Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0466006	01/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Baptist Health Medical Center Arkadelphia	3050 Twin Rivers Dr, Arkadelphia, 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
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (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 the laboratory records, lack of documentation and interview it was determined that the laboratory failed to complete compatibility testing for four of six instances of the emergency release of blood as required by CFR 606.160 (b) (3) (v). Findings follow: A) Review of Blood Bank records for emergency release of blood products for 2022 and 2023 revealed that thirty-one units were released on emergency release basis for the two-year period. The surveyor selected xix of the events at random for review. B) Review of CFR 606.160 (b)(3)(v) revealed that the laboratory must keep records of "Emergency release of blood, including signature of requesting physician obtained before or after release" and "compatability test records". C) Review of the Blood Bank record of six randomly selected occasions of the emergency release of blood products revealed that on 7/29/22 unit # WO 910 247899 was released on an emergency basis to patient 00420506 with no follow-up cross-match result being recorded, on 4/22/23 unit # WO 910 194102 was released on an emergency release basis to patient (# 1 on a separate patient identification list) with no follow-up cross-match result being recorded, on 8/14/23 unit # WO 910 270165 was released on an emergency release basis to patient (# 2 on a separate patient identification list) with no follow-up cross-match result being recorded. and on 10/25 /23 unit # WO 910 283569 was released on an emergency release basis to patient 02195250 with no follow-up cross-match result being recorded . D) Upon request, the laboratory was unable to provide documentation of cross-matches being completed for

	the cases identified above or to provide documentation of the reasons that cross-matches were unable to be completed. E) In an interviw on 1/10/24 at 01:35 p.m., laboratory staff member (# 4 on CMS 209 form) confirmed that the units identified above were released and administered to patients without follow-up cross-matches being performed or reasons for the lack of cross-matches documented.