Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D1106278	05/10/2023
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**
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) 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. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: A. Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with testing personnel #5 (TP), the laboratory failed to provide 1 of 6 API PT attestation statements for routine hematology testing in 2021 and 2022. Findings Include: 1. On the day of the survey, 5/10/2023 at 10:00 am, the laboratory could not provide the following 1 of 6 API PT attestation statements for routine hematology testing in 2021 and 2022: -API Routine Hematology: 2022 Event #3 2. TP#5 confirmed the finding above on 05/10/2023 around 12:45 p.m. B. Based on review of the American Proficiency Institute (API) proficiency records and interview with testing personnel #5 (TP), the laboratory failed to provide 3 of 6 PT attestation statements for routine chemistry testing and 1 of 6 PT attestation statements for routine hematology testing signed by the laboratory director or designee in 2021 and 2022. Findings include: 1. On the day of the survey, 05/10/2023 at 10:00 am, the following API PT attestation statements were not signed by the laboratory director or designee in 2021 and 2022. - Routine Chemistry: i-STAT Chemistry : - 2021 Event #3. - 2022 Event #2 - 2022 Event # 3 -Routine Hematology:

	i-STAT Hematology -2022 Event 2 2. TP #5 confirmed the findings above on 05/10 /2023 around 12:45 pm.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of test requisitions and interview with testing personnel #5 (TP), the laboratory failed to include the address of the authorized person requesting routine hematology and chemistry testing from 04/02/2021 to date of the survey. Findings Included: 1. On the day of survey, 05/10/2023 at 11:30 am, review of 1 of 1 patient test requisitions revealed that the test requisition did not include the address of the authorized person requesting routine hematology and chemistry testing from 04/02 /2021 to 05/10/2023. 2. TP#5 confirmed the above finding on 05/10/2023 around 12: 45 pm.
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 lack of documentation and interview with testing personnel #5 (TP), the laboratory failed to perform calibration verification at least once every six months as required for 1 of 1 Abbott iSTAT analyzer used for routine chemistry testing from 04 /02/2021 to the date of the survey. Findings include: 1. On the date of the survey, 05 /10/2023 at 11:23 am, the laboratory could not provide calibration verification records for the required analytes tested on 1 of 1 Abbott iSTAT analyzer used for routine chemistry testing from 04/02/2021 to 05/10/2023. 2.TP #5 confirmed the findings above on 05/10/2023 around 12:45 pm.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with testing personnel #5 (TP), the laboratory failed to include pertinent reference intervals/normal values on patient test reports for routine chemistry and hematology examinations performed on the Abbott iStat analyzer from 04/02/2021 to the date of survey. Findings Include: 1. On the date of the survey, 05/10/2023 at 11:30 am, review of 1 of 1 patient test reports revealed that the final patient test reports did not include reference ranges/normal values for routine chemistry and hematology testing performed on the Abbott iSTAT analyzer from 04/02/2021 to 05/10/2023 . 2.TP#5 confirmed the finding above on 05 /11/2023 around 12:45 pm.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with testing personnel #5 (TP), the laboratory director (LD) failed to ensure that 2 of 6 API PT reports for routine chemistry and 2 of 6 API PT reports for routine hematology were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action in 2021 and 2022. Findings include: 1. On the date of the survey, 05/10/2023 at 11:00 am, the laboratory could not provide documentation of the corrective actions taken for the following 2 of 6 chemistry API PT reports and 2 of 6 hematology API PT reports from 04/02/2021 to 05/10/2023: - 2021 Event #2 Routine Chemistry - 0% score -

	2021 Event #2 Routine Hematology - 33% score - 2022 Event #2, Hematology (PT) - 0% score - 2022 Event #3, Chemistry (Calcium) - 80% score. 2. TP#5 confirmed the findings above on 05/10/2023 around 12:45 pm.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) and quality assessment (QA) records, and interview with testing personnel #5 (TP), the laboratory director (LD) failed to ensure that QC and QA programs were established and maintained to identify failures in quality as they occur from 04/02/2021 to the date of the survey. Findings include: 1. On the day of the survey, 05/10/2023 at 10:00 am, a review of the laboratory's QC records revealed that two levels of QC were not performed every day of patient testing for the following moderately complexity tests performed on 1 of 1 Abbot iSTAT analyzers from 04/02/2021 to 05/10/2023: -Routine Chemistry: Basic Metabolic Panel (BMP) -Routine Hematology: -Activated Clotting Time (ACT) -Prothrombin Time (PT) -Hemoglobin/Hematocrit (Hgb/HCT) 2. The laboratory could not provide documentation of the QA activities performed in 2021. 3. TP#5 confirmed the finding above on 05/10/2023 at 12:45 p.m.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on lack of competency assessment (CA) records and interview with testing personnel #5 (TP), the technical consultant (TC) failed to assess the competency of 4 of 6 testing personnel (TP) for chemistry and hematology examinations performed on the Abbott iSTAT analyzer from 04/02/2021 to date of the survey. Finding Include: 1. On the day of the survey, 05/10/2023 at 11:06 am, the laboratory could not provide CA records for 4 of 6 TP (CMS 209 personnel #1, #2, #3, #4) who performed routine chemistry and hematology examinations using the Abbott iSTAT analyzer from 04/02/2021 to 05/10/2023. 2. TP#5 confirmed the findings above on 05/10/2023 around 12:45 pm.