Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0450827	01/08/2020
Name of Provider or Supplier	**Street Address, City, State**	
Hanover Hospital	205 S Hanover St, Hanover, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on interview on January 8, 2020 at 1030 am and the lack of documentation produced, the laboratory failed to perform two competency assessments on personnel listed on the Form 209. Findings: 1. Based on the lack of documentation provided by the laboratory, the laboratory failed to perform competency assessments on Testing Personnel (TP) #3 and #4 as determined by their policies of annual assessments for personnel employed greater than 12 months. 2. Interview with TC#5 on 01/08/2020 @1030 confirmed that the laboratory failed to perform competency assessments on TP#3 and #4.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on an absence of pipette records, microscope maintenance records and interview with Technical Supervisor (TS) #5, the laboratory failed to define a function check protocol for the pipettes and microscopes. Findings were: 1. No documentation

	was available for function checks of pipette for period between 10/09/2018 to 01/08 /2020. No documentation was available for the certification of accuracy for pipettes. 2. No documentation was available for the maintenance of microscopes for period between 10/09/2018 to 01/08/2020. 3. Interview with TS #5 on 01/08/2020 @1:20 pm confirmed the laboratory had no records of function checks or certification of accuracy for the seven pipettes used in the laboratory for the period between 10/09 /2018 to 01/08/2020. 4. Interview with TS#5 on 01/08/2020 @1:20 pm confirmed the laboratory had no records of microscope maintenance for a 15 month period.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: 1. A review of manufacturer's instructions for Thromboplastin , quality control and quality assessment records for coagulation, observation of the laboratory's equipment, and interview with staff on January 08, 2020 revealed that the laboratory did not follow manufacturer's instructions for International Normalized Ratio (INR) . Findings were as follows: a. Quality control and quality assessment records for Elite top coagulation analyzer on 01/08/2020 did not include determination of the Prothrombin Time (PT) for patient normal range for the current lot of Thromboplatin in use. Therefore the accuracy or reliability can not be verified. b. Interview with the TC#3 on 01/08/2020 @130 p.m. confirmed that the determination of the patient normal range for the current lot of Thromboplastin had not been performed.