

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D1019096	(X3) Date Survey Completed 11/09/2018
Name of Provider or Supplier Kansas Spine & Specialty Hospital, Llc	Street Address, City, State 3333 N Webb Road, Wichita, 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
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: Based on review of blood bank procedure, patient antibody history and interview with technical supervisor #4 the laboratory failed to have an up to date policy on checking patient history. Findings: 1. Review of blood bank procedure states "If review of records reveals that the patient has had a positive antibody screen in the past, units used for cross matching must be negative for that antibody, even if the current screen is negative". Interview with technical supervisor #4 revealed testing personnel are supposed to check the computer and the files for patient history. 2. Review of computer for patient history showed patient history is placed in different files in the computer with no procedure to show how to retrieve it. 3. Review of antibody patient history revealed a folder with patient histories, not in alphabetical order. 4. Interview with technical supervisor #4 on November 9, 2018 at 1:00 PM confirmed blood bank procedure for checking patient antibody history was not well defined.</p>
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p>

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on review of chemistry Horiba Pentra 400, i-Stat and Sysmex XP300 procedures shows that twice a year the laboratory did not evaluate and define the relationship between test results using different methodologies and instruments in 2016 and 2017 and to date November 9, 2018. Findings: 1. Review of chemistry analytes sodium, potassium, chloride, CO₂, BUN, creatinine and glucose showed they are performed on the Horiba Pentra 400 and the iStat. The laboratory failed to evaluate and define the relationship between test results. 2. Review of hematology analyte hematocrit showed it is performed on the iStat and the Sysmex XP300. The laboratory failed to define the relationship between test results. 3. Interview with the technical supervisor #4 on November 9, 2018 at 1:00 PM confirmed the laboratory failed to evaluate and define the relationship between test results for sodium, potassium, chloride, CO₂, BUN, creatinine, glucose and hematocrit.