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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>11D0675261 | <b>(X3) Date Survey Completed</b><br><br>08/08/2018 |
| <b>Name of Provider or Supplier</b><br><br>Athens Heart Center, Pc   | <b>Street Address, City, State</b><br><br>11973 Augusta Road, Lavonia, GA  |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D0000</b>              | A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on August, 08 2018. 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:  |
| <b>D5437</b>              | <p><b>CALIBRATION AND CALIBRATION VERIFICATION</b><br/>CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of Hematology calibration documents and an interview the laboratory coordinator, the laboratory failed to perform calibrations on the Abacus 3CP CBC analyzer at least once every 6 months in 2017 and 2018. Findings include:<br/>1. A review of hematology calibration records revealed calibrations were not performed in July 2017 and January 2018 as data dictated. 2. Calibrations were performed once in 2017 (1/5/17) and once in 2018 (3/7/2018). 3. An interview with the laboratory coordinator at approximately 11:25 AM on August 08, 2018 in the review room confirmed that the calibrations were not performed at least every 6 months in 2017 and 2018.</p> |
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**D5441**

**CONTROL PROCEDURES**

CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on Quality Control (QC) document review and an interview with the laboratory coordinator, the laboratory failed to monitor Quality Control values for the Abacus 3CP Hematology Analyzer over time to check the accuracy and precision of test performance. Findings include: 1. QC review revealed no evidence of long term monitoring of Hematology QC available to review i.e. (Levy-Jennings charts or eQC) in 2017 and 2018. 3. An interview with the laboratory coordinator on August 08, 2018 at approximately 11:50 AM in the review room confirmed QC for the Abacus 3CP Hematology Analyzer was not monitored for accuracy and precision.

**D6049**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's maintenance records and an interview with the laboratory coordinator, the Technical Consultant (TC) who is also the laboratory director failed to review maintenance records in 2017, 2018. Findings include: 1. Review of maintenance logs including refrigerators, Humidity, room temperature, eye wash and problem logs revealed logs were not reviewed and signed on a monthly basis by (TC). 2. An interview with the laboratory coordinator on August 08, 2018 at approximately 11:40 am in the review room confirmed maintenance logs were not reviewed and signed by the (TC) who is also laboratory director.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of testing personnel (TP) documents and interview with the

laboratory coordinator , the Technical Consultant(TC) failed to perform or sign off on annual competencies on all testing personnel in 2017 and 2018. Findings include: 1. Review of testing personnel documents revealed the technical consultant failed to sign off or perform annual competencies on TP #1 and #2 (CMS 209 form). 2. An interview with the laboratory coordinator at approximately 11:39 AM on August 08, 2018 in the review room confirmed the (TC) did not sign off or perform annual competencies for the aforementioned testing personnel.