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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 39D1106278 | (X3) Date Survey Completed 04/11/2019 |
| Name of Provider or Supplier Heart Care Consultants Llc | Street Address, City, State 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 |
|---------------------------|--|
| D5301 | <p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with Testing Personnel (TP) #1 on 04/11/19, the Laboratory failed to have a written or electronic laboratory test request form for all patient testing for an ordering provider from 12/10/18 to the date of the survey. Findings Include: 1. During the time of the survey, 04/11/19 at 12:00 pm, TP #1 could not provide evidence of test requisition (written or electronic) forms and could not show how many patients Activating Clotting Time (ACT) were requested from an ordering provider. 2. The TP #1 confirmed the above findings, 04/11/19 at 12:00 pm.</p> |
| D5403 | <p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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</p> |

(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 procedure manual and interview with Testing Personnel (TP) #1, the laboratory failed to include reference ranges for normal, panic and/or alert values for Activating Clotting Time (ACT) test performed on iStat Abbott analyzer from 12/10/18 to the date of survey. Findings include: 1. A review of the laboratory procedure manual for ACT tests, revealed the manual did not include reference intervals for normal, panic, or alert values from 12/10/18 to the day of survey, 04/11/19. 2. The TP #1 interviewed at 11:39 am on 04/11/19 confirmed the findings above. 3. During summation on 04/11/19 at 1:15pm, interview with Laboratory Director (LD) recited panic values but they were not documented in the procedure.

D5407

PROCEDURE MANUAL

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on record review and interview with Testing Personnel (TP) #1, Laboratory Director (LD) failed to sign the Validation Study performed on iStat analyzer and Quality Assessment Plan currently in use. Findings include: 1. The Validation Study for the iStat analyzer and Quality Assessment Plan reviewed at the time of inspection on 04/11/19 revealed the LD's signature and date of approval were not present. 2. TP #1 confirmed the finding above on 04/11/19 at 10:15 am.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 temperature logs and interview with Testing Personnel (TP) #1, the Laboratory failed to document temperature ranges for 1 of 1 refrigerator's log sheet for 12/2018 to the day of survey. Findings Include: 1. On the day of the survey, 04/11/19, review of the temperature range of 1 of 1 refrigerator log revealed the log did not indicate temperature ranges from 12/2018 to 04/11/19. 2. The surveyors were told the refrigerator holds Activating Clotting Time (ACT) cartridges used on the Abbott iStat, however they were unable to be observed due to patient procedure being

performed in the room. 3. The TP #1 confirmed the above findings on 04/11/19 at 12:45 pm.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of iStat Activated Clotting Time (ACT) quality control (QC) records and interview with Testing Personnel (TP) #1, the laboratory failed to run two control materials of different concentrations at least once each day of patient testing from 12/10/18 through the date of survey. Findings include: 1. The iStat ACT control log reviewed at the time of survey revealed, the laboratory did not perform external QC each day of patient testing. The laboratory did not have an Individualized Quality Control Plan (IQCP). 2. TP #1 interviewed on 04/11/2019 at 10:40 am confirmed external QC was not performed each day of patient testing. 3. At the time of survey, TP #1 interviewed could not provide the number of patients tested from 12/10/18 through the date of survey.

D5803

TEST REPORT
CFR(s): 493.1291(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 review of patient reports and interview with Testing Personnel (TP) #1, the laboratory failed to maintain test reports for Activating Clotting Time (ACT) testing performed from 12/10/18 to date of survey. Findings Include: 1. On the day of survey, the laboratory could not identify and provide patient test reports that were tested for ACT for 12/10/18 to the date of survey (04/11/19). 2. TP #1 stated ACT test results are not documented in the final patient reports on 04/11/19 at 11:00 am.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Testing Personnel (TP) #1 at the time of survey, the laboratory director failed to ensure that prior to testing patients' specimens, the testing personnel received the appropriate training for the type and complexity of the services offered from December 10, 2018 through the time of survey April 11, 2019. Findings include: 1. At the time of survey on 4/11/19 the Laboratory could not provide training records for 2 of 2 testing personnel performing non waived testing (Activating Clotting Time and Prothrombin Time) on the Abbott iStat from the initial start of patient testing on 12/10/18. 2. The TP #1 interviewed on 4/11/19 around 10:15 am at the time of survey confirmed the finding above.