Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0451041	10/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Kiowa County Memorial Hospital	721 West Kansas Ave, Greensburg, 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
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Review of Accu-Sed Plus control package inserts, Excyte Mini sedimentation rate (ESR) test records and interview with staff reveals that the laboratory failed to perform two levels of acceptable quality control (QC) material each day of patient testing for the Excyte Mini sedimentation rate (ESR) analyzer. Findings were: 1. Review of the Accu-Sed Plus Abnormal ESR control kit, lot. 177110, expiration date 2-28-2019 had an acceptable range of 45 to 81 mm/hr for the Excyte Mini ESR analyzer. 2. Review of the Accu-Sed Plus Normal ESR control kit, lot. 177010, expiration date 2-28-2019 had an acceptable range of 3 to 11 mm/hr for the Excyte Mini ESR analyzer. 3. Review of ESR test records, at the time of the survey, had normal quality control ranges of 4 - 12 and abnormal quality control ranges of 40 - 76 for May 2018 to September 2018. Some pages of the ESR test records had control ranges but didn't contain control lot numbers or expiration dates. 4. Controls out-of-range on the ESR test records, at the time of the survey, had no corrective action or quality control rerun for the following days of patient testing. - 6/19/18: Abnormal control - 87 - 8/3/18: Abnormal control - 92 - 8/10/18: Normal control - 14 - 8/10/18: Abnormal control - 97 - 8/28/18: Abnormal control - 44 5. The above information was confirmed by interview with the laboratory director and testing personnel #1 and #2 (refer to Laboratory Personnel Report (CMS-209)) at 10:49 on October 12, 2018.