Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0690699	07/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mcpherson Hospital	1000 Hospital Drive, Mcpherson, 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
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: A review of McPherson Hospital blood bank maintenance policy, the blood bank maintenance records, the serofuge centrifuge equipment in blood bank, and interview with general supervisor #1 found the laboratory failed to retain serofuge equipment records. Findings were: 1. Blood bank procedure manual stated that serofuge centrifuge equipment maintenance checks were to be performed every six months. 2. At the time of the survey, the surveyor observed the serofuge centrifuge equipment in blood bank labeled with serofuge timer readings without date of measurements: Immediate spin 20 seconds Wash 60 seconds Coombs 20 seconds Enhancement 20 seconds 3. The serofuge centrifuge was used during the last twelve months to perform 327 ABO RH types, antigen type 3 red blood cell units, and perform 22 cord types. 4. Interview with general supervisor #1 at 2:15 on July 12, 2018, verified that at the time of the survey the lab had no records documenting the serofuge centrifuge times and the above findings.
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 and humidity logs and interview with staff revealed the laboratory failed to document the humidity for the laboratory as the XT-4000i hematology analyzer requires and Vitros 5600 failed to document. Findings were as follows: a. Based upon review of manufacture's guide for the XT-4000i (Hematology analyzers) the laboratory failed to document the humidity 30% to 85% . The laboratory failed to define the acceptable humidity range according to the manufacture's range . b Based upon review of manufactures's guide for the Vitros 5600 (chemistry analyzer) for the humidity range 15 to 75 % the laboratory failed to document. c. This was confirmed by the Technical Supervisor on 07/12/2018 at 14::00 hrs
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: A review of documentation and staff interview for the manual check of the International Normalized Ratio (INR). The Laboratory failed to document a manual check for 2016, and 2017. Finding were as follows: 1. At the time of the survey 07/12 /2018 the laboratory failed to provide documentation that a manual check was performed this was confirmed in interview with General Supervisor # 1 from the CMS form 209 at 11:00 hrs.
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 Technical Supervisor from the CMS 209 07 /12//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).