

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2215260	(X3) Date Survey Completed 10/25/2022
Name of Provider or Supplier Advanced Heart & Vascular Institute	Street Address, City, State 1000 Towne Center Boulevard, Building 400, Pooler, 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	Based on the initial onsite survey performed on October 25, 2022, this facility was found NOT in compliance with the CLIA conditions found at 42 CFR 493.1230 General Laboratory Systems 493.1403 Condition: Laboratory Director, (moderate complexity)
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of a written policy and procedure to assess employee training and competency, and confirmed with staff interview, the laboratory failed to perform initial training and yearly competencies, on all testing personnel (TP), performing Moderate Complexity Testing as listed on the CMS-209 Personnel Testing document. Findings include: 1. There was no written policy and procedure for requirements of initial training, 6 month training, and yearly competency for all TP. 2. When asked if there were training documents, TP-1 was able to provide a copy of her training certificate provided by the manufacturer for training on the iSTAT hand held Chemistry/Hematology/ and Coagulation instrument,. Training documents for TP-2, TP-3, TP-4, and TP-5 were not available. 3. TP-1 could not provide any copies of 6 month training, and yearly competency documents for TP-1. TP-2, TP-3, TP-4, and TP-5. 4. An interview on 10/25/2022, at 12:30pm, with TP-1 confirmed the aforementioned statements.</p>
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 the lack of personnel records, competency records, and staff interview, the laboratory director failed to provide overall management and direction of the laboratory. The findings include: 1. The laboratory director failed to ensure that 4 out of 5 Testing Personnel (TP2, TP3, TP4, TP5) received the appropriate training in moderate complexity testing (Chemistry, Coagulation, and Hematology) prior to patient testing (refer to D6029). 2. The laboratory director failed to ensure written policies and procedures were established to assess, monitor, and maintain competency for 5 out of 5 Testing Personnel (TP1, TP2, TP3,TP4, TP5) performing moderate complexity testing (refer to D6030).

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 review of Centers for Medicare and Medicaid Services (CMS) 209 form, testing personnel records, and staff interview, the laboratory director failed to ensure that 4 out of the 5 Testing Personnel (TP-2, TP-3, TP-4, TP-5) received the appropriate training in moderate complexity testing (Chemistry, Coagulation, Hematology) prior to patient testing. The findings include: 1. Review of the CMS 209 form revealed that TP-1, TP-2, TP-3, TP-4, TP-5 are testing personnel, performing moderately complexity laboratory testing. 2. Review of personnel records revealed the following personnel hire dates: a. TP-1 12-01-2020 b. TP-2 03-09-2021 c. TP-3 02-02-2021 d. TP-4 02-02-2021 e. TP-5 08/26/2022 3. Personnel record review revealed there was no documentation of initial training for TP-2, TP-3, TP-4, or TP-5. 4. An Interview, on 10/25/2022, at 12:30 pm. , with TP-1 confirmed that there was no documented training for testing TP-2, TP-3, TP-4, TP-5. TP-1 provided a copy of her training Certificate from iSTAT on-site training. .

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for

monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on review of the CMS 209 form, lack of laboratory policy, and staff interview, confirmed the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor, and maintain competency for 5 out of 5 testing persons (TP-1, TP-2, TP-3, TP-4, TP-5) performing moderate complexity testing.

Findings: 1. Review of the CMS 209 form revealed 5 testing persons (TP-1, TP-2, TP-3, TP-4, TP-5) are performing moderate complexity testing. 2. The laboratory failed to provide a policy for personnel performing moderate complexity testing upon request. 3. During an interview on 10/25/2022 at 12:35 pm., TP-1 stated that there were no laboratory policies for training or competency assessments for testing personal. .