

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2142927	(X3) Date Survey Completed 05/16/2024
Name of Provider or Supplier Advanced Heart And Vascular Center	Street Address, City, State 1453 East Bert Kouns Industrial Loop, Suite 220, Shreveport, LA	
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 Validation survey was performed at Advanced Heart and Vascular Center, CLIA ID 19D2142927, on May 16, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, proficiency testing records and interview with personnel, the laboratory failed to ensure the Laboratory Director or designee signed the attestation form for six (6) of eight (8) proficiency testing events reviewed in 2023 and 2024. Findings: 1. Review of the laboratory's "Quality Management Program" policy under "Proficiency Testing" revealed the Point of Care department will review the proficiency testing paperwork for the following: all paperwork is accounted for, result form is completed properly with no clerical errors, and attestation forms are signed. Each survey will be signed by the appropriate medical director. 2. Review of the laboratory's American Proficiency Institute (API) proficiency testing records for 2023 and 2024 revealed the attestation forms were not reviewed by the Laboratory</p>

Director or designee for the following six (6) of eight (8) proficiency testing events: a) 2023 Chemistry Core 1st event - Attestation form b) 2023 Hematology/Coagulation 1st event - Attestation form c) 2023 Hematology/Coagulation 2nd event - Attestation form d) 2023 Hematology/Coagulation 3rd event - Attestation form e) 2024 Chemistry Core 1st event - Attestation form f) 2024 Hematology/Coagulation 1st event - Attestation form 3. In interview on May 16, 2024 at 11:25 am, Testing Personnel 9 stated she was unaware that the Laboratory Director or his designee should also sign the attestation statement along with testing personnel.. The Technical Consultant confirmed the attestation statements were not signed as required in 2023 and 2024.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of the laboratory's Individualized Quality Control Plan (IQCP), quality control records, patient logs and interview with personnel, the laboratory failed to perform quality control (QC) for Chem 8 and Activated Clotting Time (ACT) testing on the I-Stat analyzer every thirty (30) days of use for five (5) of seventeen (17) months reviewed in 2023 and 2024. Findings: 1. Observation by surveyor during the laboratory tour on May 16, 2024 at 1:15 pm revealed the laboratory utilizes the two (2) I-Stat analyzers for the following patient testing: a) Chem 8 cartridge to include: Sodium (NA), Potassium (K), Chloride (CL), Ionized Calcium (i CA), Glucose (GLU), Blood Urea Nitrogen (BUN), Creatinine (CREA), Hematocrit (HCT), Hemoglobin (HGB) b) Activated Clotting Time (ACT) 2. Review of the laboratory's Individualized Quality Control Plan (IQCP) revealed the following external quality control plan (QCP): a) CHEM 8: external quality control (QC) two (2) levels performed every 30 days, new lot, or new shipment b) ACT: external quality control (QC) two (2) levels performed every 30 days, new lot, or new shipment 3. Review of the laboratory's quality control (QC) records from January 2023 through May 2024 revealed the laboratory did not perform external QC every thirty (30) days for the following five (5) of seventeen (17) months reviewed: a) February 2023: QC performed January 20, 2023; due February 20, 2023; not performed until February 24, 2023 b) November 2023: QC performed October 12, 2023; due November 12, 2023; not performed until November 20, 2023 c) December 2023: QC performed November 20, 2023; due December 15, 2023; not performed until December 18, 2023 d) January 2024: QC performed December 18, 2023; due January 18, 2024; not performed until January 22, 2024 e) February 2024: QC performed January 22, 2024; due February 22, 2024; not performed until February 26, 2024 4. Review of patient test logs revealed the laboratory reported the following thirty four (34) patients for Chem 8 and ACT testing without performance of external QC per IQCP: a) February 22, 2023: MR 193384 - ACT testing b) November 13, 2023: MR 169482 - ACT testing c) November 14, 2023: MR 123256 - Chem 8 testing

d) November 15, 2023: MR 69561 - Chem 8 testing e) November 15, 2023: MR 218968 - ACT testing f) November 15, 2023: MR 218968 - ACT testing g) November 15, 2023: MR 189070 - ACT testing h) November 15, 2023: MR 189070 - ACT testing i) November 15, 2023: MR 69561 - ACT testing j) November 15, 2023: MR 69561 - ACT testing k) November 15, 2023: MR 69561 - ACT testing l) November 15, 2023: MR 69561 - ACT testing m) November 15, 2023: MR 69561 - ACT testing n) November 15, 2023: MR 69561 - ACT testing o) November 15, 2023: MR 69561 - ACT testing p) November 15, 2023: MR 69561 - ACT testing q) November 15, 2023: MR 69561 - ACT testing r) November 15, 2023: MR 54777 - ACT testing s) November 15, 2023: MR 54777 - ACT testing t) November 15, 2023: MR 54777 - ACT testing u) November 15, 2023: MR 45799 - ACT testing v) November 17, 2023: MR 222447 - ACT testing w) December 15, 2023: MR 132309 - ACT testing x) December 15, 2023: MR 132309 - ACT testing y) December 15, 2023: MR 115723 - ACT testing z) December 19, 2023: MR 147366 - Chem 8 testing aa) January 19, 2024: MR 106240 - Chem 8 testing bb) January 19, 2024: MR 223467 - Chem 8 testing cc) January 19, 2024: MR 223467 - ACT testing dd) January 19, 2024: MR 221828 - ACT testing ee) February 22, 2024: MR 223879 - ACT testing ff) February 23, 2024: MR 223952 - Chem 8 testing gg) February 23, 2024: MR 15814 - ACT testing hh) February 22, 2024: MR 15814- ACT testing 5. In interview on May 16, 2024 at 12:20 pm, the Technical Consultant confirmed the laboratory did not perform external QC every thirty (30) days per their IQCP.

D6018

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

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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
Based on laboratory policy and proficiency testing records and interview with personnel, the Laboratory Director failed to ensure proficiency testing attestation statements were signed by the appropriate personnel in 2023 and 2024. Refer to D2015.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's Individualized Quality Control Plan (IQCP),

quality control records and interview with personnel, the Laboratory Director failed to ensure the quality control program was followed to assure the quality of testing in the laboratory. Refer to D5445.

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 laboratory policy, personnel records and interview with personnel, the Laboratory Director failed to ensure policy and procedures for assessing personnel competency were maintained in 2023 and 2024. Refer to D6046.

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:
Based on review of the laboratory's Individualized Quality Control Plan (IQCP), quality control records and interview with personnel, the Technical Consultant failed to ensure the quality control program was followed to assure quality of laboratory testing. Refer to D5445.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of the laboratory policy, Laboratory Personnel Report (CMS 209), personnel records, and interview with personnel, the Technical Consultant failed to perform annual competencies in 2023 and 2024 for eleven (11) of eleven (11) testing personnel reviewed: 1. Review of the laboratory's "Quality Management Plan" policy

revealed the following: Non-Waived Testing Assessment - Initial, semiannually, annually after first year for direct observation of routine work by supervisor or designee, monitoring the recording and reporting of test results, review of intermediate test results, quality control records, proficiency test results and preventative maintenance records, direct observation or performance of instrument maintenance and function check, assessment of test performance through testing previously analyzed samples, blind testing samples, or external proficiency testing samples and evaluation of problem solving skills. 2. Review of the Laboratory Personnel Report (CMS 209) form revealed the following eleven (11) of eleven (11) serve as Testing Personnel: * Personnel 2 - 12 3. Review of the laboratory's personnel records from 2023 and 2024 revealed the Technical Consultant did not perform the competency assessments for the following eleven (11) of eleven (11) testing personnel reviewed: a) Personnel 2 b) Personnel 3 c) Personnel 4 d) Personnel 5 e) Personnel 6 f) Personnel 7 g) Personnel 8 h) Personnel 9 i) Personnel 10 j) Personnel 11 k) Personnel 12 4. In interview on May 16, 2024 at 1:15 pm, the Technical Consultant stated the competency assessments were performed in 2023 and 2024 by the cath lab supervisor. The Technical Consultant confirmed the competency assessments were not performed by qualified personnel.