

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0675261	(X3) Date Survey Completed 11/17/2022
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 completed on November 11, 2022. 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:
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on Proficiency Test (PT) document review and staff interview, the laboratory failed to have successful performance in two out of three consecutive Chemistry testing events in 2022. (Refer to D 2096).</p>

D2096

ROUTINE CHEMISTRY

CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on Proficiency Test (PT) document review and staff interview, the laboratory failed to have successful performance in two out of three consecutive Chemistry testing events in 2022. Findings include: 1. Review of American Proficiency Institute (API) PT documents revealed the laboratory failed to have successful performance in the following events: 2022 - Events #s 2 and 3, the laboratory scored 0% for (Sodium - Chemistry analyte) consecutively on both events. 2. An interview with the laboratory manager and Testing Personnel (TP#2 CMS 209), in the review room, at approximately 1:00 PM, on 11/17/2022, confirmed the unsuccessful PT findings in 2022.

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 record review and interview with the lab manager, the laboratory director who is also the Technical Consultant (TC), failed to ensure that annual competency assessments were completed for all testing personnel (TP) in 2021. Findings include: 1. A review of the training and competency records revealed that the laboratory director, who is also the (TC), failed to complete and sign the competency assessment form for TP (#2 CMS 209) in 2021 as specified in the laboratory procedure manual. 2. An interview with the laboratory manager (TP #2 CMS 209) , on 11/17/2022, at approximately 1:05 PM, in the review room, confirmed that the technical consultant and lab director did not ensure that all annual competencies for testing personnel were completed and signed in 2021.