

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0508127	(X3) Date Survey Completed 08/25/2021
Name of Provider or Supplier Mitchell County Hospital	Street Address, City, State 997 West I20, Colorado City, 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	<p>IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Review of policies and procedures, patient test records, quality control records and interview of facility personnel found the laboratory failed to ensure that quality control procedures were performed each day of patient testing in Immunohematology. The laboratory failed to document quality control testing for ABO and Rh testing on two of 57 days between January 1, 2021 and August 24, 2021. The findings included: 1. Review of the procedure titled Blood Bank Quality Control procedure using Immucor Reagent corQC Test System (approved by the laboratory director 11/21/2006) found under the heading Purpose: " The purpose of Daily quality assurance in the Blood Bank is to confirm the reliability of the test system which includes reagents, test procedures and equipment. The minimum quality control testing required each day of use is: Positive control tested daily Anti-A, Anti-A,B, Reverse Group A1 and B, Screening Cells Monospecific Anti-IgG. Negative Control tested daily Anti-A, Anti-A,B, Reverse Group A1 and B, Screening Cells Monospecific Anti-IgG. " 2. Review of patient test records between January 1, 2021 and August 24, 2021 found that the laboratory failed to perform and document quality control procedures on the</p>

following dates when patient specimens were tested for ABO, Rh, and antibody screening procedures: March 16, 2021 - patient 668644 was tested for ABO and Rh without documentation of quality control procedures. August 20, 2021 - patient 685720 (crossmatch only) had one unit of blood tested for ABO and Rh without documentation of quality control procedures. 3. Review of Blood Bank quality control records found: a. March 5 through March 25, 2021, quality control procedures were documented for the following dates: March 5, 2021 March 6, 2021 March 8, 2021 March 10, 2021 March 25, 2021 Quality control records were reviewed by the General supervisor on April 16, 2021 and by the Laboratory Director on May 28, 2021. b. August 19 through August 23, 2021, quality control procedures were documented for August 19, 2021 and August 23, 2021. No documentation of Quality control records review by the laboratory director and or the general supervisor as of August 24, 2021. 4. Interview of the General Supervisor conducted on August 24, 2021 at 2:12 PM confirmed that there was no documentation of quality control activities conducted prior to testing patients and donor units on the two dates.