Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2150723	02/28/2023
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 unannounced complaint survey was performed on 02/28/2023 in response to TX00444363. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. All allegations were substantiated and related deficiencies cited. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, surveyor observations, quality control and patient test records from November 2022 to February 2023, and confirmed in interview, the laboratory failed to ensure quality control material were not used past the open stability for five of ten analytes reviewed on the Beckman Coulter and DXI chemistry analyzers: Total Bilirubin (TBili), Cholesterol (CHOL), Triglyceride (TRIG), and Troponin I. Findings included: 1. Review of the package insert for the Biorad Liquid Assayed Multiqual (5351-00, 2020-02) under storage and stability stated "once thawed, opened, and stored tightly capped at 2-8, this product will be stable as follows: TBili, ALP: 9 days CHOL, TRIG: 7 days 2. Review of the package insert for the Biorad Liquichek Cardiac Markers Plus Control LT (16000202-00S, 2023-02) under Storage and Stability stated "once thawed, opened, and stored tightly capped at 2-8C, this product will be stable as follows: Troponin I: 5 days 3. Surveyor observations on 02/28/2023 at 0944 hours in the laboratory indicated the following controls were put into use on the dates written on the bottle. Biorad Liquichek Cardiac Markers Plus Control LT Level 3 lot 67673, exp 08/31/2024 with

	the tech [initials] and "02/13" - [open stability expiration for Troponin 2/18/2023] Biorad Liquid Assayed Multiqual level 1 lot 45891, 10/31/2023 with the tech [initials] and "02/03" - [open stability expiration for TBili, ALP 2/12/2023 and 2/10/23 for CHOL and TRIG] 4. Random review of patient and laboratory test records from February 2023 confirmed the laboratory analyzed and reported the following five patients when they used expired open stability controls for the daily testing on the corresponding analytes. Tbili, ALP, CHOL, TRIG, Troponin I Accession #55176, collected 2/24/2023, analyzed 2/24/2023 Tbili, ALP, CHOL, TRIG Accession #55131, collected 02/24/2023, analyzed 02/24/2023 Accession #55196, collected 02 /27/2023, analyzed 02/27/2023 TBili, ALP Accession #54610, collected 02/13/2023, analyzed 02/13/2023 Accession #55190, collected 2/27/2023, analyzed 2/27/2023 5. An interview with the technical consultant on 02/28/2023 at 1435 hours in the laboratory confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, random review of the laboratory and patient test records from 2022, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions and document one of two calibration verification every 6 months for the following 10 analytes: DBili, TBili, BUN, MG, PHS, GLU, CAL, TP, CHOL, and Trig. Findings included: 1. Review of the calibration verification records from 2022 for the following 10 analytes DBili, TBili, BUN, MG, PHS, GLU, CAL, TP, CHOL, and Trig contain documentation the laboratory used the following linearity materials. Audit Microcontrols Linearity FD Bilirubin Beckman AU - DBili, TBili Audit Microcontrols Linearity FD General Chemistry AU - BUN, MG, PHS, GLU, CAL, TP Audit Microcontrols Linearity FD Lipids Beckman AU - CHOL, Trig 2. Review of the package insert for the Audit Microcontrols Linearity FD Bilirubin Beckman AU (K825m-5, exp 09-15-23) under Storage and Stability stated "Linearity FD Bilirubin Beckman AU is stored at 2-8C and will remain stable in the unopened vial until the expiration date. After opening,

	the contents should be used according to the instrument manufacturer ' s instructions and immediately returned to 2-8C. When used to monitor the precision of laboratory testing procedures for its assays, Linearity FD Bilirubin Beckman AU has a reconstituted stability of up to 2 days under the proper storage conditions. Leaving the vial uncapped, or prolonging its time at room temperature, will void this open vial stability claim. Make sure the contents of the vial are well mixed before use." 3. Review of the package insert for the Audit Microcontrols Linearity FD General Chemistry AU (K824M-5, exp 06/09/2024) under storage and stability stated " Linearity FD General Chemistry AU is stored at 2-8C and will remain stable in the unopened vial until the expiration date. After opening, the contents should be used according to the instrument manufacturer ' s instructions and immediately returned to 2-8C. When used to monitor the precision of laboratory testing procedures for its assays, Linearity FD General Chemistry AU has a reconstituted stability of up to 7 days under the proper storage conditions. Leaving the vial uncapped, or prolonging its time at room temperature, will void this open vial stability claim. Make sure the contents of the vial are well mixed before use." 4. Review of the package insert for the Audit Microcontrols Linearity FD Lipids Beckman AU (K826M-5, exp 08/10/2023) under storage and stability stated "Linearity FD Lipids Beckman AU is stored at 2-8C and will remain stable in the unopened vial until the expiration date. After opening, the contents should be used according to the instrument manufacturer ' s instructions and immediately returned to 2-8C. When used to monitor the precision of laboratory testing procedures for its assays, Linearity FD Lipids Beckman AU has a reconstituted stability of up to 5 days under the proper storage conditions. Leaving the vial uncapped, or prolonging its time at room temperature, will void this open vial stability claim. Make sure the contents of the vial are well mixed before use." 5. Surveyor observed on 02/28/2023 at 0948 hours the following Audit Microcontrols with the following open and run dates stored in the laboratory refrigerator. Audit Microcontrols Linearity FD Bilirubin Beckman AU (lot 06828, exp 09/15/2023) - "o [opened]: 05/12/2022; r [run]: 05/12; run: 11/04/2022) Audit Microcontrols Linearity FD General Chemistry AU (lot 06886, exp 06/09/2024) - "r [run]: 05/18; run: 11/04 /2022) Audit Microcontrols Linearity FD Lipids Beckman AU (lot 06889, exp 08/10 /2023) - o [opened]: 05/12/2022; r [run]: 05/12; run: 11/04/2022) 6. An interview with the primary testing person on 02/28/2023 at 1130 hours in the laboratory confirmed that the dates on the box were when they were reconstituted and used. 7. Review of the calibration verification records from 2022 confirmed the laboratory documented calibration verification for the following 10 analytes (DBili, TBili, BUN, MG, PHS, GLU, CAL, TP, CHOL, and Trig) in 05/2022 and 11/2022 using the linearity materials observed. No other calibration verification records were available for review. 8. Review of the CMS116 record state the laboratory performed 8000 chemistry tests annually. 9. An interview with the technical consultant on 02/28/2023 at 1430 hours in the laboratory confirmed the above findings. key: DBili - Direct Bilirubin TBili - Total Bilirubin BUN - blood urea nitrogen MG - Magnesium PHS - Phosphorus GLU- Glucose CAL -Calcium TP - Total Protein CHOL - Cholesterol Trig - Triglycerides