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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 03D2113345 | (X3) Date Survey Completed 05/29/2019 |
| Name of Provider or Supplier Heart Health Center Llc | Street Address, City, State 1848 E Thomas Rd, Ste 200, Phoenix, AZ | |
| 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 |
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| D5445 | <p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of one patient test result for activated clotting time (ACT) testing performed on the i-Stat instrument on 03/07/2019 and interview with the laboratory personnel, the laboratory failed to provide evidence of liquid QC testing for ACT for the month of March 2019. Findings include: 1. The laboratory has an Individualized Quality Control Plan (IQCP) in place that indicates liquid QC testing for ACT is to be conducted whenever the following occur: monthly, new lot or new shipment. 2. No monthly liquid QC log was presented for March 2019 when the patient was run. 3. The laboratory personnel did not have an explanation for the missing QC log for March 2019. 4. It could not be determined at the time of the survey hoe many patients were tested in March 2019 for ACT.</p> |
| D5469 | <p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>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-- Establish or verify the criteria for acceptability of all control materials. (i) When</p> |

control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 Based on review of the the laboratory's quality control (QC) logs for activated clotting time (ACT) testing on the i-Stat instrument and interview with the laboratory personnel, the laboratory failed to retain the manufacturer's QC acceptable ranges for QC level 1 lot #261097 and QC level 3 lot #271097 for the ACT quality controls run on 01/25/2019. Findings include: 1. The laboratory has an individualized quality control plan (IQCP) in place that indicates liquid QC to be run on the following schedule: monthly, new lot or new shipment of controls. 2. No manufacturer's ranges for the control lot numbers referenced above were presented for review for the purpose of verifying that the QC results from the runs were acceptable. 3. At the time of the survey it could not be determined how many patients were tested under these QC lot numbers. 4. The testing personnel acknowledged that none of the manufacturer's QC lot number assay sheets retained by the laboratory matched the QC lot numbers referenced above.

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 lack of patient test reports for review for activated clotting time (ACT) and PT/INR testing and interview with the laboratory personnel, the laboratory failed to have an adequate system in place to track when each patient was tested and the testing that was ordered. Findings include: 1. A corrective action was presented for review for the QC records and patient test results missing since testing began on the i-Stat in August 2018 for ACT testing and in December 2018 for PT/INR testing. 2. Patient test results were suppose to be scanned into the patients' charts per policy, but during the survey conducted on May 29, 2019 the laboratory could not readily produce the test reports that were scanned into the patient's charts. 3. The corrective action did not include chart audits to determine how many patients were tested for ACT and PT /INR, if the testing was ordered, if the testing was performed and if the results were scanned into the patients' charts. 4. The laboratory personnel acknowledged that the patients' charts ere not audited for the information indicated above.

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 have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on lack of verification of educational requirements and interview with the laboratory personnel, the laboratory failed to provide required documentation of testing personnel qualifications for one out of three testing personnel. Findings include: 1. No documentation of education qualifications were presented for review for one out of three testing personnel who perform moderate complexity patient testing under the specialty of Hematology. 2. The facility personnel confirmed that the education documentation for the testing personnel indicated above was not available at the time of the survey.