Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0648288	12/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Hospital District No 6 Of Harper County Kansas	1101 E Spring St, Anthony, 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation of the phlebotomy area located within the laboratory, observation of stool testing area for clostridium difficile (C. Diff) and interview with the technical supervisor the laboratory failed to provide a safe environment in which employees and patients are protected from physical, chemical and biological hazards. Findings: 1. Observation of the phlebotomy area located in the laboratory showed one phlebotomy chair with a patient having their blood drawn. This procedure was occurring while laboratory testing personnel were analyzing patient specimens. 2. Observation of area for testing stool specimens for C. Diff showed no ventilation for testing of stool specimens. 3. Observation of phlebotomy area and stool specimen testing area showed close proximity to each other. 4. Interview with the technical supervisor on December 7, 2018 at 12:15 PM confirmed the laboratory failed to ensure laboratory personnel and patients were protected from physical, chemical and biohazardous materials.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on review of procedure manuals and interview with the technical supervisor on December 7, 2018 at 12:15 PM the laboratory failed to provide a urine microscopic procedure.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Quick Vue serum pregnancy quality control (QC), One Step Drug Screen Test Card QC, Tox A/B Quik Chek clostridium difficile (C Diff) QC and interview with the technical supervisor on December 7, 2018 at 12:15 PM the laboratory failed to perform QC each day of patient testing for serum pregnancy, urine drug screens and C Diff from 2016 to present date.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of wright's stain and interview with the technical supervisor on December 7, 2018 at 12:15 PM confirmed the laboratory failed to check stain quality each day of testing and failed to document when stain was changed.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of blood gas quality control (QC) and interview with the technical supervisor on December 7, 2018 at 12:15 PM confirmed the laboratory failed to test one sample of blood gas control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing from 2016 to present date.

D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) results for 2017, 2018 and interview with the technical supervisor the laboratory director failed to ensure PT results are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. Review of PT results for 2018, 2nd event showed blood cell identification had one not graded sample and was not evaluated to identify any problems that require corrective action. 2. Review of PT results for 2018, 2nd event showed APTT(sec) had one not graded sample and was not evaluated to identify any problems that require corrective action. 3. Interview with the technical supervisor on December 7, 2018 at 12:15 PM confirmed the laboratory director failed to ensure PT results are reviewed.