

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2190122	(X3) Date Survey Completed 06/09/2021
Name of Provider or Supplier Conway Cardiovascular Surgery Center	Street Address, City, State 650 United Drive Suite 120, Conway, AR	
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
D2009	<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: . Through a review of proficiency testing documentation, lack of documentation, and interviews with staff, it was determined the laboratory testing personnel and director failed to sign the attestation statements for two of two proficiency testing events. Survey findings follow: A. A review of the proficiency testing documentation revealed for the third testing event of 2020 and the first testing event of 2021 the attestation statement had no signatures of testing personnel or director. B. In an interview on 6/9/2021 at 10:20, laboratory employee #1 (as listed on CMS form 209) confirmed that the forms lacked the required signatures.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: . Through a review of the laboratory procedure manual, lack of documentation, and interviews with laboratory staff, it was determined the laboratory director failed to approve, sign, and date the laboratory procedures. Survey findings include: A. During a review of the laboratory procedures it was determined the procedure manual and individual procedures lacked the directors approval signature and date of approval. B.</p>

In an interview at 10:20 on 6/9/21, laboratory employee #1 (as listed on the form CMS-209) confirmed the laboratory directors written approval of the laboratory procedures was not available.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

. 1. Through a review of new instrument validation records for the Accrvia Hemochron Activated Clotting (ACT) analyzer, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to validate method correlation for the Accrvia Hemochron to verify that the manufacturer's reference intervals are appropriate for the laboratory's patient population. Survey findings follow: A. A review of the new instrument validation for the Accrvia Hemochron analyzer revealed the analyzer validation was performed on 10/13/2020 and revealed that no data was present to verify that the manufacturer's reference intervals (normal ranges) are appropriate for the laboratory's patient population. B. Upon request, the laboratory was unable to provide method correlation data for the validation of the Accrvia Hemochron analyzer. C. In an interview, at 1145 on 6/09/2021, laboratory personnel #1 (as listed on the form CMS-209) confirmed that method correlation was not performed as part of the validation of Accrvia Hemochron ACT the analyzer. 2. Through a review of new instrument validation records for the Accrvia Hemochron Activated Clotting (ACT) analyzer, lack of documentation, as well as interviews with staff, it was determined the laboratory director failed to approve or sign the validation procedure. A. A review of the validation documentation revealed the laboratory director failed to sign or approve the validation of the Accrvia Hemochron. The documents were signed by laboratory personnel #3. B. In an interview on 6/9/2021 at 1:00, laboratory personnel #3 confirmed the validation documents were not signed by laboratory director.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Through a review of quality control documentation, and interviews with laboratory staff, it was determined the laboratory failed to perform two levels of quality control each day of moderate complexity patient testing on the Accrvia Hemochron Activated

Clotting (ACT) analyzer. Survey findings follow: A. A review of the quality control documentation for six of six months in 2021 revealed the laboratory were performing quality controls on a weekly basis. B. A review of quality control documentation for January 2021 revealed the laboratory had no quality control documentation for 1/20/2021, 1/27/2021, and 1/29/2021. Seven patients had ACT testing on the days mentioned. C. A review of quality control documentation for February 2021 revealed the laboratory had no quality control documentation for 2/01/2021, 2/03/2021, 2/08/2021 and 2/10/2021. Seven patients had ACT testing on the days mentioned. D. A review of quality control documentation for March 2021 revealed on 3/10/2021 and 3/17/2021 the laboratory had no documentation of quality controls. On 3/10/2021 four patients had ACT testing and one patient on 3/17/2021. E. A review of quality control documentation for April 2021 revealed on the laboratory had no documentation of quality controls on the following days 4/7/2021,4/8/2021, 4/9/2021, 4/13/2021, 4/14/2021,4/21/2021, 4/23/2021, 4/27/2021, 4/28/2021 and 4/30/2021. The laboratory performed ACT testing on twenty patients on the days mentioned. F. A review of quality control documentation for May 2021 revealed on the laboratory had no documentation of quality controls On 5/4/2021, 5/5/2021, 5/7/2021, 5/12/2021, 5/19/2021, 5/21/2021 and 5/27/2021. The laboratory performed ACT testing on twelve patients on the days mentioned. G. In an interview on 6/9/2021 at 10:30 a.m., laboratory personnel #2 (as listed on the form CMS-209) confirmed that the laboratory only performs external quality control on an weekly basis instead of each day of testing. The surveyor asked if the laboratory had developed an Individualized Quality Control Plan (IQCP) for the Accrvia Hemochron Activated Clotting (ACT) analyzer cartridges in order to perform testing less frequently than each day of testing. Laboratory personnel #1 confirmed that the laboratory did not develop an IQCP.

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:
 . Through a review of personnel records for three of three testing personnel, lack of documentation, and interviews with laboratory staff, it was determined the laboratory director failed to specify, in writing, the procedures each individual is authorized to perform, and whether supervision is required for reporting patient test results. Survey findings follow: A. During a review of personnel records for three of three testing personnel, it was determined that testing personnel #1, #2 and #3 (as listed on form CMS-209) had no written authorization to perform testing without direct supervision. B. During an interview, at 10:30 a.m. on 6/08/2021, laboratory employee #1 (as listed on the form CMS-209) confirmed that written authorizations to test were not available.

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:

. Through review of the CMS form 209, personnel records, lack of documentation, and interview with staff, it was determined that the technical consultant failed to document personnel competency on an annual basis for one of three testing personnel identified on the CMS form 209. Survey findings follow: A. A review of personnel records for testing personnel revealed that the technical consultant failed to evaluate the competency for testing personnel #1 (as listed on form CMS 209) for 2020 and 2021. B. Upon request, the laboratory could not provide competency evaluations for the personnel identified above. C. In an interview on 6/9/2021 at 10:30 a.m., laboratory personnel #1 confirmed that competency evaluations had not been performed on testing personnel #1 (as listed on form CMS 209).