Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D1106278	04/15/2025
Name of Provider or Supplier	**Street Address, City, State**	
Heart Care Consultants Llc	5600 Chestnut Street, Philadelphia, PA	

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 recertification survey was conducted by the Pennsylvania State Agency at Heart Care Consultants on 4/15/2025. The laboratory was found out of compliance with the following conditions: 493.1250 Condition: Analytic systems. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: Based on lack of documentation, review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, and interview with testing personnel (TP) #3, the laboratory failed to provide 1 of 3 API PT attestation statements for Chemistry Core testing events performed in 2023. Findings include: 1. On the day of survey, 4/15/2025, the laboratory failed to provide attestation statements for the following 1 of 3 API Chemistry Core PT events for Abbott iSTAT chemistry testing performed in 2023: - Chemistry Core 2nd Event 2023 2. TP #3 confirmed the finding above on 4/15/2025 at 10:10 am.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250

	Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review, lack of documentation, and interview with testing personnel (TP) #3, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed from 5/10/2023 to 6/30/2024. Refer to: 5413, 5439, and 5785
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of laboratory temperature records, and interview with Testing Personnel (TP) #3, the laboratory failed to monitor and document room and refrigerator temperatures to ensure reagent stability and proper operating conditions of 1 of 1 Abbott iSTAT analyzer from 5/10/2023 to 6/30/2024. Findings include: 1. On the day of survey, 4/15/2025 at 9:30 am, review of laboratory temperature records revealed the laboratory failed to monitor and document refrigerator and room temperatures when the laboratory was closed to ensure reagent stability and proper operating conditions of 1 of 1 Abbott iSTAT analyzer used for chemistry and hematology testing for the following days from 5/10/2023 to 6/30/2024: - Refrigerator Temperature- 251of 396 days - Room Temperature- 201 of 396 days 2. TP #3 confirmed the findings above on 4/15/2025 at 9:45 am.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 review of policies and procedures, lack of documentation, and interview with Testing Personnel (TP)#3, the laboratory failed to perform calibration verification at least every six months for the 1 of 1 Abbott iSTAT analyzer used to chemistry examinations from 5/10/2023 to 6/30/2024. Findings include: 1. The laboratory's policy titled "Calibration and Calibration Verification" stated "CAL VER is performed: on any new, or replacement device before clinical use, every 6 months, as part of troubleshooting when controls reflect an unusual trend or consistently out of range." 2. On the date of survey, 4/15/2025 at 10:00 am, the laboratory failed to provide calibration verification records for 1 of 1 Abbott iSTAT used to perform chemistry examinations from 05/10/2023 to 06/30/2024. 3. TP #3 confirmed the finding above on 4/15/2025 at 10:30 am.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's daily temperature log records and interview with testing personnel (TP) #3, the laboratory failed to document all corrective actions taken when 4 of 201 room temperature and 25 of 201 humidity readings exceeded the laboratory's acceptable ranges from 5/10/2023 to 6/30/2024. Findings include: 1. The laboratory daily temperature log stated, optimal laboratory room temperatures (65 to 72 degrees Fahrenheit) and relative humidity (30 to 60%). 2. On the day of the survey, 4/14/2025 at 10:00 am, review of the laboratory's daily temperature log records revealed room temperature and humidity readings exceeded acceptable ranges from 5 /10/2023 to 6/30/2024: - Room Temperature - 4 of 201 readings were above the acceptable range. - Relative Humidity - 25 of 201 readings were above the acceptable range. 3. The laboratory failed to provide documentation of the corrective actions taken for out-of-range readings from 5/10/2023 to 6/30/2024. 4. TP #3 confirmed the finding above on 4/15/2025 at 10:30 am.
D5803	TEST REPORT CFR(s): 493.1291(b) (b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with Testing Personnel (TP) #3, the

	laboratory failed to provide patient test reports for 13 of 13 months chemistry and hematology exmaniations were performed from 5/10/2023 to 6/30/2024 upon request of the surveyor. Findings Include: 1. On the day of survey, 4/15/2025, the laboratory failed to provide provide patient test reports for 13 of 13 months chemistry and hematology exmaniations were performed from 5/10/2023 to 6/30/2024 upon request of the surveyor. 2. The laboratory performed 9376 test Chemistry and Hematology examinations . (CMS 116 estimated annual test volume) 2. During an interview on 4 /15/2025 at 11:00 am, 2. TP#3 stated that the records were "currently located on a truck somewhere".
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of laboratory records, and interview with the Technical Consultant (TC), the Laboratory Director failed to provide overall management and direction of the laboratory in accordance with 493.1407 for a moderate complexity laboratory from Refer to 6020, 6029, 6031, 6032.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and interview with Testing Personnel (TP) #3, the laboratory director (LD) failed to ensure that 2 of 6 API PT reports were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action in 2023 and 2024. Findings include: 1. The Laboratory Policies & Procedure for Proficiency Testing stated, "When PT results are unsatisfactory, we will evaluate the results and take appropriate action as specified in Corrective Action Checklist" and "PT results that are not graded will be self-graded by comparing the results to the expected results of the PT agency or peer results". 2. API's Performance Evaluation instructions stated, "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 samples that have not been graded." 3. On the day of survey, 4/15/2025, at 10:00 am, review of the laboratory's API PT records revealed the laboratory failed to verify the accuracy for the following 2 of 6 CAP Hematology/Coagulation testing events for 2023 and 2024. - API Hematology/ Coagulation testing event #2 for 2023 - API Hematology/Coagulation testing event #2 for 2024 4. TP #3 confirmed the findings above on 4/15/2025 at 11:10 am

D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: A. Based on record review, lack of documentation, and interview with testing personnel (TP) #3, the Laboratory Director (LD) failed to ensure a Quality Assessment (QA) program was established and maintained to assure the quality of laboratory services provided for laboratory analyses performed for 2 of 2 years from 5 /10/2023 to 6/30/2024. Findings include: 1. On the day of survey, 4/15/2025, review of the laboratory's "Quality Assurance Plan" stated: "Frequency of Reviews and Data Collection - Initially and once every 3 months". 2. The laboratory failed to provide copies of the QA reports showing oversight and review of the laboratory quality activities for 2 of 2 years from 05/10/2023 to 06/30/2024. 3. TP #3 confirmed above findings on 4/15/2025 at 10:30 am.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the CLIA ' s laboratory Personnel Report (Form CMS-209), lack of Personnel Qualification records, and interview with testing personnel (TP) #3, the laboratory failed to ensure 5 of 5 TP performing moderate complexity testing meet the qualification requirements of 493.1423. Refer to D6065
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by:

	Based on review of the CLIA' s laboratory Personnel Report (Form CMS-209), lack of Personnel Qualification records, and interview with Testing Personnel (TP) #3, the laboratory failed to ensure that 5 of 5 TP met the minimum requirements to perform moderate complexity testing from 05/10/2023 to 06/20/2024. Findings Include: 1. Review of the CMS-209 form signed by the Laboratory Director on 4/2/2025, listed personnel #1, #2, #3, #4, and #5 as TP. 2. On the day of survey, 4/15/2025, the laboratory failed to provide education credentials for 5 of 5 TP (CMS 209 TP #1, #2, #3, #4, and #5) who performed moderate complexity hematology and chemistry examinations from 05/10/2023 to 06/30/2024. 3. TP #3 confirmed the findings above on 4/15/2025 at 10:30 am.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on lack on documentation and interview with Testing Personnel (TP) #3, the laboratory failed to have the required records accessible during the laboratory survey performed on 4/15/2025. Findings Include: 1. On the day of the survey, 4/15/2025, the laboratory could not provide the following records upon request: - Quality Assessment Documents - Individualized Quality Control Plan(IQCP) Assessments and Documentation - Quality Control Records for Activated Clotting Time from March 2024 to June 2024 - Quality Control Records For Prothrombin Time from February 2024 to June 2024 - Technical Consultant Qualification records - Test Requisitions and Patient Reports - Equipment Maintance Records 2. During interview on 04/15/2025 at 11:30 am, TP #3 stated "the following records were in a box in the back of a truck somewhere."