

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0675261	(X3) Date Survey Completed 01/07/2021
Name of Provider or Supplier Athens Heart Center, Pc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was January 7, 2021. 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:
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to ensure the laboratory was enrolled in an HHS approved PT program for the testing performed as required. Findings include: Refer to D2003 for details.</p>
D2003	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)</p>

	<p>This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to ensure the laboratory was enrolled in an HHS approved PT program for the testing performed as required. Findings include: 1. American Proficiency Institute (API) document reviewed revealed the lack of PT documents for brain natriuretic peptide (BNP) for the following Chemistry PT: 2019 - Events Two and Three; 2020 -- Events One, Two, and Three. 2. An interview with Staff #3 (CMS 209) in a medical office on 1/7/2021 at approximately 11:30 a.m. confirmed the lack of BNP PT enrollment for the aforementioned PT events.</p>
<p>D2009</p>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) and testing personnel (TP) failed to attest to the integration of PT samples into the patient workload as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed the LD and TP did not sign the 2020 Hematology/Coagulation attestation statement for Event 3. 2. An interview with Staff #3 (CMS 209) in a medical office on 1/7/2021 at approximately 11:45 a.m. confirmed the aforementioned lack of attestation statement signatures.</p>
<p>D5200</p>	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on policy and procedure manual (SOP) review, proficiency test document review, and staff interview, the laboratory failed to monitor and evaluate the overall quality of the general laboratory systems and correct identified problems as required. Findings include: For details refer to D5221 and D5291.</p>
<p>D5221</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory</p>

	<p>failed to document evaluation and verification activities as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed corrective action was not performed for the following PT analytes: Alanine Aminotransferase (ALT) -- 80 percent (2020 Core Chemistry Event Two); Thyroid Stimulating Hormone (TSH) and Total Iron -- 80 percent (2020 Core Chemistry Event Three). 2. An interview with Staff #3 (CMS 209) in a medical office on 1/7/2021 at approximately 11:30 a.m. confirmed the lack of corrective action for the aforementioned unacceptable PT scores.</p>
<p>D5291</p>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of the policy and procedure manual (SOP) and staff interview, the written quality assurance (QA) policy and procedure was not followed, as required. Findings include: 1. SOP review revealed a monthly QA checklist policy and procedure was established and approved by the laboratory director 6/26/2015. 2. At the time of survey there were no monthly QA checklist documents for the following time periods: 2018 - September through December; 2019, 2020, and 2021 thus far. 3. An interview with Staff #3 (CMS 209) in a medical office on 1/7/2021 at approximately 2:45 p.m. confirmed the lack of aforementioned QA monthly checklist available at the time of survey.</p>
<p>D5400</p>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on quality control (QC) document review and staff interview, the laboratory failed to monitor the accuracy and precision of the complete analytic process over time as required. Findings include:For details refer to D5441.</p>
<p>D5441</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(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)</p>

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 staff interview, the laboratory failed to monitor the accuracy and precision of the complete analytic process over time as required. Findings include: 1. Review of Abacus Hematology QC documents revealed the lack of Levey-Jennings charts available at the time of survey for the following time periods: 2018 -- August through December; 2019 -- January through March and May through July; 2. Review of Tosoh Chemistry analyzer QC documents revealed the lack of Levey-Jennings charts available at the time of survey for the following time periods: 2018 -- September through December; 2019, 2020, and 2021 thus far. 3. An interview with Staff #3 (CMS 209) in a medical office on 1/7/2021 at approximately 2:30 p.m. confirmed the lack of Levey-Jennings charts for the aforementioned specialties and time periods. This is a REPEAT DEFICIENCY.

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 review of the policy and procedure manual, quality control documents, quality assurance documents, testing personnel documents, and proficiency test documents, the laboratory director failed to provide overall management and direction of the laboratory as required. Findings include: For details refer to D5291, D5441, D6015, D6029.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)

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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to ensure the laboratory was enrolled in an HHS approved PT program for the testing performed as required. Findings include: 1. American Proficiency Institute (API) document reviewed revealed the lack of PT documents at the time of survey for brain natriuretic peptide (BNP) for the following Chemistry PT: 2019 - Events Two and Three; 2020 -- Events One, Two, and Three. 2. An interview

with Staff #3 (CMS 209) in a medical office on 1/7/2021 at approximately 11:30 a.m. confirmed the lack of BNP PT enrollment for the aforementioned PT events.

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 testing personnel (TP) document review and staff interview, the laboratory director (LD) failed to ensure all TP receive the appropriate training for the type and complexity of the services offered prior to testing patient specimens as required. Findings include: 1. TP competency document review revealed an initial training competency was not performed for Staff #3 (CMS 209) in 2019. 2. An interview with Staff #3 (CMS 209) in a medical office on 1/7/2021 at approximately 11:15 a.m. confirmed the lack of initial competency performance for the aforementioned TP in 2019. .

D6032

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on policy and procedure manual (SOP) review and staff interview, the laboratory director (LD) failed to specify in writing the duties and responsibilities of each person engaged in the performance of all phases of testing as required. Findings include: 1. SOP review revealed the lack of a Duties and Responsibilities policy and procedure at the time of survey.. 2. An interview in a medical office with Staff #3 (CMS 209) on 1/7/2021 at approximately 2 p.m. confirmed the SOP did not contain a Duties and Responsibilities policy and procedure.