Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0450820	10/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Republic County Hospital	2420 G St, Belleville, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: A review of manufacture's package insert for Bio- Rad Liquicheck Cardiac Markers Plus Control LT and Multiqual 1,2,3, revealed the laboratory failed to follow manufacture's instructions for storage. . Findings were as follows a. Based upon Bio-Rad Cardiac and Multiqual Quality Control package insert states " Do not store this product in a Frost Free freezer'.At the time of the survey 3 packages were stored in a standard refrigerator freezer (frost free freezer) This was confirmed in interview with Technical Consultant the CMS form 209 #1 on 10/08/18 at 10:30 hrs
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by:

	A review of Temperature logs and interview with staff revealed the laboratory failed to establish a temperature log for laboratory storage room and drawing room to monitor temperature for vacationer tubes. Findings were as follows: a. Based upon review of manufacture's requirements the laboratory failed to establish a temperature log and range for the vacationer tubes 5-25 degrees C . b. At the time of the survey 10 /08/2018 the laboratory failed to produce corrective action documentation of temperature, This was confirmed by the Technical Consultant from the CMS 209 form on 10/0/2018 at 1000 hours.
D5485	CONTROL PROCEDURES CFR(s): 493.1256(h) If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented. This STANDARD is not met as evidenced by: A review of Microbiology Quality Control (QC) revealed the laboratory failed to document the Quality Control the media from Remel. Finding were as follows: a. Based upon interview with General Supervisor #1 stated " the laboratory does not have documentation of the QC that the manufacture performs on Blood Agar, Chocolate , MacConkey and Blood/MacConkey Biplatate" on 10/08/2019 at 1300hrs.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (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 review of the laboratory's immunohematology thermographic temperature charts, temperature corrective action documentation, and interview with General Supervisor (GS) #2 , the laboratory failed to store immunohematology blood and blood products under appropriate conditions that include an adequate temperature alarm system. Findings Include: a. Review of the laboratory's 08/04/18 thermographic temperature charts for the blood bank refrigerator found the blood bank refrigerator log and recording chart failed to match the temperature for the high and low check on the log sheet the temperature for the low side was 1.6 high 5.5 degrees Celsius (C) , the recording chart low 1.6 and high not recorded
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must

	be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: A review of the Quality Control (QC) procedure and interview with staff revealed the laboratory failed to produce a policy concerning a failed QC concerning patient results Finding were as follows a. Interview with General Supervisor #1 from the CMS 209 10/08//2018 at 09:30 hrs. confirmed the laboratory failed to have the policy, (All patients test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected).
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: A review of Quality Assessment and Interview with staff revealed the laboratory failed to have a plan that covered all aspects of the laboratory. Finding were as follows: 1. Based upon the Quality Assessment Action plan the laboratory failed to establish a action plan for any manual calculation (INR)for any analyte that is reported . Therefore, the accuracy or reliability of the analyte cannot be verified. This was confirmed in interview with Technical Consultant on 10/08/2018 at 11;30 hrs.