Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2196275	09/20/2023
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
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Through review of CFR 606.151, the laboratory policy and procedure for emergency release of un-crossmatched blood, emergency release forms for 2022 and 2023, and interviews with hospital staff, it was determined that the laboratory failed to have the physician in charge sign the authorization for the emergency release of un-crossmatched blood in 4 of 13 cases reviewed. Findings follow: A) Review of CFR 606.151 reveals that for procedures to expedite transfusions in life-threatening emergencies "records of all such incidents shall be maintained, including complete documentation justifying the emergency action, which shall be signed by a physician". B) Review of the laboratory policy for the emergency release of un-crossmatched blood revealed under the heading of 'procedure' "the physician in charge must authorize the use of un-crossmatched blood" and under the heading of "final documentation", "the emergency release authorization form signed by the physician". C) Review of the emergency release authorization forms for thirteen emergency release of un-crossmatched blood for 2022 and 2023 revealed that 4 were signed by personnel identifying with the credentials "APRN"as the authorizing physician D) In a

	telephone interview on 9/20/23 ay 09:57 a.m. the hospital risk management staff member (identified on a separate staff identification form) confirmed that there were no privileges granted or official documentation of delegation of authority to order the emergency release of un-crossmatched blood in emergency situations to non-physician personnel.
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 of fifteen testing personnel performing moderately complex laboratory assays and interviews with laboratory staff, it was determined the laboratory director failed to give written authorization for seven of fifteen testing personnel to perform moderately complex procedures without direct supervision. Survey findings follow: A) A review of personnel records of fifteen randomly selected testing peronnel, who have completed training for performing moderately complex procedures, revealed that seven (#17, #18, #23, #26, #28, #33, #36 as listed on the form CMS-209) failed to have the laboratory director's written authorization to perform moderately complex testing without supervision. B) In an interview, at 10:40 a.m. on 9/19/23, laboratory employee (#2 as listed on the form CMS-209) confirmed the lack of written authorizations for the seven personnel identified above and that they performed moderately complex testing for Arterial Blood Gas and/or Activated Clotting time Determinations.