Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0453076	11/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Gove County Medical Center	520 W 5th Street, Quinter, 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
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, manufacturer operator manuals and interview with staff revealed the laboratory failed to define an acceptable humidity range for the main laboratory and then document the humidity as required by the GeneXpert Dx system, Architect chemistry system, Sysmex XS-1000i analyzer and the Sysmex CA-600 analyzer. Findings were: 1. Based upon review of temperature and humidity logs humidity was not being documented for the main laboratory room and no range had been established. 2. Architect chemistry manufacturer's operators manual show the instrument requires 10 - 85% humidity. 3. Sysmex XS-1000i and Sysmex CA-600 manufacturer's operators manuals show the instruments require 30 - 85% humidity. 4. GeneXpert Dx System operator manual show the instrument requires 10 - 95% humidity. 5. The above information was confirmed by General Supervisor #1 (refer to laboratory personnel report (CMS-209)) at 9:55 AM on November 13, 2018.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations

	Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based upon a review of policies/procedures for microbiology,and virology quality control records and staff interview, the laboratory failed to complete the Individualized Quality Control Plan (IQCP) to demonstrate equivalent quality control . Findings were as follows: a. The laboratory's procedure manual for microbiology showed that the laboratory was performing Quality Control (QC) for the GeneXpert DxSystem (Cephied) for the analytes Flu A&B, RSV, C Diff, and MRSA every 30 days without doing an IQCP b. The laboratory stated the Manufacture says " External QC only need to be done every 30 days " Documentation failed to be produced at the time of the survey making this statement. The IQCP must have the following elements. 1. Risk Assessment (RA) - must include risk assessment of: a. Specimen b. Test System c. Reagent d. Environment e. Testing Personnel 2. Quality Control Plan (QCP) - describes the practices, resources and procedures to control the quality of a particular test process. 3. Quality Assessment (QA) - the new QCP must be incorporated into the lab's ongoing quality assurance plan, and should include elements of the risk assessment c. The above findings were confined by interview with the lab manager/technical supervisor on 11/13/2018 at 1020 hours in the laboratory.
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 11/13//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: a. Based upon the Quality Assessment Action plan the laboratory failed to establish a action plan for ACL Elite and CA 660 (coagulation Instruments) comparative results (INR) . Therefore, the accuracy or reliability of the analyte cannot be verified. This was confirmed in interview with Technical Supervisor #1 from the CMS form 209 on 11/13/2018 at 10:30 hrs. .b. Shifts and Trends for. Chemistry and Hematology were failed to be addressed. This was confirmed by the Technical Supervisor #1 on 11/13/2018 at 13:30