Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0453261	02/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Scott County Hospital	201 Albert Ave, Scott City, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) during calendar year 2017and through the PT provider, American Proficiency Institute (API), the laboratory failed to attest that proficiency testing samples were handled in the same manner as patient samples. Findings were: A. A review of proficiency testing events during 2017 events 1,2,and 3 revealed that attestation statement did not contain the signature of the laboratory director or designee, attesting that the laboratory handled proficiency testing samples in the same manner as patients. B. The testing event was: event 1 was Chemistry event 2 was coagulation event3 was chemistry coagulation and microbiology C. The above findings were confirmed by interview with the technical consultant on 2/21 /2018 at 1115 hours in the lab conference room.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by:

	A review of proficiency testing records from American Proficiency Institute (API) (a year consists of three testing events) and interview with laboratory Supervisor revealed the laboratory failed to verify the accuracy of analytes for which the proficiency testing program does not obtain the agreement required for scoring. Findings were as follows: a. Proficiency testing records form API for the first and second events of 2017, revealed that the proficiency testing program failed to obtain the agreement required for scoring the (APTT). 2017 event 1: 100% 2017 event 2: 100% At the time of survey (02/21/2018), there was no evidence of verification activities of accuracy by self grade (comparison to the published expected results) for any of these analytes available for review. An interview with the Technical Consultant #! from the CMS form 209 on 02/21/2018, at 13:20 hrs confirmed that no verification of accuracy.
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 Sysmex Xn 1000 hematology analyzer an requires specific humidity.. Findings were as follows: a. Based upon review of manufacture's operators guide the laboratory failed to document the humidity 30% to 85% for the laboratory . b. At the time of the survey 02/21/2018 the laboratory failed to produce documentation of specific humidity ranges, This was confirmed by the Technical Consultant #1 from CMS 209 form on 02/21/2018 at 10: 30 hours.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: A review of IQCP for OPTI CCa Blood Gas instrument and Cepheid GeneXPert revealed the lab failed to include in the IQCP the history of the Quality Control frequency the QC is performed Findings were as follows; a. Based upon IQCP plan the laboratory failed to provide the documentation of the QC history for the Cepheid GeneXpert. this was confirmed in interview with Technical Consultant #1 02/21/2018 at 13:00 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 Consultant #1 and 2 from the CMS form 209 08/21/2017 at 10:30 hrs. confirmed the laboratory failed to produce 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).