Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0525341	05/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Moab Regional Hospital	450 W Williams Way, Moab, UT	

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 on patient test records review and interview with the laboratory manager and general supervisor for immunohematology, the laboratory procedure failed to ensure they followed requirments to follow manufacturer's and Federal Food and Drug Administration (FDA) instructions to include an antibody screen for IgG antibody detection and an immediate spin crossmatch step for IgM antibody detection for patients that are being crossmatched for red blood cell compatibility. The labortory performed approximately 5 crosmatches per month. No cross matches were observed that included a positive antibody screen between May 2017 and May 2019. Findings include: 1. Patient test records review failed to include documentation the laboratory performed antibody screen plus an immediate spin cross match for patient logged as MRN#9432 on 08/27/2017. The laboratory performed the crossmatch but failed to document the antibody screen was performed. 2. The laboratory procedure manual failed to include the inclusion of an immediate spin crossmatch step for patients with a previously identified positive antibody screen or currently testing positive for an antibody screen. 3. In an interview conducted on 05/14/2019 at approximately 10:00

	A.M. the laboratory manager stated the actual laboratory process was to perform an immediate spin crossmatch for patients with a negative antibody screen but proceded to an IgG only crossmatch (immediate spin is not performed) for patients that have a positive antibody screen or had a previously identified antibody. The MTS manufacturer has updated their procedure to include the FDA requirement to ensure compatibility is confirmed for IgM (immedicate spin crossmatch as well as IgG (via an indirect Coombs procedure) antibody presence detection.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on patient test reports review and confirmation by the laboratory manger, three of three histopathology test reports reviewed failed to include the location for where frozen section tests were performed. Findings include: 1. Patient test reports for patients S17-2877, S18-0957, and S19-6632 failed to include the location for where testing was performed. 2. In an interview conducted on 05/13/2019 at approximately 5: 45 P.M. the laboratory manager confirmed the test reports did not include the location where frozen section tests were performed