

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2215260	(X3) Date Survey Completed 10/23/2024
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	A recertification survey was performed on October 23, 2024. The facility was found to be NOT in compliance with the CLIA conditions and standards for specialties /subspecialties for 42 CFR. CONDITION LEVEL: D5400 - Analytic System 493.1250 D6000 - Laboratory Director Responsibilities 493.1403
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) provider, and staff interview, the laboratory testing personnel failed to label the API PT samples during testing. 2024 event 1, Specialty Chemistry (Ionized Calcium, Chloride, Creatinine, Glucose, Hematocrit, Hemoglobin, Potassium, Sodium, TCO₂, and Urea Nitrogen). The Laboratory scored an unsatisfactory score for 4 out of 5 specimens. It was determined that the sample printouts from the instrument were not labeled with the sample numbers assigned by the PT provider. A review of the Policy and Procedure manual confirmed that the laboratory did not have a Policy for labeling of sample specimens and documents. Findings: 1. Review of the API PT Performance Review and corrective action for 2024 Chemistry Core 1st event confirmed there was documentation that the "samples were mixed up, sample numbers were unknown due to mislabeling". 2. Review of the Laboratory Policy and Procedure manual, the laboratory did not have a Policy for proper labeling of specimens and report documents. 3. A self evaluation was performed documenting that sample 1 was switched with sample 2, sample 4 was switched with sample 5. 4. Interview with the</p>

Laboratory Supervisor, on 10/23/2024, at approximately 2:30 pm, confirmed that the instrument printouts were not labeled and that the results were entered incorrectly. Also confirmed was that there is no Policy for labeling specimens.

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

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.

This CONDITION is not met as evidenced by:
Based on review of the American Proficiency Testing documentation, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems. The laboratory did not have a written Policy and Procedure for labeling testing samples and instrument printouts with two unique identifiers. This is a CONDITION level citation: REFERENCE D-5403 - Procedure Manual

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
The Laboratory failed to provide a written procedure listing the requirements for the labeling of patient/testing samples before testing and labeling patient results after testing. Review of the American Proficiency Institute (API) Proficiency Testing (PT) provider documents for 2024, the laboratory failed to label instrument printouts with sample numbers for the 1st event of 2024. The laboratory received an unsuccessful score of 20% for 4 of the 5 API PT samples. Findings: 1. Review of the API PT

documents for the 1st event for 2024, the laboratory received an unsuccessful score of 20%. 2. Interview with the Laboratory Supervisor, on 10/23/2024 at approximately 1 pm in the Laboratory Supervisor's office, confirmed the aforementioned statements.

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:
Document review of the American Proficiency Institute (API) Proficiency Testing Provider (PT), revealed the Laboratory Director (LD) failed to provide oversight for the laboratory and provide a written procedure for Labeling of testing samples and instrument printouts with patient identifiers on the sample result printouts from the analyzer performing the test. Document review of 6 of the 6 testing personnel training and competency records revealed that 5 of the 5 testing personnel, listed on the Centers for Medicare and Medicaid Services Form 209 Laboratory Personnel Report, did not have an annual current competency. REFERENCE: D6004 - Laboratory Director Responsibilities - 493.1407 (a)(b)(c) D6030 - Laboratory Director Responsibilities - 493.1407(e)12 -

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on review of the American Proficiency Institute (API) Proficiency Testing Provider (PT), the Laboratory Director (LD) failed to provide oversight for the laboratory and provide a written procedure for Labeling of testing samples and instrument printouts with patient identifiers on the sample result printouts from the analyzer performing the test. FINDINGS: 1. Review of the 1st event of the API PT instrument printouts, the testing personnel (TP) failed to document the sample ID on the printouts for all 5/5 samples provided by API. 2. Review of the evaluation report for the 1st event of 2024, the laboratory received a score of 20 percent. 3. Self evaluation was performed to determine the correct sample identification and confirmed that specimen 1 and specimen 3 were switched, specimen 4 and 5 were also switched. 4. An interview with the laboratory supervisor confirmed on 10/23/2024, at approximately 1 pm, in the laboratory supervisor's office, confirmed the aforementioned statement.

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:

Document review of the Testing Personnel Training and Competency records revealed that 5/5 Testing personnel did not have an annual competency. This is a repeat Standard from the previous Recertification. Findings: 1. Testing personnel listed on the Centers For Medicare and Medicaid Form 209 (Laboratory Personnel Report) 5/5 personnel did not have competencies in 2023 as follows: TP 01: did not have an annual competency for 2023 TP 02, T3 and TP 04: did not have a six month or annual competency for 2023 2. Interview with the Laboratory Supervisor, on 10/23/2024, at approximately 2:15 pm in the office confirmed the aforementioned statement.