Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 04D2196275	**(X3) Date Survey Completed** 08/20/2025
Name of Provider or Supplier Arkansas Heart Hospital Llc-Encore	**Street Address, City, State** 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based upon review of the laboratory's records for establishing the Normal Patient Mean Prothrombin Time (MNPT), the user's manual for the Stago Compact Max coagulation analyzer, confirmation of the MNPT set in the Stago Compact Max instrument for calculating the International Normalized Ratio (INR) and interview, the laboratory was using the incorrect MNPT value in the Stago Compact Max coagulation analyzer for the Neoplastine CL Plus reagent Lot # 271563 used fron 6/27/25 until date of survey . Findings follow: A) Review of the user's manual for the Stago Compact Max coagulation analyzer revealed that the MNPT must be determined specifically for each lot of Neoplastine CL Plus and entered into the instrument settings. B) Review of records used to establish the MNPT for Neoplastine CL Plus lot # 271563 dated 1/25/25 revealed that the geometric mean of the 20 samples used to establish the MNPT was determined to be 13.1 seconds. C) In an interview on 8/19/25 at 01:38 p.m., the laboratory staff member (#2 on the form CMS 209) stated the MNPT set in the Stago Compact Max coagulation analyzer was 14.4 instead of 13.1, as reported on the records for establishment of the MNPT, which would have caused an error in the calculation of the INR affecting all patient INR tests reported since Neoplastine CL Plus reagent lot # 271635 was placed into use on 6/27/25 (56 days). D) In an interview on 8/19/25 at 02:15, the laboratory staff member (#2 on the form CMS 209) confirmed that the correct MNPT determined for Neoplastine CL Plus lot # 271563 was 13.1 seconds and the MNPT set in the Stago Compact Max coagulation instrument was 14.4. The MNPT of 14.4 was the MNPT

	value of the previous lot number of Neoplastine CL Plus reagent and was not changed when the lot 271563 was implemented on 6/27/25.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on policy, lack of documentation and an interview, the laboratory failed to follow established written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in analytic systems. Findings include: A. Policy titled "Chemistry Calibrations and QC Policy" (5161.71 version 3.0 Effective Date 8/20/2019) states "4. On-going review of quality control data is performed by all technologists with particular attention to patterns of shifts or trends in the method. Shifts or trends are to be addressed immediately and be accompanied by documentation of remedial actions." B. For C-reactive protein chemistry testing, level I quality control results for lot 10031110 Biorad Cardiac Markers Plus LT were above the mean for 59 of 61 days from 6/20/25 to 8/19/25. C. Upon request, no documentation showing how the shift was addressed was available. D. At 3:43 on 8/20/25 Technical Consultant #1 (as listed on the CMS-209 form) confirmed that documentation addressing the above shift was not available.