Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2190475	02/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
Heart And Vascular Care, Inc	1495 Hickory Flat Highway Suite 140, Canton, GA	

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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on February 11, 2025. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual (SOP) and interview with the technical consultant (TC), the laboratory director failed to provide current step by step procedures for the Abbott I-Stat-1 analyzer in the specialty of Chemistry for 2024 -

	2025 as required by CLIA Regulation 493.1251(b). Findings: 1.) A review of current SOPs confirmed the lack of step by step procedures for Treponin testing for the Abbott I-Stat-1 Chemistry analyzer. 2.) There were no protocools for critical value alerts, specimen handling and established QC procedures. 3.) Interviews with the laboratory coordinator and (TC), in the review room, on 02/11/2025, at approximately 11:30 a.m, confirmed the above 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 observation during the laboratory tour and staff interview, the laboratory failed to perform and document equipment function checks as required in 2023 thru the date of survey (February 11, 2025). Findings: 1. Observation during the laboratory tour on 2/11/2025 at approximately 10:30 a.m. revealed the Pathgroup centrifuge by Cardinal Health had it's last rpn calibration on 01/30/2018. 2. An interview with the Laboratory Coordinator and Technical Consultant at approximately 10:40 a.m, in the review room confirmed the centrifuge was not calibrated from January 2018 through day of survey February 11, 2025.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: A review of a patient test results report provided by the lab, confirmed that the laboratory reporting system failed to meet this requirement. THE FINDINGS INCLUDE: 1. A review of the patient report provided for in-house testing confirmed that the laboratory provided the test order requisition with the analyzer printout attached in lieu of a standard patient report. 2. A review of the patient results report confirmed that the report DID NOT contain: a) Patient identifiers to assure the correct patient identification; b) the name and address of the laboratory performing the testing; c) the test report date; d) specimen source; e) test results with unit of measure and with interpretation; f) reference intervals or normal values established by the laboratory. 3. An exit interview conducted with the Lab Team, in the breakroom, on February 11, 2025, at 12:00pm confirmed that the in-house patient test report did not include reference ranges.