Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0046994	(X3) Date Survey Completed 09/17/2019
Name of Provider or Supplier Hillsboro Hospital, Llc	**Street Address, City, State** 101 Industrial Road, Hillsboro, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a lack of available documentation and confirmed during interview, the laboratory failed to have procedures approved, signed, and dated by the laboratory director before use. Findings: 1. Upon review of the laboratory procedures, the current laboratory director did not approve, sign, and date the laboratory procedures for Hematology, Chemistry, Immunology, Blood gases, Urinalysis. 3. Confirmed during interview with the Technical Supervisor#1 on September 17, 2019 at 10 A.M. that the current laboratory director had not signed the procedure manuals.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected

	by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: A review of calibration verification records for the Beckman Coulter AC*T diff 2, and interview with technical supervisor revealed that the laboratory failed to perform calibration verification once every six months. Finding were as follows 1. Review of the Beckman Coulter AC*T diff calibration verification documentation revealed the laboratory failed to perform calibration verification at least once every six months on CBC analytes. The laboratory performed a calibration verification on November 20, 2017 but failed to perform the calibration verifications that were due in May and November 2018. A calibration validation was performed on July 19th, 2019. This was confirmed in interview with Technical Supervisor #1 on September 17, 2019 at 11:00 hrs. .
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Review of 2019 personnel records, selected 2019 patient test records and interview with technical consultant #1 reveals that evaluation of competency is not available for one individual who performs testing and also fulfills the duties and responsibilities of the technical consultant.