Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D1081363	07/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ozarks Community Hospital At Gravette	1101 Sw Jackson Street, Gravette, 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 the laboratory policy for "Release of Blood in Emergency Situations", review of "Release for Uncrossmatched Blood" forms, the Blood Bank Crossmatch log, lack of documentation, and interview it was determined that the laboratory failed to ensure and keep records of post release crossmatches on units released under emergency release protocol on one of one unit released since January 1, 2021. Findings follow: A) Review of the laboratory policy number 800.709.212 "release of Blood in Emergency Situations" states in paragraph 8 "complete antibody screen testing and crossmatch all units that were released that were issued uncrossmatched" and, in paragraph 9 it states "notify physician and the pathologist immediately of abnormal test results that may affect patient safety". . B) Review of emergency release forms revealed that on 3/29/21 the laboratory released two units of packed RBC's under emergency release protoocol to one patient. The receiving patient and unit numbers are documented on a separate "Blood Bank Patient and Blood Unit" identification list. C) Review of the Blood Bank log revealed that on 3/29/21 units WO 451 21 071133 and WO 451 21 124278 were released on emergency release

	protocol. Unit WO 451 21 124278 was crossmatched but subsequently returned to the Blood Bank without having been given to the patient and unit WO 0451 21 171133 was given to the patient but there were no records of a crossmatch having been performed on or after 3/29/21. D) In an interview on 6/30/21 at 2:12 PM, the laboratory staff members identified as numbers 3 and 4 on the CMS 209 form, stated that there is no record of crossmatch being performed for the patient, identified on the separate "Blood Bank Patient and Blood Unit" identification list, for the unit, identified above, which had been administered to the patient.