Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0507318	11/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
W J Mangold Memorial Hospital Lab	320 N Main St, Lockney, TX	

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: Based upon review of manufacturer's instructions, quality control records, transfusion service records and interview of facility personnel, the laboratory failed to perform quality control procedures for ABO and D typing on 4 of 689 days between January 1, 2023 and November 20, 2024 using the MTS A/B/D Monoclonal Grouping Card. The findings included: 1. Review of the Micro Typing Systems MTS A/B/D Monoclonal Grouping Card instructions for use found on page 6 under the heading quality control: "To confirm the reactivity and specificity of the microtubes containing Anti-A and Anti-B, it is recommended that each lot of cards be tested each day of use with antigen positive and antigen negative red blood cells. To confirm the reactivity and specificity of the microtubes containing Anti-D, it is recommended that each lot of gel cards be tested on each day of use with D-positive or weak D-positive and D-negative red blood cells." 2. Review of quality control records found no quality control procedures documented on the following dates when donor units were typed for crossmatch: 01/17/2023 01/20/2023 09/23/2023 10/31/2024 3. Review of transfusion service logs found the following units typed for crossmatch on the following dates: 01

	/17/2023 - Units W041523001308 and W041523000339 01/20/2023 - Units W041523000005 and W041523000312 09/23/2023 - Unit W041523028772 10/31 /2024 - Unit W04152403255600 4. During interview of the Technical Consultant conducted November 20, 2024 at 10:46 AM she confirmed that the laboratory did not test quality control materials each day of patient testing.