Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2196275	10/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Arkansas Heart Hospital Llc-Encore	1901 Encore Way, Bryant, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: . Through a review of Respiratory Therapy policy, proficiency testing documentation for 2021, as well as interviews with staff, it was determined that proficiency testing samples were not tested by all personnel who routinely perform Blood Gas patient testing. Survey Findings follow: A. A review of the Respiratory Therapy Policy revealed the procedure for proficiency testing:" Follow the same procedure as patient testing." B. A review of Respiratory Therapy proficiency test attestation statements for three of three events in 2021 revealed that Respiratory personnel #2, #3, #4 and #5 (as listed on form CMS 209) had not participated in proficiency testing. C. In an interview, at 10:23 a.m. on 10/13/2021, laboratory personnel #1 (as listed on the form CMS-209) confirmed that Respiratory personnel who routinely test patient sample for Blood Gas Analysis did not participate in proficiency testing for three of three events in 2021.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in

	electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: . Through observation, review of manufacturer's user's manual, lack of documentation and interviews with laboratory and hospital staff it was determined that the laboratory failed to monitor room humidity level in one of one room in which instruments with an operating humidity level were utilized for patient testing. Findings follow: A) During a tour of the laboratory on 10/12/21 at 09:55 AM two Dimension EXL 200 instruments were observed in operation performing patient testing. B) Review of the manufacturer's manual for the Dimension EXL 200 analyzer revealed an operating humidity requirement of 20% to 80%. C) Review of the laboratory's policy and procedure for laboratory environmental requirements revealed an acceptable humidity range of 10% to 85% which does not conform to the requirement specified for the Dimension EXL 200 analyzer. D) Upon request, the laboratory could not provide record of room humidity level for the room in which the Dimension EXL 200 analyzers were in operation. E) In an interview on 10/13/21 at 10:40 AM the laboratory staff member, identified as number one on the CMS 209 form, said the laboratory had no record of room humidity level but stated that hospital engineering services might have computerized records of room humidity. F) In an interview on 10 /13/21 at 01:00 PM, the hospital engineering staff member, identified as number one on a separate staff member list, said that no parameters have been set for acceptable humidity levels and there is no system for notification of laboratory staff if levels are outside of acceptable range and records of humidity maintained are for "return air" and do not accurately represent the ambient room humidity in the laboratory.
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: . Through a review of the new instrument verification documentation for the Siemens Dimension Exl 200 dated 12/7/2020 and interviews with laboratory staff, it was determined the laboratory failed to verify the reportable range of Cholesterol and Aspartate Aminotransferase (AST) and failed to verify the manufacturer's normal values for five of thirty-five chemistry tests (HDL Cholesterol, Triglyceride, Cholesterol, C Reactive Protein, and AST) are appropriate for the laboratory's patient population. Survey findings include: A. Through a review of the Analytic Range Verification for Cholesterol on the Dimension Exl 200 (serial number 272830) it was determined the analytical range listed on the documentation is 50 - 600 but the laboratory only documented verification to 426.667. Although the laboratory only validated to 426.667 they continue to use the analytic range of 50 - 600. This was confirmed with laboratory employee #1 (as listed on the form CMS-209) in an interview at 1:45 p.m. on 10/12/2021. B. Through a review of the Analytic Range Verification for AST on the Dimension Exl 200 (serial number 272845) it was

	determined the analytical range listed on the documentation is 0 - 1000 but the laboratory only documented verification to 823.667. Although the laboratory only validated to 823.667 they continue to use the analytic range of 0 - 1000. This was confirmed with laboratory employee #1 (as listed on the form CMS-209) in an interview at 1:45 p.m. on 10/12/2021. C. During a review of the Normal Reference Range Verification documentation, it was revealed that the laboratory tested five laboratory employees who were used to represent the normal population. Normal ranges for the following tests are not verified due to the employees results for these tests being reported outside of the normal range: HDL Cholesterol (2 of 5 outside of normal range); Triglyceride (3 of 5 outside of normal range); Cholesterol (4 of 5 outside of normal range); C-Reactive Protein (3 of 5 outside of normal range) and AST (4 of 5 outside of normal range). In an interview, at 1:50 p.m. on 10/12/2021, laboratory employee #1 confirmed the five employees tested did not validate the normal ranges in use and further confirmed that there was no other validation performed.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Through a review of the Chemistry Calibration and QC Policy, a review of chemistry Levey-Jennings Charts, and interviews with laboratory staff, it was determined the laboratory failed to monitor over time the accuracy on four of twelve tests reviewed. Survey findings include: A. The Chemistry Calibration and QC Policy states, "The mean must fall within the reference range set by the manufacturer guidelines. The range is then set by using the mean of the reference and the historical SD. These values are reviewed weekly by Chemistry Supervisor or designee and monthly by Administrative Laboratory Director and are adjusted as needed. Shifts and Trends will be documented... Guidelines for acceptance or rejection of quality control run are programmed internally to the analyzer. The following Westgard rules are activated: R1 (2s) and R10x. Any data point flagged by the analyzer will require a decision from the technologist to accept or reject the data. The technologist will monitor the data for shifts and trends." The policy further states, "Shifts or trends are to be addressed immediately and be accompanied by documentation of remedial actions." B. Through a review of quality control Levey-Jennings Charts for Bio-Rad Multiqual Control (lot #45870) it was revealed that the graph for Lipase Level 2 Control included a shift below the mean, starting on 2/5/2021 and continuing through the date of the survey (10/13/2021). The shift included 272 consecutive points below the mean. The quality control documentation failed to include R10 flags (10 consecutive points on one side of the mean) and failed to have documentation that the shift was addressed as required by the QC policy. C. During the review of quality control Levey-Jennings Charts for

	Bio-Rad Multiqual Control (lot #45870) the following additional shifts without R10 flags were noted by the surveyor: Alkaline Phosphatase Level 2 shifted below the mean 29 consecutive points from 9/6/2021 through 10/13/2021; Calcium Level 2 shifted above the mean 17 points from 9/17/2021 through 10/13/2021, and Glucose Level 2 shifted below the mean 23 consecutive points from 9/21/2021 through 10/12 /2021. D. In an interview, at 9:37 a.m. on 10/13/2021, employee #1 (as listed on the form CMS-209) stated that the R10 flag (used to identify shifts) was not turned on and confirmed the shifts noted by the surveyor had no documented actions.
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: . Through a review of Individualized Quality Control Plan (IQCP) for the Hemochron Signature Elite-ACT, Quality Control (QC) documentation, Quality Control (QC) records for March and August 2021, patient testing log, lack of documentation as well as interview with staff it was determined that Cath-Lab #2 (E-CL 2) laboratory failed to document QC according to the frequency establish in their IQCP policy. Survey Findings Follow: A. A review of the IQCP for Hemochron Signature Elite for performing Activating Clotting Times (ACT) revealed the Quality Control Plan "Two levels of Liquid Quality Control (LQC) will be performed every thirty-days that the instrument is in use." B. A review of the ACT Quality Control documentation for March and July 2021 (two of ten months) revealed on March 24,2021 LQC level 2 (lot #G0DCA0062) was analyzed with a result of 451. There was no documentation that E-CL 2 laboratory had analyzed LQC level 1 on March 24, 2021. C. The surveyor requested ACT Quality Control documentation for Level 1 on March 24, 2021. None was provided. D. A review of the ACT patient logs revealed patient #941997 had an ACT ran on April 2, 2021 @ 10:13 am. E. In an interview on 10/13/2021 at 10:40, laboratory personnel #1(as listed on form CMS 209) confirmed patient was tested and reported with only one level of acceptable ACT QC on March 24, 2021.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

	This STANDARD is not met as evidenced by: . Through review of the laboratory policy and procedure for Quality Control (QC), the Coagulation Problem Log for July 2021, notes of corrective action, patient result reports, lack of documentation and interviews with laboratory staff it was determined that the laboratory failed to evaluate patient results back to the last successful performance of QC, on one of one occasions in one of 31 days of operation when QC failed criteria for acceptability for Prothrombin Time (PT) analysis and corrective action required changes to the analytic systems. Finding follow: A) Review of the laboratory policy and procedure revealed that action to be taken when QC fails criteria for acceptability incuded"with-hold patient results until the problem is solved and both controls are in acceptable limits" and "then you must rerun patients from the previous day" B) Review of the Coagulation Problem log for July 2021 revealed that level 1 STA Coagulation Control N Plus lot # 257263 at 2030 on 7/12/21 was noted as out of acceptable range with a note "repeat not ok, remade QC material and reagent" . The corrective action represented a change in the analytic system. C) Review of QC results revealed the previous acceptable QC results for PT testing was performed on 7 /12/21 at 1400. D) Review of patient result reports revealed that a PT test was performed and reported on one patients, identified as number 957888 on 7/12/21 at 1435. E) Upon request, the laboratory was unable to provide documentation that the patient result performed at 1435 on 7/12/21 reported had been evaluated. F) In an interview on 10/12/21at 01:50 PM the laboratory staff member, identified as number one on the CMS 209 form, confirmed that the PT test performed at 1435 on 7/12/21 had not been evaluated and it should have been.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting and whether supervisory 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 laboratory personnel, lack of documentation, and interviews with laboratory staff, it was determined the Laboratory Director failed to specify, in writing, the procedures twelve of twelve testing personnel surveyed can perform, and whether supervision is required. Survey findings follow: A) Personnel records for clinical laboratory employees #2 through #7, #18, #16, #21, #26, #31 and # 36, as listed on the form CMS-209, failed to include written authorization to perform testing, signed by the laboratory director. B) Upon request, the laboratory could not provide written authorization to perform testing for the personnel identified above. C) In an interview at 10:58 on 10/12/21, laboratory staff member, identified as #1 on the CMS 209 form, confirmed that lack of signed authorizations for laboratory testing personnel.