents in use did not have documented open dates or amended expiration dates: a. L1 Coulter 6C Cell Control (Lot: 123175250; expiration date: 2024-03-02) - stored in the refrigerator b. L2 Coulter 6C Cell Control (Lot: 133185250; expiration date: 2024-03-02) - stored in the refrigerator c. L3 Coulter 6C Cell Control (Lot: 143195250; expiration date: 2024-03-03) - stored in the refrigerator d. Coulter Latron CP-X Control (Lot: 103157330; expiration date:) - stored on the countertop e. 2 vials labeled Clean B (no lot number or preparation/expiration date annotated on the secondary container) - stored on the countertop 2. In an interview on 02/13/2024 at 0930 in the laboratory, testing person number one confirmed the above controls /reagents were currently in use. 3. Review of manufacturer instructions for the above controls/reagents revealed: a - c. Coulter 6C Cell Control (L1, L2 and L3) manufacturer instructions for use (document A59928-AM, Ref. A59925, 628027) stated: "For opened vial stability, refer to the TABLE OF EXPECTED RESULTS for your system." And, the "Table of Expected Results" stated: "Assumes that the Instruction for Use section of the package insert is performed a maximum of 18 times within 16 days. " The laboratory did not track number of piercings/use of the control vials. d. Coulter Latron CP-X Control manufacturer instructions for use (document A59931-AM, Ref. 628024) stated: "Opened tubes are stable for 30 days when stored at recommended temperatures." e. Clean B solution did not have manufacturer instructions for use. The laboratory did not have on hand ACL Elite instrument's User Manual to determine preparation and/or stability requirements of Clean B solution. 4. Review of laboratory's policies/procedures revealed the laboratory did not address protocols for labeling of controls/reagents with amended expiration or open /preparation dates to ensure that reagents are not used beyond their stability, or to comply with the requirements. 5. In an interview on 02/13/2024 at 0930 hours in the laboratory, the facility's Technical Supervisor confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the review of the manufacturer's training manual, the laboratory's maintenance logs in 2023, CMS 116 application, and confirmed in an interview, the laboratory failed to document 12 of 12 monthly maintenance on Beckman Coulter AU680 Chemistry Analyzer according to the manufacturer's training manual. The findings were: 1. Review the manufacture's training manual titled AU680 Chemistry

	Analyzer In-Lab Training Manual (AU680 In-Lab Training Manual Version 1.0 (February 2016) under Chapter 6 Maintenance page 85 revealed "Monthly maintenance includes the following procedure: -Clean the Sample Probe, Reagent Probe, and HbA1c Wash Wells -Clean the Mix Bar Wash Wells -Clean the Wash Nozzle Unit and Check the Tube Mounting Joints -Clean the DI Water Tank, DI Filter, and Sample Probe Filter 2. Review the laboratory's maintenance logs in 2023 revealed no documentation for 12 of 12 monthly maintenance. 3. Review the CMS 116 application, signed by the laboratory director on 02/23/2024, revealed the routine chemistry annual volume was 10,000. 4. In an interview on 02/13/2024 at 2:39 pm in a conference room, the technical consultant confirmed the findings. Key: CMS=Center of Medicare and Medicaid Services
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: A. Based on review of manufacturer instructions for use, laboratory's Recombiplastin (thromboplastin) new lot rollover studies, policies/procedures, prothrombin time (PT) test volumes and staff interview, the laboratory failed to ensure 2 of 20 donors used in the 2023 new Recombiplastin lot's normal mean study passed the laboratory's donor screening prior to being included in the calculations of the new lot's mean of PT normal range. Findings included: 1. Review of manufacturer instructions for use for Recombiplastin reagent (document 0020002950, revision 03/2019) revealed: "Expected Values: (Normal) Ranges were calculated as recommended by CLSI document C28-A. These results were obtained using a specific lot of reagent. Due to many variables which may affect clotting times, each laboratory should verify its own normal range." 2. Review of laboratory's Recombiplastin lot rollover studies for new lot N0138518 (expiration date 2025-01-31), conducted on 08/10/2023 revealed the following donor questionnaire was used to determine donor acceptability for inclusion in calculation of new lot's mean of PT normal range: Questionnaire included: "True or False: Are you a (sic) healthy? True or False: I do not have a coagulopathy. True or False: I do not take any medications designated "blood thinners". True or False: I do not bleed easily. True or False: I can participate in coagulation studies as "normal control patient." Patient Signature: _____ Date: _____ Director/ Instructor: _____ Date: _____ Circle one: Pass Reinstruct Failed" 3. Review of the donor questionnaires for patients used in the Recombiplastin lot's N0138518 establishment study of mean of PT normal range revealed the following 2 of 20 patients had responses related to coagulation issues: a. Patient number 2 responded as follows: "True or False: I do not have a coagulopathy." - documented response by circling "False" "True or False: I do not take any medications designated "blood thinners"." - documented response by circling "False" b. Patient number 3 responded as follows: "True or False: I do not bleed easily." - documented response by circling "False" 4. Further review of the above questionnaires revealed there was no documentation of Director/Instructor signature/date, or documentation of whether the patient passed, failed or was reinstructed during the screening process. 5. Review of laboratory's Recombiplastin lot rollover studies for new lot N0138518 revealed Patient 2 and 3 were included in the calculation of new lot's mean of PT normal range.

	6. Review of laboratory's policies/procedures revealed there were no protocols delineated for performing patient screening, nor criteria established for patients acceptability for inclusion in the establishment studies of the new lot's mean of PT normal range. 7. Review of laboratory's test volumes revealed the laboratory performed 3279 PT tests in 2023. 8. In an interview on 02/13/2024 at 1410 hours in the conference room, the laboratory's Technical Supervisor confirmed the findings. B. Based on review of laboratory's Recombiplastin (thromboplastin) new lot rollover studies, policies/procedures, prothrombin time (PT) test volumes and staff interview, the laboratory failed to ensure ACL Elite hemostasis instrument's INR (International Normalized Ratio) calculations were accurate for one of one new Recombiplastin lot numbers placed in use in 2023. Findings included: 1. Review of laboratory's Recombiplastin lot rollover studies for new lot N0138518 (expiration date 2025-01-31), conducted on 08/10/2023 revealed the laboratory did not verify whether the ACL Elite hemostasis instrument calculated the reportable INR correctly for the new lot number of Recombiplastin. 2. Review of laboratory's policies/procedures revealed the laboratory did not have protocols in place delineating steps to verify if the ACL Elite hemostasis instrument calculates the reportable INR correctly. 3. Review of laboratory's test volumes revealed the laboratory performed 3279 PT tests annually. 4. In an interview on 02/13/2024 at 1410 hours in the conference room, the laboratory's Technical Supervisor confirmed the findings.
D6126	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limted to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on a review of the laboratory's CMS 209 form, the laboratory's annual competency assessments and staff interview, the laboratory failed to assess problem solving skills for the annual competency assessment performed for one of one testing personnel performing high complexity testing in 2023. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory employed one testing person performing high complexity testing in 2023. 2. A review of the laboratory's annual competency assessments performed in 2023 revealed the laboratory failed to assess problem solving skills for testing person #1. 3. In an interview on 2/13/24 at 10:50 a.m. in the conference room, after review of the records, the technical supervisor (as indicated on the CMS 209 form) confirmed the above findings.