Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0452987	01/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Russell Regional Hospital	200 S Main, Russell, 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
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the laboratory's policy and procedure manuals, quality control documentation, patient test records and final test reports, instrument maintenance and function check documentation, transfusion records, quality assessment documentation and Allegation of Compliance (AOC) from the survey conducted on 09 September 2018 the laboratory failed to meet the immunohematology requirements by following written policies and procedures to monitor, assess and when indicated, correct problems identified in the analytic systems as specified in standard D5791.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of Quality Assurance (QA) procedures, the lack of available QA documents, and interview with General Supervisor GS#1 and Laboratory Director reveal that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems

	identified in the analytic systems for 16 out of 24 months from January 2019 - December 2020. The findings include: Findings: 1. The "2018 Quality Management Plan" policy approved by the Laboratory Director on 09/18/2018 states under 3. Monthly Monitors section 3(e)" Blood Bank (iv) Monthly review by Laboratory Director. Also the Allegation of Compliance for Survey performed on 09/11/2018 under D6079 Laboratory Director Responsibilities section 4 stated "The Laboratory Director will make monthly visits to the laboratory to review all QA activities, blood bank records, and ensure all necessary corrective actions have been taken" 2. The laboratory failed to follow their Quality Assurance Plan ,written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. There was a lack of evidence of monthly Blood Bank (BB) review from 09/17/2020 to 12/24/2020 by Laboratory Director. Lack of documentation of monthly review of Temperature Blood Bank charts from 3/11/2020 to 05/20/2020 and 09/17/2020 to 12/24/2020. In the American Proficiency Institute for Immunohematology Proficiency testing records: 2019 BB 1st event:evaluated 05/19/2019 Laboratory Director reviewed on 9/19/2019 2019 BB 3rd event:evaluated 01/3/2020 Laboratory Director reviewed on 03/12/2020 2020 BB 1 event evaluated 05/12/2020 Laboratory Director reviewed on 09/18/2020 3. Review of the Blood Bank Quality Assessment Monitors for time period of January 2019 to December 2020 indicated that the Laboratory Director in her role as Technical Supervisor of Immunohematology did not perform the monthly review of patient logs and worksheets for 16 months out of the 24 months. 4. On February 28, 2021@230 P. M. in an interview with the General Supervisor #1 and telephone conference with the Laboratory Director @ 300 P.M. confirmed that the laboratory had not performed the monthly Blood Bank review in 2019 and 2020 as indicated in the current Quality Assurance Plan.