Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0452929	11/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Graham County Hospital	304 W Prout St, Hill 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
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based upon review of manufacturer's instructions, preventive maintenance function check records from the period 4/13/2017 to 10/18/2018 and staff interview, the laboratory failed to ensure that the urinalysis centrifuge was checked for appropriate speed and duration in accordance with the manufacturer's instructions when used to perform manual microscopic urine analysis (urinalysis). Findings were: 1. The laboratory uses the Fisherbrand UriSystem for standardized (microscopic) urinalysis. The manufacturer's instructions stated under Fisherbrand UriSystem Test Procedure, step 3.: "Centrifuge 12 ml urine in the UriSystem Tube, or UriSystem Transport Tube at 1800 revolutions per minute (RPM) for 5 minutes. 2. Review of Biomedical reports for the Drucker Centrifuge, model 614B, Serial number 330407-11 showed the following data with the lowest reading and the next reading above 1800 RPM. There were no documented timer checks for the centrifuge timer.: Biomedical Report Date Set RPM Measured RPM 4-13-2017 2000 2056 10-16-2017 1600 1648 10-16-2017 2400 2456 4 - 9 -2018 1600 1635 4 - 9 -2018 2400 2428 10-18-2018 1600 1623 10-18-2018 2400 2417 3. The above findings were verified by interview with general supervisor #1 (refer to personnel report CMS-209)) at 3:00 PM on November 12, 2018.