Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0452541	04/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Osborne County Memorial Hospital	237 West Harrison Street, Osborne, KS	

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
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on the review of Immunohematology Post Transfusion Reaction reports, compatability review forms and interview, the laboratory failed to document any optional testing and the pathologist interpretation on 2 of 2 post transfusion reaction patient reports. Findings: 1. Review of 2 of 2 Blood Bank Compatility Review forms revealed the signature and date of the Technical Supervisor (TS) for unit W200920353373 and an interpretive comment, signature and date of TS for unit W200920332317. 2. Review of 2 of 2 Post Transfusion Reaction Reports for the same patient who received the 2 units reveals both reports listed postive Direct Antibody Test (DAT) results for both the pre-transfusion and post-transfusion specimens tested (listed as step 3 on the form). 3. The form states: "If any results in steps 2, 3, or 4 are positive, continue with optional testing ordered by the pathologist. 4. No optional testing reference was present on 2 of 2 patient report forms. 5. No interpretive comment by the pathologist was present on 2 of 2 patient report forms. 6. The signature and date of the TS was present on both patient report forms. 7. The General Supervisor (GS) #1 stated the Blood Bank Compatability Review form was not a

	patient test report and was not placed into the patient's EMR. The documents labeled as Post Transfusion Reaction Reports are used as the patient test report. 8. Interview with GS #1 on 19 April, 2021 at 3:45 p.m. confirmed, the laboratory failed to document any optional testing and the pathologist interpretation on 2 of 2 post transfusion reaction patient reports.